



Health

Hunter New England
Local Health District

Understanding Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring(FGM) Systems

16 February 2021

Lisa Blomley

Clinical Nurse Consultant

Credentialed Diabetes Educator RN

GNS Diabetes Service

4016 4666

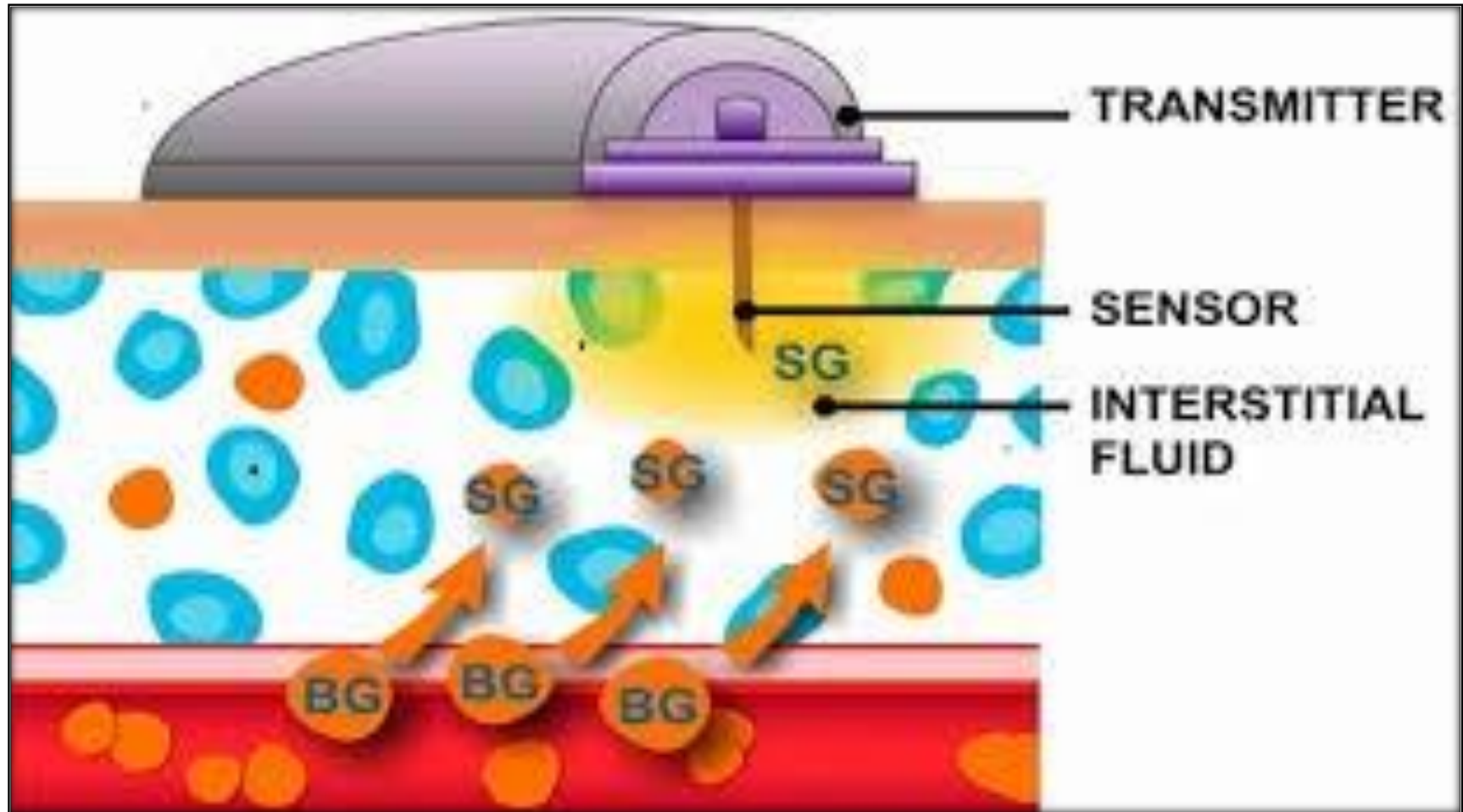


Overview of presentation



- What is flash and continuous glucose monitoring
- The development road to current devices
- Devices available in Australia
- Which patients are suitable and cost considerations
- Reports generated by CGM/FGM – (Ambulatory Glucose Profile (AGP) reports) educational opportunities, and information for clinical decision making
- Examples of real patient data

CGM/FGM measure interstitial glucose levels



Continuous Glucose Monitoring



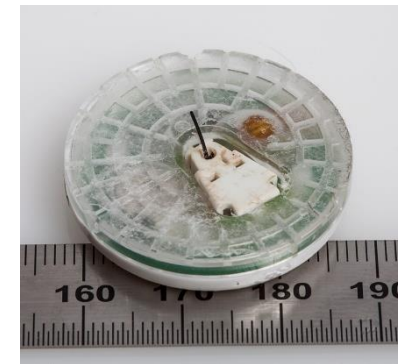
- Continuous Glucose Monitoring (CGM) is sensor technology measuring glucose levels continuously in order to gain insight into patterns and trends in glucose levels throughout the day and night.
- **The system has 3 parts:** a sensor, a transmitter and a reader/receiver. Phone apps available.
- A CGM sensor (about the size of a twenty cent coin) is inserted under the skin - a filament is left under the skin. The attached transmitter “sends” glucose readings to a receiver or pump. The sensor is disposable and changed according to manufacturer recommendations (~ every 7-10 days).
- The transmitter is not disposable. The life of the transmitter varies depending on the manufacturer. Data can be transferred to software systems and reports are generated to give a deeper understanding of glucose patterns and variability
- **Dexcom** G5 G6 and **Medtronic** Guardian, Guardian Link 3 CGMs are available in Australia.



Flash (iCGM) glucose monitoring



- Flash glucose monitoring is sensor technology that can provide continuous glucose monitoring data but requires a 'scan' by the user at least every 8 hours.
- The system has 2 parts:** A sensor and a scanner (or reader) A small white disc (about the size of a twenty cent coin) is positioned on the back of the upper arm. This holds the 'sensor', which is worn just under the skin. And, a 'reader' which when held over the sensor, gives a glucose reading. The sensor is disposable and lasts for 14 days.
- Each scan provides the last eight hours of glucose data and a trend arrow showing if glucose levels are going up, down or changing slowly. This data can be downloaded from the Freestyle Libre Software to give a deeper understanding of glucose patterns and variability.
- Abbott Freestyle Libre is the only flash glucose monitoring device currently available on the Australian market.



Glucose monitoring: A brief history



- 1908 Urine testing- used for more than 50 years.
- 1965 First blood glucose strip developed by Ames-Dextrostix
- 1970's Home BGM- Dextrometer. Termed "SMBG"
- 1980s to 2000s SMBG technology continued to improve
- 1999 First professional CGM - "blinded"
- 2004 Real-time CGM-Medtronic
- 2006 Integrated sensor and pump-Medtronic
- 2006 Dexcom sensor
- 2016 Libre FGM
- 2016 to present "Closed-loop" systems, DIY closed loop technology

Blood Glucose Monitors



- The first portable blood glucose monitor was invented by Australian Stanley Clark in the late 1970s.



Stanley's daughter - Lisa



Why choose CGM?



Self Monitoring of Blood Glucose

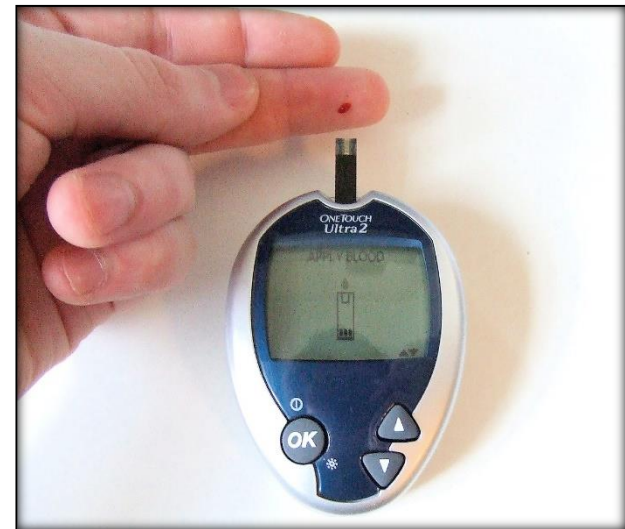


Limitations

- Pain
- One point in time - no trend
- Frequency of insufficient sampling
- Fails to detect overnight hypos

Benefits

- NDSS subsidized (low cost)
- Patient preference
- Minimal technology barrier

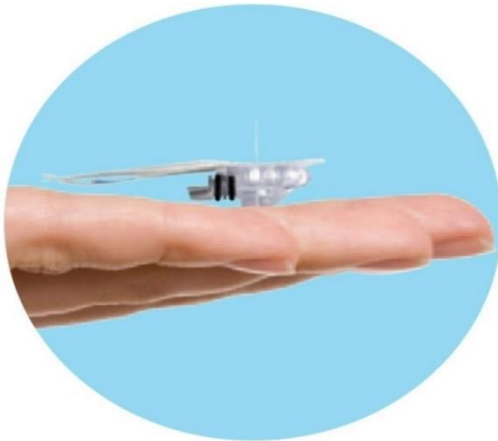


Continuous Glucose Monitoring



Limitations

- Cost
- Attached device
- Technology barrier
- May require calibration by finger stick blood sample
- Alarm fatigue



Benefits

- Continual readings
- Detects patterns and trends
- Can predict hypos and hypers
- Alarms can alert patient, carers, parents
- Can communicate with an insulin pump for insulin dosing rates/decisions
- Can link to HCP account (data sharing)

Flash Glucose Monitoring (iCGM)



Limitations

- Cost
- Attached device
- Technology barrier
- Requires scanning

Benefits

- Continual readings if scanned every 8 hours
- Detects patterns
- Trend arrows
- Requires no finger stick blood glucose calibration
- 14 day sensor wear
- Can link to HCP account (data sharing)



Appropriate patient selection for CGM



- Type 1 - both insulin pump users and non pump users
- Complex Type 2 with wide glycaemic excursions
- Hypoglycaemia unawareness
- Severe hypoglycaemia
- Risk of severe nocturnal hypoglycaemia - given the morbidity and possible mortality associated with severe nocturnal hypos
- Pregnant Type 1(pre-pregnancy, pregnant and post pregnancy)
- Consider for patients whose occupations may require warning of hypoglycaemia (drivers, offshore/remote workers)

Patient selection - other considerations



- Cost- are they eligible for NDSS subsidy?
- *Technology - phone compatibility?
- * Dexterity/Cognitive ability?

* these are not barriers necessarily - especially if family or carers can assist.

NDSS subsidy eligibility



- Type 1 < age 21
- “Other” eligible conditions < age 21
- Type 1 $\geq$ age 21 with additional criteria*
- Type 1 - pregnancy planning/pregnant/post pregnancy

*

Concessional status, Aboriginal/Torres Strait Islander



Health

Hunter New England
Local Health District

Type 1 DM age < 21 years



ndss
National Diabetes Services Scheme
An Australian Government Initiative

NDSS Helpline 1800 637 700
ndss.com.au

Continuous and Flash Glucose Monitoring Access Form

Type 1 Diabetes; Age Under 21 Years

PLEASE COMPLETE BOTH SIDES OF THIS FORM

This form allows an eligible person who is already registered with the NDSS to apply for access to continuous glucose monitoring (CGM) and flash glucose monitoring (Flash GM) products through the Scheme.

Person with diabetes

1 Title Given name(s)

2 Family name

3 Date of birth
Day / Month / Year
If the person named in Q1 and Q2 is under 15 years old, the "Carer or guardian" section must also be completed.

4 Medicare card (preferred) or DVA file number

5 NDSS card number

6 Email (preferred method of contact)

7 Mobile number

8 Address
Suburb State Postcode

9 By signing here, I am confirming that:

- any CGM or Flash GM products supplied to me through the NDSS are for the person named in Q1 and Q2 only me; and
- the information I have provided on this form is true and complete; and
- I agree to the collection, use and disclosure of my information for the purposes set out in this form and the NDSS Registration Form; and
- I understand giving false or misleading information is a serious offence.

Signature Day / Month / Year

Carer or guardian

This section must be completed by a primary carer or guardian if the person named in Q1 and Q2 is:

- aged 15 years or under; or
- aged 16 years or older and requires a primary carer or guardian

10 Title Given name(s)

11 Family name

12 Date of birth
Day / Month / Year

13 Email (preferred method of contact)

14 Mobile number

15 Address
Suburb State Postcode

16 Relationship to person named in Q1 and Q2

17 By signing here, I am confirming that:

- I am the primary carer or guardian for the person named in Q1 and Q2; and
- any CGM or Flash GM products supplied to me through the NDSS are for use by the person named in Q1 and Q2 on this form only; and
- the information the person named in Q1 and Q2 and I have provided on this form is true and complete; and
- both the person named in Q1 and Q2 and I agree to the collection, use and disclosure of the provided information for the purposes set out in this form and the NDSS Registration Form; and
- where I am providing personal information about the person named in Q1 and Q2, I will advise that person of the privacy information contained in this form; and
- I understand giving false or misleading information is a serious offence.

Signature Day / Month / Year

Certifier

This section must be certified by an authorised health professional whose usual scope of practice includes the ongoing management and care of people with type 1 diabetes.

This form cannot be certified by a general practitioner (GP) or practice nurse.

18 Which of these are you?

☐ CDE
☐ Endocrinologist/Diabetologist
☐ Nurse Practitioner
☐ Paediatrician
☐ Paediatric endocrinologist
☐ Physician

19 Eligibility Criteria

The person meets ALL of the following criteria:

- the child/young person is expected to benefit clinically from the use of CGM or Flash GM; AND
- the child/young person or family/carer has the willingness and capability to use CGM or Flash GM; AND
- the child/young person or family/carer has the commitment to actively participate in a diabetes management plan which incorporates CGM or Flash GM.

AND

Category A

☐ aged 10 or under ☐ Go to 20

OR

Category B

- aged from 11 to less than 21 years and meets one or more of the following criteria (tick as appropriate)
 - frequent significant hypoglycaemia – more than one episode a year of significant hypoglycaemia requiring external, third party assistance; AND/OR
 - impaired awareness of hypoglycaemia; AND/OR
 - inability to recognise, or communicate about, symptoms of hypoglycaemia; AND/OR
 - significant fear of hypoglycaemia for the child/young person or a family member/carer which is seriously affecting the health and wellbeing of the child or young person or contributing to hyperglycaemia as a reaction to this fear.

20 What type of device will the person be using?

☐ CGM (starter kit may be required) ☐ Go to 21

OR

☐ Flash GM
FreeStyle Libre (starter kit is not required) ☐ Go to 24

21 Which CGM device will the person be using?

☐ Dexcom G4 Platinum
☐ Dexcom G5 Mobile
☐ Dexcom G6
(available for Tandem t:slim X2 insulin pump users only)
☐ Medtronic Guardian 2 Link
☐ Medtronic Guardian Connect (3)
☐ Medtronic Guardian Link (3)
☐ Medtronic Bluetooth Guardian Link (3)
(compatible only with MiniMed 770G insulin pump)

22 Is the person currently using the CGM device selected above?

Yes – they can continue to use their current device and can access CGM products through NDSS Access Points. No starter kit is required.
☐ Go to 24

No – this is a new CGM device or this is a new CGM user. A starter kit is required. The starter kit will be sent to the health professional listed at 23.
☐ Go to 23

23 Contact details for the health professional receiving the CGM starter kit.

Health professional full name
Email
Clinic/Hospital
Address line 1
Address line 2
Suburb State Postcode
Phone number

24 Certifier details

Your full name
Medicare provider, CDE or AHPRA number
Email
Clinic/Hospital
Address line 1
Suburb State Postcode
Phone number

25 By signing here, I am certifying that:

- I have assessed the person named in Q1 and Q2 and confirm that they have met all relevant eligibility criteria, as indicated by my answers; and
- I am aware that not all CGM/Flash GM products are indicated for use in all conditions or all age groups, and have considered available advice about the selected device including the relevant AETG listing and any specific condition comments (if unsure search the device information at: ndss.com.au); and
- I have obtained informed consent from the person named in Q1 and Q2, their carer or guardian, or family for the specific device chosen for use.
- I understand giving false and misleading information is a serious offence.

Signature Day / Month / Year

Type 1 ≥ 21 Years



ndss
National Diabetes Services Scheme
An Australian Government Initiative

Continuous and Flash Glucose Monitoring Access Form

NDSS Helpline 1800 637 700
ndss.com.au

Type 1 Diabetes; Age 21 Years and Over; Eligible Concessional Status

PLEASE COMPLETE BOTH SIDES OF THIS FORM

This form allows an eligible person who is already registered with the NDSS to apply for access to continuous glucose monitoring (CGM) and flash glucose monitoring (Flash GM) products through the Scheme.

Person with diabetes

1 Title Given name(s)

2 Family name

3 Date of birth
Day / Month / Year

4 Medicare card (preferred) or DVA file number

5 NDSS card number

6 Are you of Aboriginal or Torres Strait Islander origin? (tick all boxes that apply)
☐ No ☐ Yes, Aboriginal ☐ Yes, Torres Strait Islander

7 Type of Concession (tick boxes)
☐ Health Care Card ☐ Pensioner Concession Card
☐ Veteran Gold Card ☐ Veteran White Card

8 Concession Card or DVA File Number

9 Expiry Date
Day / Month / Year

10 Email (preferred method of contact)

11 Mobile number

12 Address
Suburb State Postcode

13 By signing here, I am confirming that:
• any CGM or Flash GM products supplied to me through the NDSS are for the person named in Q1 and Q2 only me; and
• the information I have provided on this form is true and complete; and
• I agree to the collection, use and disclosure of my information for the purposes set out in this form and the NDSS Registration Form; and
• I understand giving false or misleading information is a serious offence

Carer or guardian

This section is to be completed by a primary carer or guardian if the person named in Q1 and Q2 is aged 21 years or older and requires a primary carer or guardian.

14 Title Given name(s)

15 Family name

16 Date of birth
Day / Month / Year

17 Email (preferred method of contact)

18 Mobile number

19 Address
Suburb State Postcode

20 Relationship to person named in Q1 and Q2

21 By signing here, I am confirming that:
• I am the primary carer or guardian for the person named in Q1 and Q2; and
• any CGM or Flash GM products supplied to me through the NDSS are for use by the person named in Q1 and Q2 on this form only; and
• the information the person named in Q1 and Q2 and I have provided on this form is true and complete; and
• both the person named in Q1 and Q2 and I agree to the collection, use and disclosure of the provided information for the purposes set out in this form and the NDSS Registration Form; and
• where I am providing personal information about the person named in Q1 and Q2, I will advise that person of the privacy information contained in this form; and
• I understand giving false or misleading information is a serious offence.

Signature Day / Month / Year

Certifier

This section must be certified by an authorised health professional whose usual scope of practice includes the ongoing management and care of people with type 1 diabetes.

This form cannot be certified by a general practitioner (GP) or practice nurse.

22 Which of these are you?
☐ CDE
☐ Endocrinologist/Diabetologist
☐ Nurse Practitioner
☐ Physician

23 Eligibility criteria
The person has filled in their valid concessional details on page 1 and meets ALL of the following criteria:
☐ the person is expected to benefit clinically from the use of CGM or Flash GM; AND
☐ the person or family/carer has the willingness and capability to use CGM or Flash GM; AND
☐ the person or family/carer has the commitment to actively participate in a diabetes management plan which incorporates CGM or Flash GM;

Device
The choice of device to be used remains a decision of the health professional in consultation with the person named in Q1 and Q2, their carer or guardian, or family, noting that not all CGM/Flash GM products are indicated for use in all conditions or all age groups. Please view devices at ndss.com.au.

24 What type of device will the person be using?
☐ CGM (starter kit may be required) ☐ Go to 25
OR
☐ Flash GM
FreeStyle Libre (starter kit is not required) ☐ Go to 28

25 Which CGM device will the person be using?
☐ Dexcom G4 Platinum
☐ Dexcom G5 Mobile
☐ Dexcom G6
(available for Tandem t:slim X2 insulin pump users only)
☐ Medtronic Guardian 2 Link
☐ Medtronic Guardian Connect (3)
☐ Medtronic Guardian Link (3)
☐ Medtronic Bluetooth Guardian Link (3)
(compatible only with Minimed 770G insulin pump)

26 Is the person currently using the CGM device selected above?
Yes – they can continue to use their current device and can access CGM products through NDSS Access Points. No starter kit is required.
☐ Go to 28
No – this is a new CGM device or this is a new CGM user. A starter kit is required. The starter kit will be sent to the health professional listed at 27.
☐ Go to 27

27 Contact details for the health professional receiving the CGM starter kit.
Health professional full name
Email
Clinic/Hospital
Address line 1
Address line 2
Suburb State Postcode
Phone number

28 Certifier details
Your full name
Medicare provider, CDE or AHPRA number
Email
Clinic/Hospital
Address line 1
Suburb State Postcode
Phone number

29 By signing here, I am certifying that:
• I have assessed the person named in Q1 and Q2 and confirm that they have met all relevant eligibility criteria, as indicated by my answers; and
• I am aware that not all CGM/Flash GM products are indicated for use in all conditions or all age groups, and have considered available advice about the selected device including the relevant AATQ listing and any specific condition comments (if unsure search the device information at: ndss.com.au); and
• I have obtained informed consent from the person named in Q1 and Q2, their carer or guardian, or family for the specific device chosen for use; and
• I understand giving false or misleading information is a serious offence.

Signature Day / Month / Year

Version 5 January 2021. First published March 2019: NDSS/1800637
Diabetes Australia ABN 47 008 528 461

Type 1 Pregnancy



NDSS
National Diabetes Services Scheme
An Australian Government initiative

NDSS Helpline 1800 637 700
ndss.com.au

Continuous and Flash Glucose Monitoring Access Form

Type 1 Diabetes; Pregnancy Planning, Pregnancy or Immediately Post Pregnancy

PLEASE COMPLETE BOTH SIDES OF THIS FORM

This form allows an eligible person who is already registered with the NDSS to apply for access to continuous glucose monitoring (CGM) and flash glucose monitoring (Flash GM) products through the Scheme.

Person with diabetes

- Title Given name(s)
- Family name
- Date of birth
Day / Month / Year
- Medicare card (preferred) or DVA file number
- NDSS card number
- Email (preferred method of contact)
- Mobile number
- Address

Suburb State Postcode

9 By signing here, I am confirming that:

- I am actively and regularly engaging with a health care service to assist with self management of my type 1 diabetes during pregnancy planning, pregnancy or immediately post pregnancy; and
- any CGM or Flash GM products supplied to me through NDSS are for person named in Q1 and Q2 only me; and
- the information I have provided on this form is true and complete; and
- I agree to the collection, use and disclosure of my information for the purposes set out in this form and the NDSS Registration Form; and
- I understand giving false or misleading information is a serious offence.

Signature Day / Month / Year

Carer or guardian

This section must be completed by a primary carer or guardian if the person named in Q1 and Q2 is:

- aged 15 years or under; or
- aged 16 years or older and requires a primary carer or guardian

- Title Given name(s)
- Family name
- Date of birth
Day / Month / Year
- Medicare card (preferred) or DVA file number
- NDSS card number
- Email (preferred method of contact)
- Mobile number
- Address

Suburb State Postcode

16 Relationship to person named in Q1 and Q2

17 By signing here, I am confirming that:

- I am the primary carer or guardian for the person named in Q1 and Q2; and
- any CGM or Flash GM products supplied to me through the NDSS are for use by the person named in Q1 and Q2 only; and
- the information the person named in Q1 and Q2 and I have provided on this form is true and complete; and
- both the person named in Q1 and Q2 and I agree to the collection, use and disclosure of the provided information for the purposes set out in this form and the NDSS Registration Form; and
- where I am providing personal information about the person named in Q1 and Q2, I will advise that person of the privacy information contained in this form; and
- I understand giving false or misleading information is a serious offence.

Signature Day / Month / Year

Certifier

This section must be certified by an authorised health professional whose usual scope of practice includes the ongoing management and care of people with type 1 diabetes.

This form cannot be certified by a general practitioner (GP) or practice nurse.

18 Which of these are you?

☐ CDE
☐ Endocrinologist/Diabetologist
☐ Nurse Practitioner

19 Eligibility criteria

The person meets ALL of the following criteria:

- the person is expected to benefit clinically from the use of CGM or Flash GM; AND
- the person or family/carer has the willingness and capability to use CGM or Flash GM; AND
- the person or family/carer has the commitment to actively participate in a diabetes management plan which incorporates CGM or Flash GM;

AND

If the woman is actively planning pregnancy
☐ Go to PART A

OR

If the woman is currently pregnant or immediately post pregnancy
☐ Go to PART B

PART A (6 months)

☐ Pregnancy Planning – the woman with type 1 diabetes is actively and frequently engaging with a health professional to manage their diabetes and pregnancy planning, ideally at least every 6-8 weeks or more frequently if required; AND

☐ The authorised health professional is confirming eligibility for an initial 6 month period.

OR

☐ Access to CGM or Flash GM for pregnancy planning care is to be continued, the authorised health professional is confirming eligibility for a further 6 month period. Access will continue from the expiry of the initial 6 month period, for a maximum period of 12 months in total.

OR

PART B

☐ Pregnant or Immediately Post Pregnancy – the woman with type 1 diabetes is regularly engaging with a health professional to manage their diabetes and is pregnant or immediately post pregnancy.

Expected or actual date of birth*
Day / Month / Year

* When pregnancy is confirmed, an authorised health professional may now confirm eligibility. The eligibility period ends 3 months after the expected or actual date of birth provided above.

Device

The choice of device to be used remains a decision of the health professional in consultation with the person named in Q1 and Q2, their carer or guardian, or family, noting that not all CGM/Flash GM products are indicated for use in all conditions or all age groups. Please view devices at ndss.com.au.

20 What type of device will the person be using?

☐ CGM (starter kit may be required) Go to 21

OR

☐ Flash GM
FreeStyle Libre (starter kit is not required) Go to 24

21 Which CGM device will the person be using?

☐ Dexcom G4 Platinum
☐ Dexcom G5 Mobile
☐ Dexcom G6
(available for Tandem t:slim X2 insulin pump users only)
☐ Medtronic Guardian 2 Link
☐ Medtronic Guardian Connect (3)
☐ Medtronic Guardian Link (3)
☐ Medtronic Bluetooth Guardian Link (3)
(compatible only with Minimed 770G insulin pump)

22 Is the person currently using the CGM device selected above?

Yes – They can continue to use their current device and can access CGM products through NDSS Access Points. No starter kit is required. Go to 24

No – This is a new CGM device or this is a new CGM user. A starter kit is required. The starter kit will be sent to the health professional listed at 23. Go to 23

23 Contact details for the health professional receiving the CGM starter kit.

Health professional full name

Email

Clinic/Hospital

Address line 1

Address line 2

Suburb State Postcode

Phone number

24 Certifier details

Your full name

Medicare provider, CDE or AHPRA number

Email

Clinic/Hospital

Address line 1

Address line 2

Suburb State Postcode

Phone number

25 By signing here, I am certifying that:

- I have assessed the person named in Q1 and Q2 and confirm that they have met all relevant eligibility criteria, as indicated by my answers; and
- I am aware that not all CGM/Flash GM products are indicated for use in all conditions or all age groups, and have considered available advice about the selected device including the relevant AATCO listing and any specific condition comments (if unsure search the device information at: ndss.com.au); and
- I have obtained informed consent from the person named in Q1 and Q2, their carer or guardian, or family for the specific device chosen for use;
- I understand giving false and misleading information is a serious offence.

Signature Day / Month / Year

Change of device/Ceasing access



ndss
National Diabetes Service Scheme
An Australian Government Initiative

NDSS Helpline 1800 637 700
ndss.com.au

Continuous and Flash Glucose Monitoring Access Form

Update or Ceasing Access

PLEASE COMPLETE BOTH SIDES OF THIS FORM

This form allows an eligible person who is already registered with the NDSS to alter access to continuous glucose monitoring (CGM) and flash glucose monitoring (Flash GM) products through the Scheme.

Person with type 1 diabetes or 'other' eligible condition

1 Title Given name(s)
[] []

2 Family name
[]

3 Date of birth
Day / Month / Year
If the person named in Q1 and Q2 is under 15 years old, the 'Carer or guardian' section must also be completed.

4 Medicare card (preferred) or DVA file number
[] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []

5 NDSS card number
[] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []

6 Email (preferred method of contact)
[] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []

7 Mobile number
[] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []

8 Address
[]
Suburb State Postcode

9 By signing here, I am confirming that:

- any CGM or Flash GM products supplied to me through the NDSS are for the person named in Q1 and Q2 only me; and
- the information I have provided on this form is true and complete; and
- I agree to the collection, use and disclosure of my information for the purposes set out in this form and the NDSS Registration Form; and
- I understand giving false or misleading information is a serious offence

Signature Day / Month / Year

Carer or guardian

This section must be completed by a primary carer or guardian if the person with named in Q1 and Q2 is:

- aged 15 years or under; or
- aged 16 years or older and requires a primary carer or guardian

10 Title Given name(s)
[] []

11 Family name
[]

12 Date of birth
Day / Month / Year

13 Email (preferred method of contact)
[] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []

14 Mobile number
[] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []

15 Address
[]
Suburb State Postcode

16 Relationship to person named in Q1 and Q2
[] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []

17 By signing here, I am confirming that:

- I am the primary carer or guardian for the person named in Q1 and Q2; and
- any CGM or Flash GM products supplied to me through the NDSS are for use by the person named in Q1 and Q2 on this form only; and
- the information the person named in Q1 and Q2 and I have provided on this form is true and complete; and
- both the person named in Q1 and Q2 and I agree to the collection, use and disclosure of the provided information for the purposes set out in this form and the NDSS Registration Form; and
- where I am providing personal information about the person named in Q1 and Q2, I will advise that person of the privacy information contained in this form; and
- I understand giving false or misleading information is a serious offence.

Signature Day / Month / Year

Certifier

This section must be certified by an authorised health professional whose usual scope of practice includes the ongoing management and care of people with type 1 diabetes or 'other' eligible condition.

Please ensure you are permitted to certify this form for the person with type 1 diabetes or 'other' eligible condition. Please refer to the Health professionals authorised to certify access at ndss.com.au/cgm

This form cannot be certified by a general practitioner (GP) or practice nurse.

18 Which of these are you?

- ☐ CDE
- ☐ Endocrinologist/Diabetologist
- ☐ Nurse Practitioner
- ☐ Paediatrician
- ☐ Physician

19 Reason for completing this form:

- ☐ You are ceasing access to CGM or Flash GM
Go to 20 - Part A Ceasing of access
- OR
- ☐ You are changing CGM or Flash GM device
Go to 21 - Part B Changing of device

Part A Ceasing of access

20 Select the reason for ceasing access to CGM or Flash GM products (please tick)

- ☐ Person named in Q1 and Q2 no longer wishes to use CGM or Flash GM
- ☐ Person named in Q1 and Q2 no longer:
 - ☐ has impaired awareness of hypoglycaemia
 - ☐ is unable to recognise, or communicate about, symptoms of hypoglycaemia
 - ☐ experiences significant fear of hypoglycaemia
- ☐ Person named in Q1 and Q2 is not experiencing clinical benefit from CGM or Flash GM
- ☐ Person named in Q1 and Q2 is not using the device as originally intended
- ☐ Person named in Q1 and Q2 is moving overseas
- ☐ Other (please specify):
[] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []

Go to 24

Part B Change of device

21 The choice of device to be used remains a decision of the health professional in consultation with the person named in Q1 and Q2, their carer or guardian, or family, noting that not all CGM/Flash GM products are indicated for use in all conditions or all age groups. Please view devices at ndss.com.au.

Which device will the person be using?

- ☐ Freestyle Libre (Starter kit is not required)
- ☐ Go to 24
- ☐ Dexcom G4 Platinum
- ☐ Dexcom G5 Mobile
- ☐ Dexcom G6 (available for Tandem t:slim X2 insulin pump users only)
- ☐ Medtronic Guardian 2 Link
- ☐ Medtronic Guardian Connect (3)
- ☐ Medtronic Guardian Link (3)
- ☐ Medtronic Bluetooth Guardian Link (3) (compatible only with MiniMed 770G insulin pump)

22 Has the person used this device previously?

- ☐ Yes - A starter kit is not required Go to 24
- ☐ No - A starter kit is required Go to 23

23 Contact details for the health professional setting up the CGM. A starter kit will be sent to the health professional listed below.

Health professional full name
[]
Email
[]
Clinic/Hospital
[]
Address line 1
[]
Address line 2
[]
Suburb State Postcode
[]
Phone number
[] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []

24 Certifier details

Your full name
[]
Medicare provider, CDE or AHPRA number
[]
Email
[]
Clinic/Hospital
[]
Address line 1
[]
Suburb State Postcode
[]
Phone number
[] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []

25 By signing here, I am certifying that:

- I have assessed the person named in Q1 and Q2, and that they no longer have a clinical need for CGM or Flash GM as indicated by my answers; OR
- I am the person named in Q1 and Q2, or are authorised to sign on their behalf, and confirm that they no longer require access to CGM or Flash GM through the NDSS; OR
- I have assessed and certified that the person named in Q1 and Q2 is changing a CGM or Flash GM device; and
- I am aware that not all CGM or Flash GM products are indicated for use in all conditions or all age groups, and have considered available advice about the selected device including the relevant AKTIO listing and any specific condition comments (if unsure search the device information at: ndss.com.au); and
- I have obtained informed consent from the person named in Q1 and Q2, their carer or guardian, or family for the specific device chosen for use;
- I understand giving false or misleading information is a serious offence.

Signature Day / Month / Year

Cost annually- if not eligible for subsidy



FGM

- Abbott Libre
- ~ \$2500

CGM

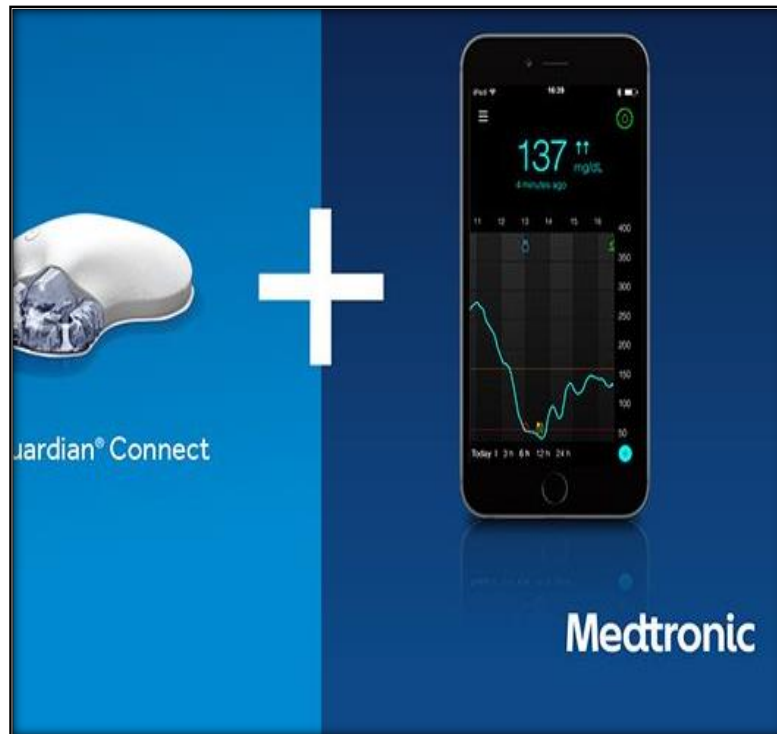
- Dexcom G6 : ~ \$4200
- Dexcom G5 : ~ \$4800
- Medtronic : \$3000-3300

- These costs vary and companies offer subscriptions which may lower cost

Review of CGM available in Australia - Dexcom G6 and G5



Review of CGM available in Australia - Medtronic Guardian, G3



Medtronic “blinded” professional CGM



Sensor worn 7 days



Data uploaded



Review of FGM available in Australia - Abbott Libre



Freestyle Libre 2 (not yet available in Australia)



Libre Link App compatibility



MOBILE DEVICE & OS COMPATIBILITY

Popular mobile devices and operating systems (OS) are regularly tested to evaluate NFC scan performance, Bluetooth connectivity, and app compatibility with Sensors. We recommend checking this guide before installing a new OS version on your phone or before using the app with a new phone.

Recommended app, device, and operating systems

APP / VERSION	DEVICE	OS
FreeStyle LibreLink (version 2.4)	iPhone 7, 7 Plus, 8, 8 Plus, X, XS, XS Max, XR	iOS: 13.2 Android: 8, 9, 10
	Samsung Galaxy S6, Galaxy S7 Edge, Galaxy S8, Galaxy S8+, Galaxy S9	
	Google Pixel, Pixel 2, Pixel 2 XL	
	LG Nexus 5X	
FreeStyle LibreLink (version 2.3)	iPhone 7, 7 Plus, 8, 8 Plus, X, XS, XS Max, XR	iOS: 11, 12, 13 Android: 5, 6, 7, 8, 9, 10
	Samsung Galaxy S5, Galaxy S6, Galaxy S7, Galaxy S7 Edge, Galaxy S8, Galaxy S8+, Galaxy S9	
	Google Pixel, Pixel 2, Pixel 2 XL	
	LG Nexus 5X	
FreeStyle LibreLink (version 2.2)	iPhone 7, 7 Plus, 8, 8 Plus, X	iOS: 11, 12, 13 Android: 5, 6, 7, 8, 9, 10
	Samsung Galaxy S5, Galaxy S6, Galaxy S7, Galaxy S7 Edge, Galaxy S8, Galaxy S8+, Galaxy S9	
	Google Pixel, Pixel 2, Pixel 2 XL	
	Nexus 5X, 6P	
	OnePlus 5T	

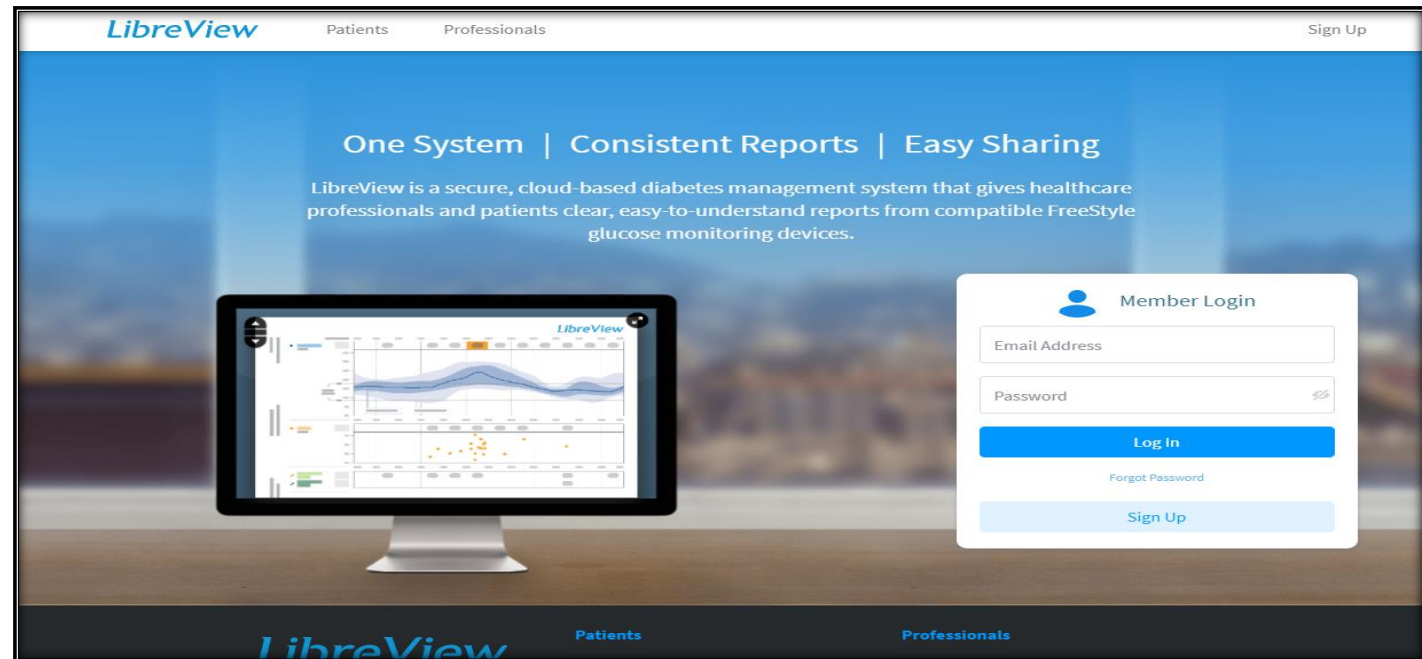
Download the app to use the phone as a scanner



Patient can link to HCP account using Libre link app



- HCP can download software and create a professional account
- Patients give consent and can easily link to account
- HCP can view reports



Referring your patients

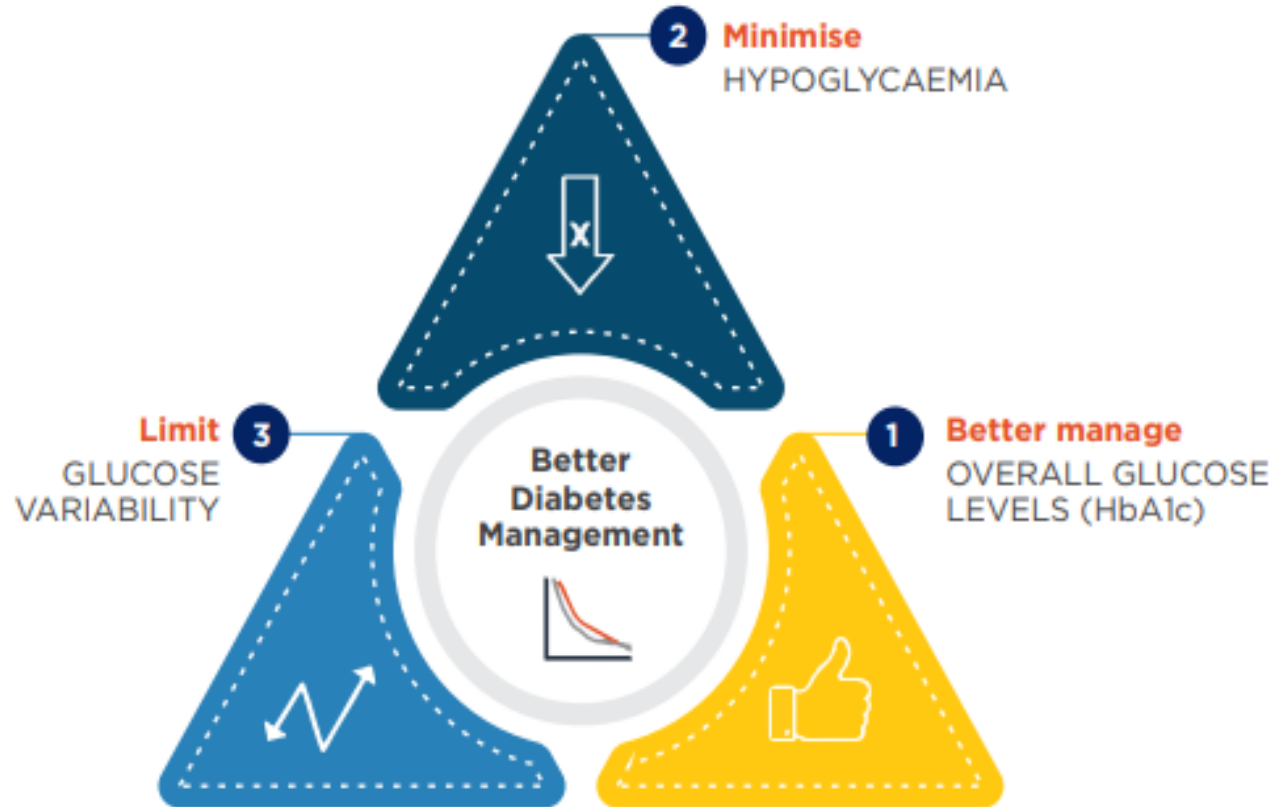


- Your Type 1 patients will likely already be on service with JHH endocrinology team. JHH team will assess and refer patient's interested/eligible for NDSS subsidy.
- Your other patients can be referred for assessment by CDE (eReferral on Health Pathways). We can help determine with the patient which system may be optimal for them.
- If NDSS eligible –form can be signed by us.
- Once approved or purchased, options for initiation include self starting(Abbott Libre) rep/HCP training (Abbott Libre, Dexcom/AMSL,Medtronic)
- If participating in the Diabetes Alliance - GP's offices can liaise with us
For more information contact 4016 4534.

Diabetes management goals



Fig. 2: The Triangle of Diabetes Care⁶





Currently HbA1c is the only prospectively evaluated tool for assessing risk for diabetes complications but limitations include:

1. Lack of information on acute glycaemic excursions
2. Certain conditions may confound results
3. May not accurately reflect mean glucose

Emergence of CGM as a data source



- How do I interpret my patients reports?
- Stakeholders identified a need for standardization of reports



*Advanced Technologies and Treatments for Diabetes

Feb 2019

Objective: To develop clinical CGM targets to provide guidance for clinicians, researchers and individuals with diabetes.

Panel included representatives from these areas.

- There was a recognised need for metrics beyond HbA1c.
- Long term trials demonstrating how CGM metrics relate to and/or predict clinical outcomes have not been conducted.
- There is suggestive evidence showing correlations of time in target range with reduction in microvascular complications.
(Comparison to DCCT** showed similar reductions in microvascular complications)

Standardised Metrics



Standardization of CGM Metrics

Core CGM metrics for clinical care

1. Number of days CGM worn (minimum 10–14 days)
2. Percentage of time CGM is active (minimum 70% of data from 10–14 days)
3. Mean glucose
4. Glucose Management Indicator (GMI)[†]
5. Glycaemic variability (%CV) target <36%
6. Time Above Range (TAR) - % of readings and time >250 mg/dL (>13.9 mmol/L) Level 2 Very high
7. Time Above Range (TAR) - % of readings and time > 181–250 mg/dL (10.1–13.9 mmol/L) Level 1 High
8. Time In Target Range (TIR) - % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L) In range
9. Time Below Range (TBR) - % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L) Level 1 Low
10. Time Below Range (TBR) - % of readings and time <54 mg/dL (<3.0 mmol/L) Level 2 Very low

Use of Ambulatory Glucose Profile (AGP) for CGM report

AGP, ambulatory glucose profile; CGM, continuous glucose monitor; CV, coefficient of variation
Battelino T, Danne T, Bergenstal R. et al. Diabetes Care 2019;42:1593–1603

[†] Bergenstal RM, et al GMI Diabetes Care 2018

*Xu Y., Dunn T. Ajjan, R. et al JDST Jan 2020

*Nayak A. A1C Mismatch Endocrine Reviews 40: 988 – 999, 2019



Health

Hunter New England
Local Health District

CGM / Ambulatory Glucose Profile (AGP) reports:

Time in range (TIR)

Time below range (TBR)

Time above range (TAR)

Glucose Variability (GV)



Time in Range (TIR) targets for most individuals



CGM TIR Targets for Most Individuals with T1D and T2D

T1D and T2D



TAR <5% > 250 mg/dl
< 1 h 12 min > 13.9 mmol/l

TAR <25% > 180 mg/dl
< 6 h > 10.0 mmol/l

TIR >70% 70–180 mg/dl
>16 h 48 min 3.9–10.0 mmol/l

TBR <4% < 70 mg/dl
< 58 min < 3.9 mmol/l

TBR <1% < 54 mg/dl
< 14 min < 3.0 mmol/l

High risk individuals have different targets
(with complications or comorbidities or pregnancy)

Battelino T, Danne T, Bergenstal RM, et al. *Diabetes Care* 2019;42:1593–1603



Park Nicollet
International Diabetes Center



CGM-based targets for different diabetes populations

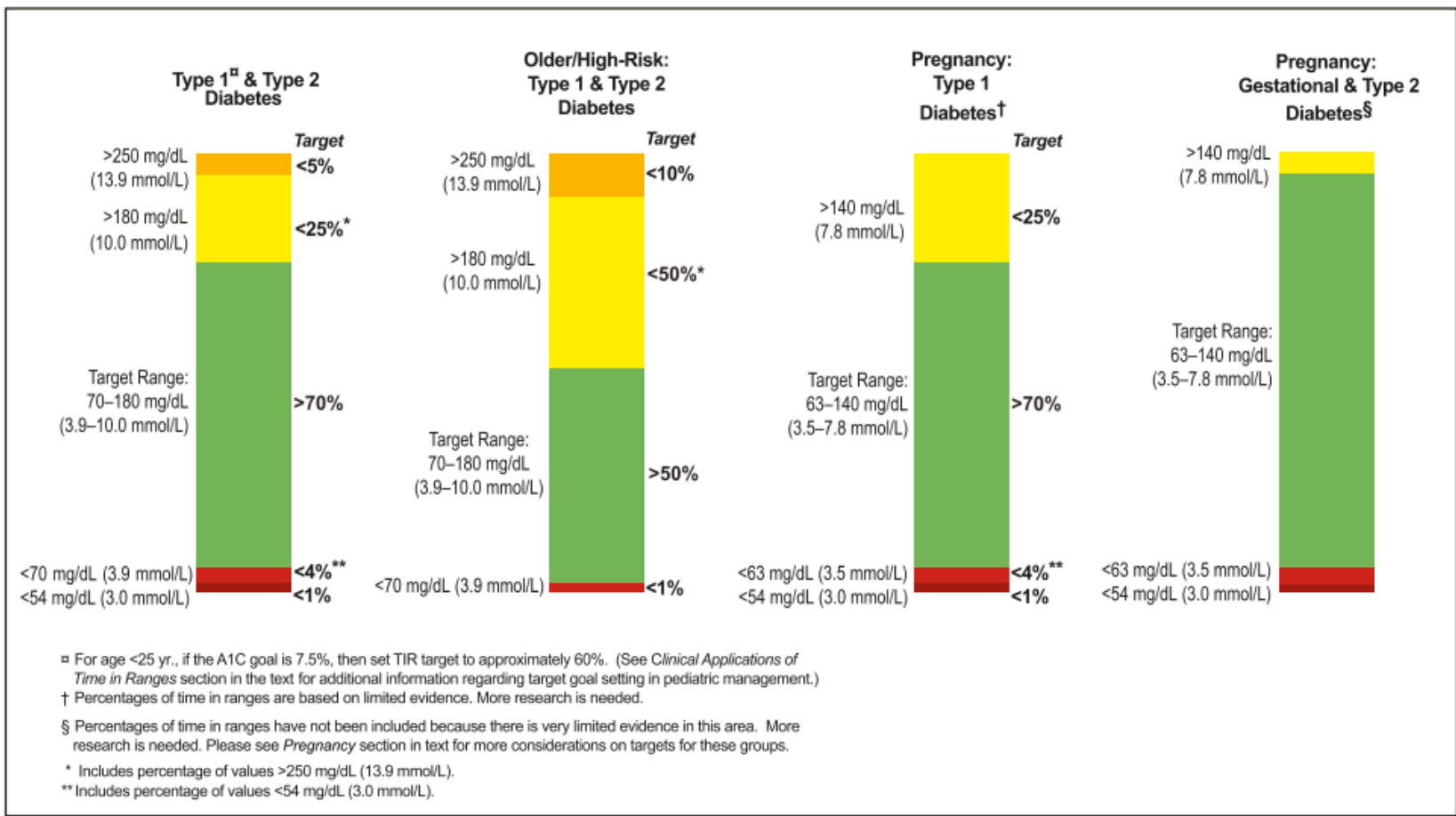


Figure 1—CGM-based targets for different diabetes populations.



Example of an AGP report



GLUCOSE STATISTICS AND TARGETS

2 February 2021 - 15 February 2021

14 Days

% Time Sensor is Active

• Rectangular Snip 92%

Ranges And Targets For		Type 1 or Type 2 Diabetes
Glucose Ranges	Targets % of Readings (Time/Day)	
Target Range 3.9-10.0 mmol/L	Greater than 70% (16h 48min)	
Below 3.9 mmol/L	Less than 4% (58min)	
Below 3.0 mmol/L	Less than 1% (14min)	
Above 10.0 mmol/L	Less than 25% (6h)	
Above 13.9 mmol/L	Less than 5% (1h 12min)	
Each 5% increase in time in range (3.9-10.0 mmol/L) is clinically beneficial.		

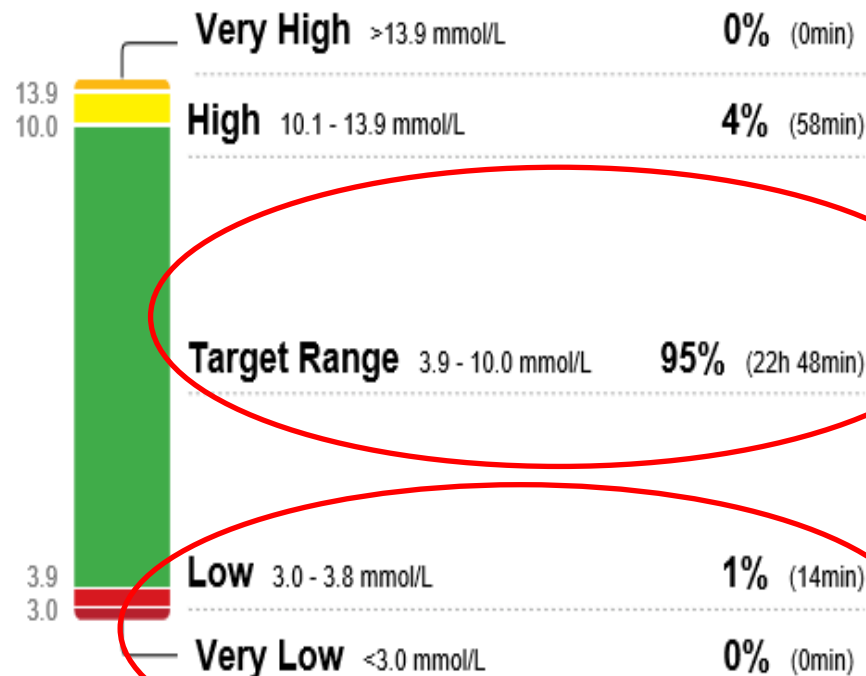
Average Glucose 7.1 mmol/L

Glucose Management Indicator (GMI) 6.4% or 46 mmol/mol

Glucose Variability 20.8%

Defined as percent coefficient of variation (%CV); target $\leq 36\%$

TIME IN RANGES

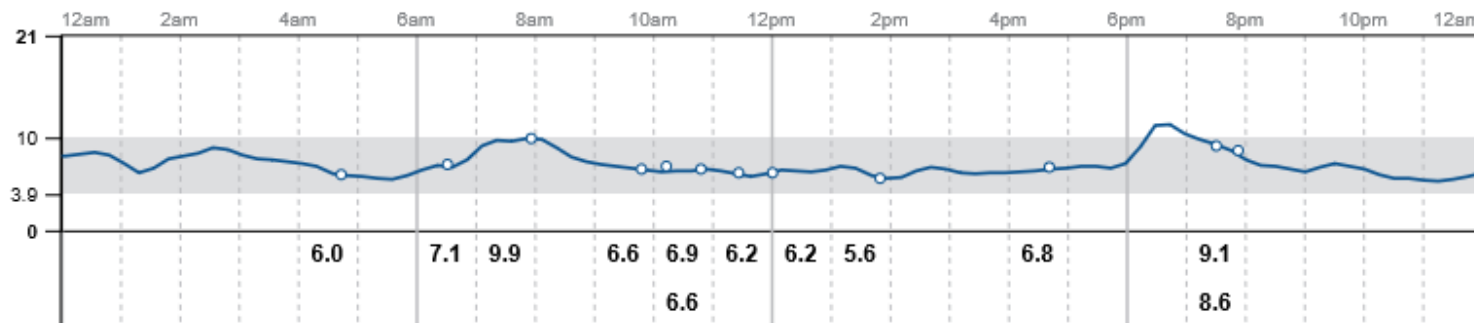


LibreView daily glucose report



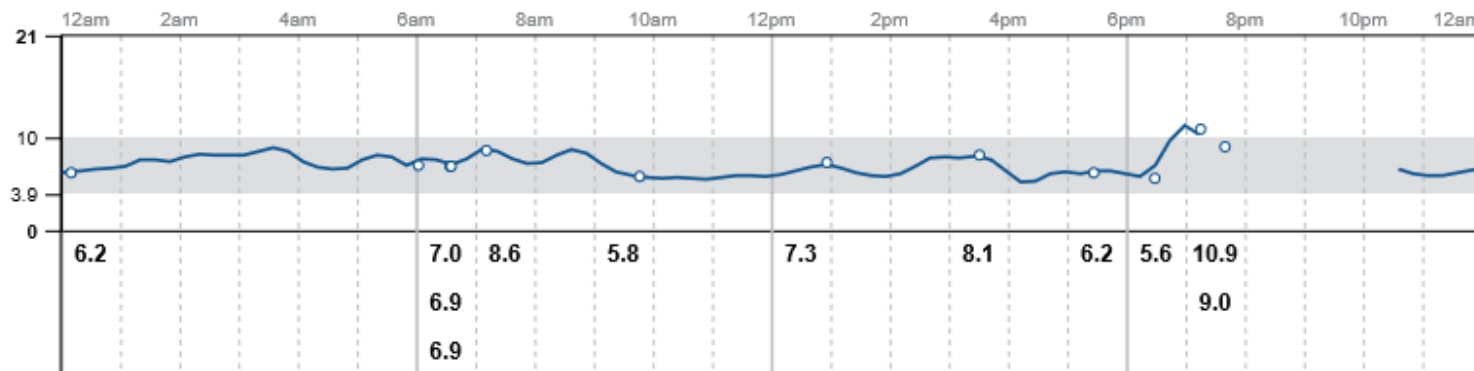
TUE 2 Feb

 Glucose mmol/L

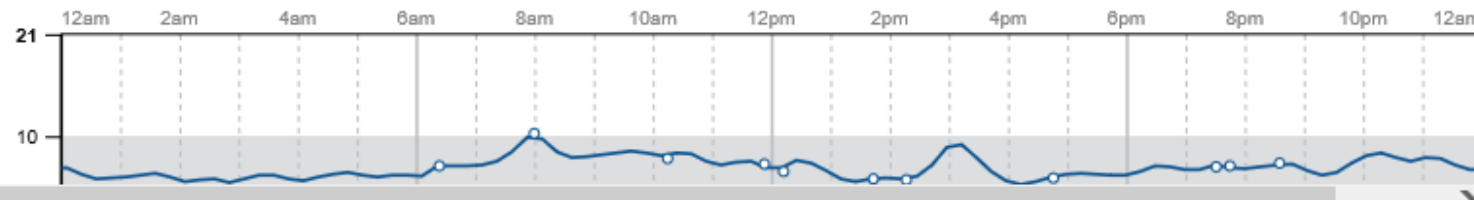


WED 3 Feb

 Glucose mmol/L



THU 4 Feb



Example of an AGP report



GLUCOSE STATISTICS AND TARGETS

2 February 2021 - 15 February 2021

14 Days

% Time Sensor is Active

69%

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	Targets % of Readings (Time/Day)
Target Range 3.9-10.0 mmol/L	Greater than 70% (16h 48min)
Below 3.9 mmol/L	Less than 4% (58min)
Below 3.0 mmol/L	Less than 1% (14min)
Above 10.0 mmol/L	Less than 25% (6h)
Above 13.9 mmol/L	Less than 5% (1h 12min)
Each 5% increase in time in range (3.9-10.0 mmol/L) is clinically beneficial.	

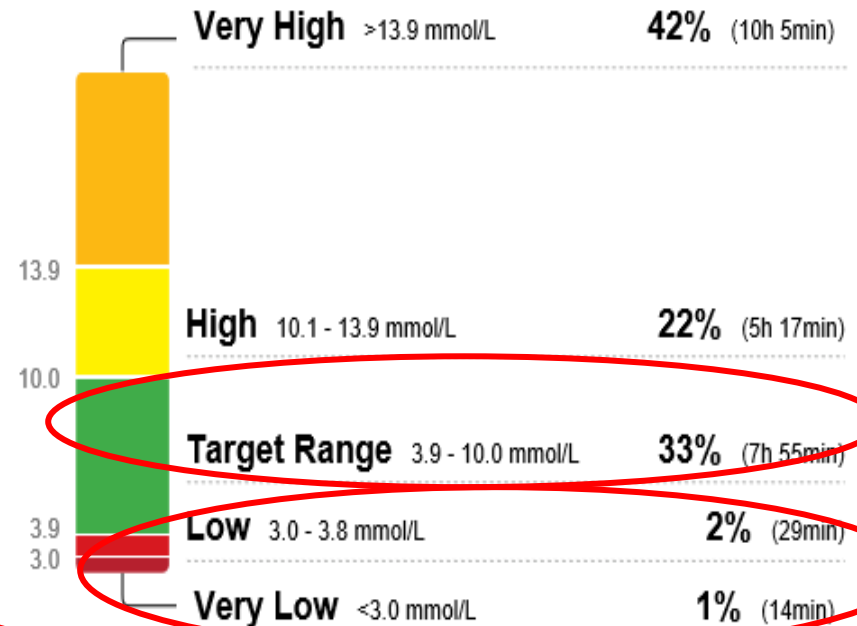
Average Glucose 13.1 mmol/L

Glucose Management Indicator (GMI) 9.0% or 74 mmol/mol

Glucose Variability 44.4%

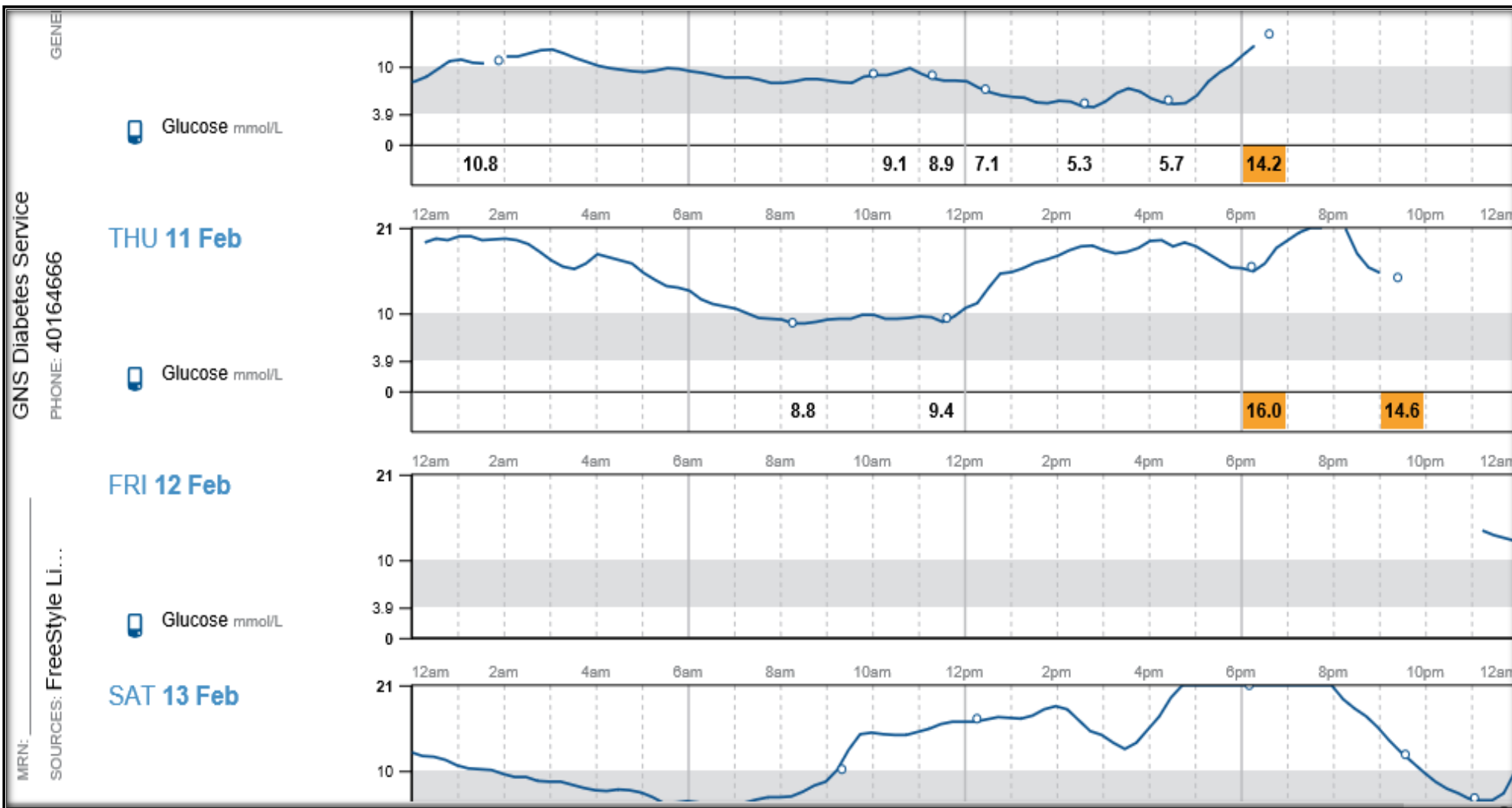
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES



AMBULATORY GLUCOSE PROFILE (AGP)

Same patient - daily log





- 66 year old female with Type 1 DM for > 20 years
- Employed as a commercial cleaner
- Hypo unaware
- Insulin pump Tx started 2009, stopped, resumed pump Tx 2018 with CGM
- Stopped CGM due to alarm fatigue
- Libre 2020



JCMZ094-T3062

MRN: _____

GNS Diabetes Service

PAGE: 1 / 1

DEVICE: FreeStyle Libre

PHONE: 40164666

GENERATED: 09/02/2021

AGP Report

23 January 2021 - 5 February 2021 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

23 January 2021 - 5 February 2021

14 Days

% Time Sensor is Active

92%

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	Targets % of Readings (Time/Day)
Target Range 3.9-10.0 mmol/L	Greater than 70% (16h 48min)
Below 3.9 mmol/L	Less than 4% (58min)
Below 3.0 mmol/L	Less than 1% (14min)
Above 10.0 mmol/L	Less than 25% (6h)
Above 13.9 mmol/L	Less than 5% (1h 12min)
Each 5% increase in time in range (3.9-10.0 mmol/L) is clinically beneficial.	

Average Glucose

9.4 mmol/L

Glucose Management Indicator (GMI) 7.4% or 57 mmol/mol

Glucose Variability

41.8%

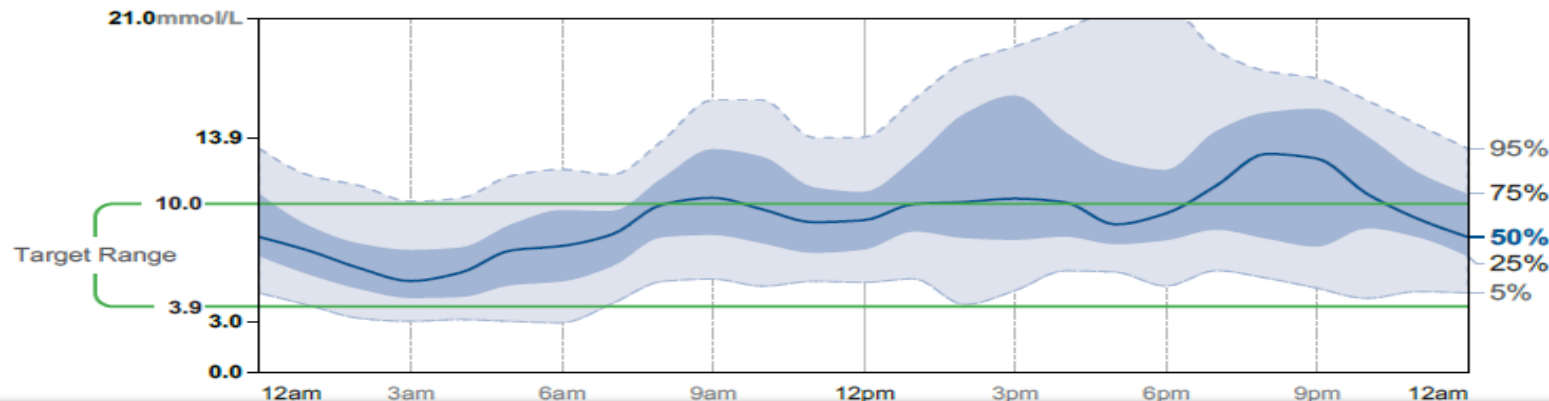
Defined as percent coefficient of variation (%CV); target $\leq 36\%$

TIME IN RANGES

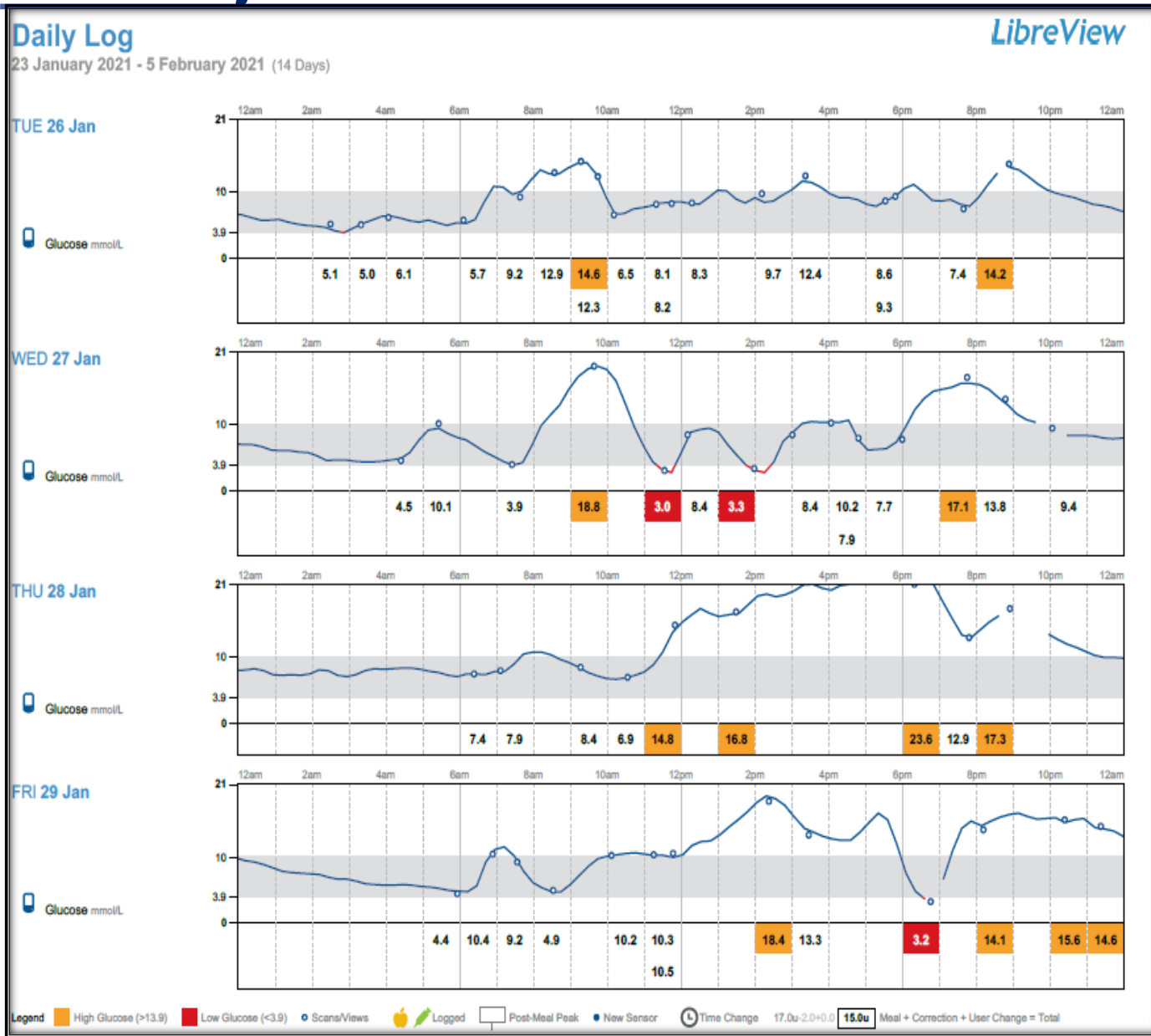


AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.



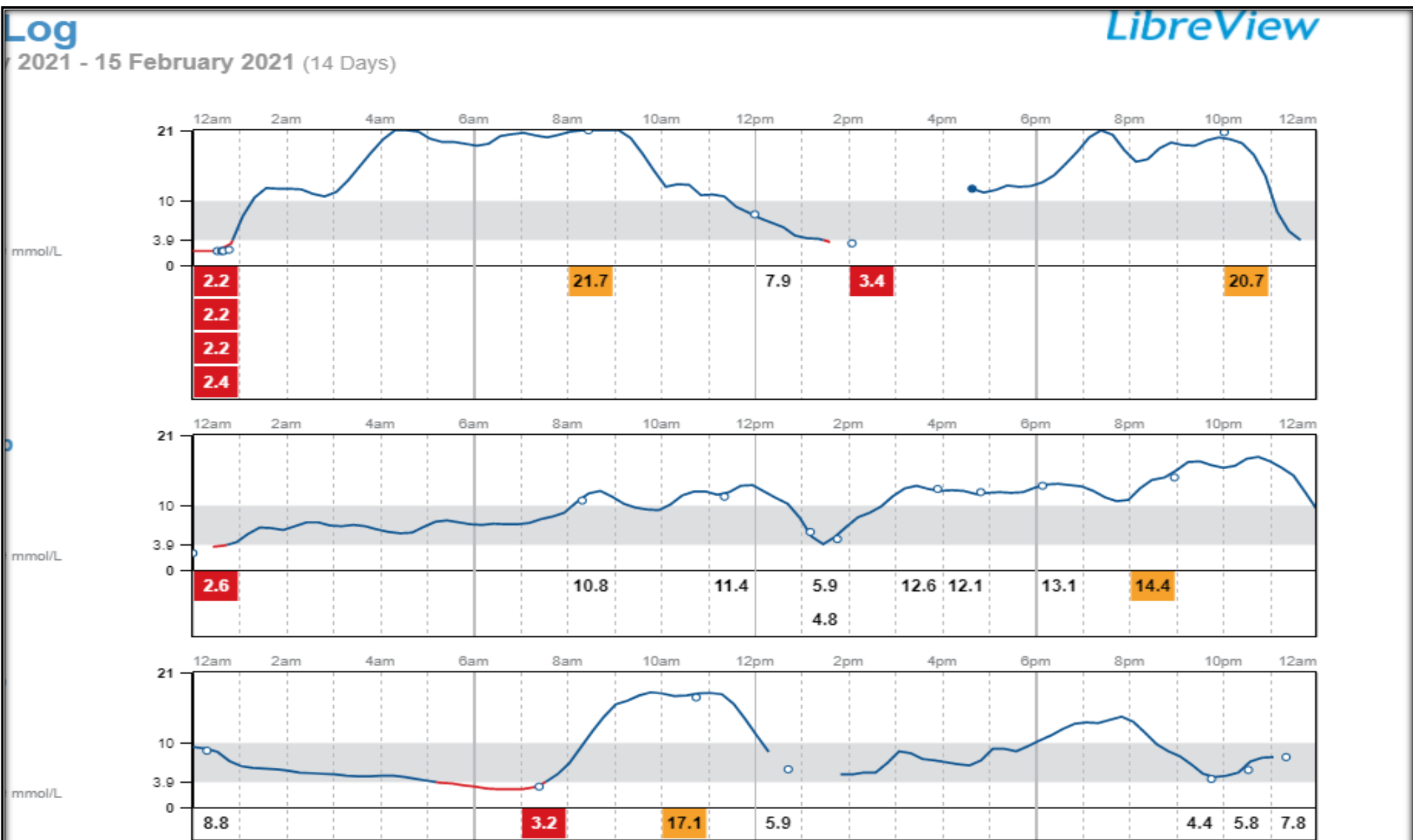
Sonja



Issues identified

Overtreatment of hypos -
hypers-dosing insulin -
more hypos

Daily report for another patient - look for patterns and educational opportunities





- 35 year old male with Type 1 for 20 years
- Autism spectrum disorder, severe intellectual impairment with schizophrenia. Easily agitated, has emotional outbursts and can be violent at times
- Lives in a small group home with 24 hr care
- H/O hypoglycaemic seizures, labile BGLs
- Multiple ED presentations for hypo/hyperglycaemia
- Hypo unaware
- Self administers insulin, SMBG



- Multiple Issues: Carer turnover, carer anxiety over high and low BGLs - especially overnight when Antony was sleeping. Carers would overfeed Antony at night to prevent nocturnal hypos.
- Antony would often skip finger pricks due to pain.
- Obtained Libre device in January 2018 (funded by his parents)
- Became eligible for NDSS subsidy in March 2019.



- Glucose control remains problematic. However, less ED presentations as carers can see the trend on Libre - less carer fear.
- Carers can also scan Antony's arm overnight while asleep if concerned.
- Attends GP office every 2 weeks for review of report and sensor replacement.
- Connected to HCP sharing account. Endocrinologist can access Antony's data on consult phone calls or in-person appointment.

Diabetes technology



Not just humans....



References and further information



- Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations from the International Consensus on Time in Range
<https://care.diabetesjournals.org/content/early/2019/06/07/dci19-0028>
- Clinical Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials*
<https://care.diabetesjournals.org/node/56970.full.print>
- My Interact website: <https://www.myinteract.technology/myinteract/> Go to clinical support materials.
- <https://AMSL.com.au>
- <https://dexcom.com.au>
- <https://freestylelibre.com.au>
- ADA 2020 Symposium: Translating Clinical Evidence for Sensor-Based Glucose Monitoring and Technological Innovations to the Front Lines of Clinical Practice
- <https://NDSS.com.au>



Thank you !!

Questions

