ABCD audits update

Dr Bob Ryder

ABCD Spring Meeting, Loughborough

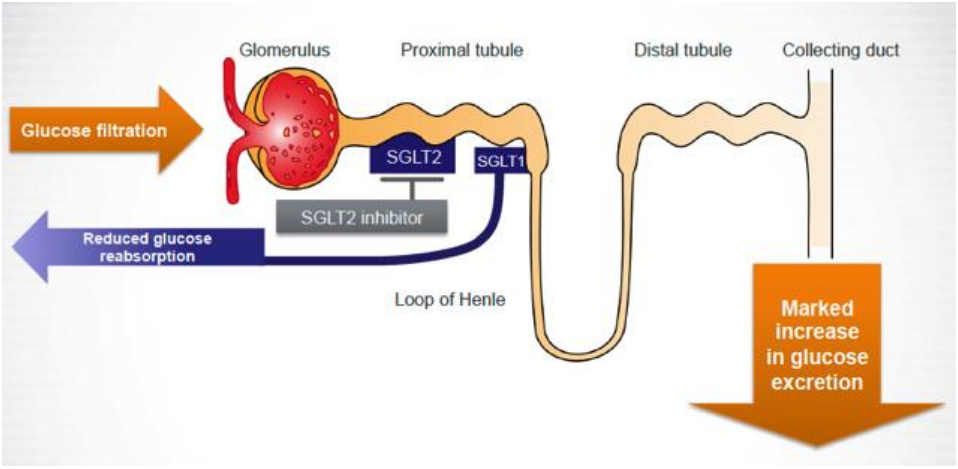
May 17, 2019

Association of British Clinical Diabetologists

ABCD Spring and Autumn Meeting Presentations - 2018

- Please see those presentations for lots of information about the audit programme and what we have learned etc
- What has happened since?

SGLT2 inhibitors audit update



Bailey CJ (2011) *Trends Pharmacol Sci* **32**: 63–71

- Two posters from the empagliflozin audit and one from the canagliflozin audit being presented at the ADA in San Francisco in June, 2019

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Poster from the canagliflozin audit for ADA 2019

Relationship Between Canagliflozin Treatment Response and Duration of Diabetes: The Association of British Clinical Diabetologists (ABCD) Nationwide Canagliflozin Audit

Robert E.J. Ryder[1], Suzanne M. Phillips[2], Alison Evans[2], Devesh K. Sennik[3], Anurita Rohilla[3], Alex Bickerton[4], Ken Thong[5], Mahender Yadagiri[1], Melissa L. Cull[1], Melanie C. Wyres[1], Peter Winocour[6], Ken H. Darzy[6], Anna Strzelecka[7], Shailesh G. Gohil[8], Alison Gallagher[8], Ian W. Gallen[9]

[1]*Birmingham, United Kingdom,* [2]*Gloucester, United Kingdom,* [3]*Essex, United Kingdom,* [4]*Yeovil, United Kingdom,* [5]*Perth, Australia,* [6]*Stevenage, United Kingdom,* [7]*Antrim, United Kingdom* [8]*Leicester, United Kingdom,* [9]*Reading, United Kingdom*

INTRODUCTION

- In the ABCD nationwide liraglutide audit[1] the impact of liraglutide on HbA1c was found to lessen with increasing duration of diabetes (abstract 1038-P, ADA 2012)[1]
- Treatment with canagliflozin, a sodium glucose transporter 2 (SGLT2) inhibitor, increases glycosuria and improves glycaemic control in patients with type 2 diabetes.
- This action is independent of beta cell function. Conceptually, canagliflozin should be equally efficacious among patients with early or advanced type 2 diabetes.
- We investigated whether the glycaemic response to canagliflozin duration of diabetes diagnosis. We analysed data from a nationwide audit in UK.

METHODS

- The Association of British Clinical Diabetologists (ABCD) conducted a nationwide audit of the use of canagliflozin based in real-life clinical practice. Diabetes centres across UK were invited to participate.
- Participating physicians provided anonymised information on demographic data (age, gender, ethnicity, height, weight), duration of diabetes, cardio-metabolic parameters (glycaemia, blood pressure, lipids, alanine aminotransferase and creatinine) and treatments prescribed, before and after treatment with canagliflozin. Information on adverse events was also collected.
- Between January 2016 and December 2018, 57 data was submitted on 972 patients started on canagliflozin in routine practice.

ANALYSIS OF OUTCOMES

- Patients were stratified according to diabetes duration of 0-5, 6-10 and >10 years.
- Changes in HbA1c were compared across groups (ANOVA).
- The baseline HbA1c and HbA1c at first return to clinic after commencing canagliflozin were used.

Subjects

- Inclusions
  - 604 patients with baseline and follow up HbA1c were analysed
  - 434 patients with duration of diabetes data were analysed
- Exclusions
  - HbA1c <7%
  - No follow up HbA1c data

RESULTS

Table 1: Baseline characteristics of 604 patients on canagliflozin

Data Input	Jan 2016 – Dec 2018
Number of patients	604
Sex (%male)	62
Age (years)	60.3 ± 11.1
Diabetes duration (years)*	6.0 (2.6-11)
HbA1c (%)	9.2 ± 1.5
BMI (kg/m²)	33.7 ± 6.7

*Median (IQR)

Figure 1: Change in HbA1c at median (IQR) 4.1 (3-6.1) months after starting canagliflozin, stratified by duration of diabetes

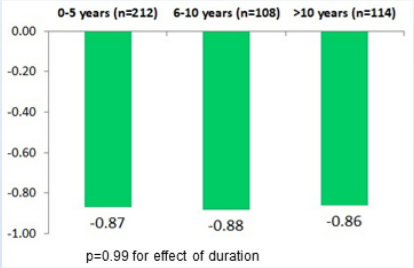
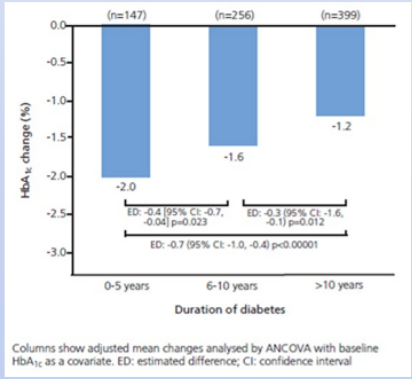


Figure 2: Change in HbA1c at 6 (3-9) months after starting liraglutide, stratified by duration of diabetes (From ABCD nationwide liraglutide audit[1] – see abstract 1038-P, ADA 2012).



- It can be seen for figure 1 that no differences in glycaemic reduction were observed between patients with short or long diabetes duration
- By contrast it can be seen from figure 2 from the ABCD nationwide liraglutide audit, that glycaemic response to liraglutide decreases with increasing duration of diabetes

CONCLUSION

- There was thus no relationship between duration of diabetes and fall in HbA1c in this audit of canagliflozin in real clinical use in the UK
- Canagliflozin should be considered comparably as effective in patients with all durations of diabetes
- This result contrasts with that from the ABCD nationwide liraglutide audit and is in keeping with the differing modes of action of liraglutide and canagliflozin.

REFERENCE

1. Thong KY et al. Br J Diabetes Vasc Dis 2015; 15(4): 169–172

ACKNOWLEDGEMENT

We thank all the nationwide contributors for submitting data of patients on canagliflozin. The ABCD nationwide canagliflozin audit is supported by unrestricted grants from Janssen and Napp. The audit was independently initiated and performed by ABCD and the authors remained independent with the analysis and writing of this report.

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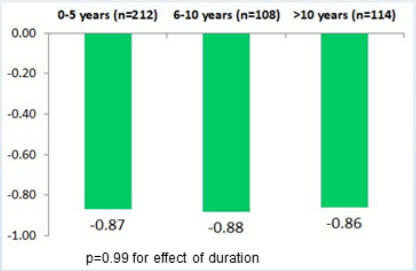

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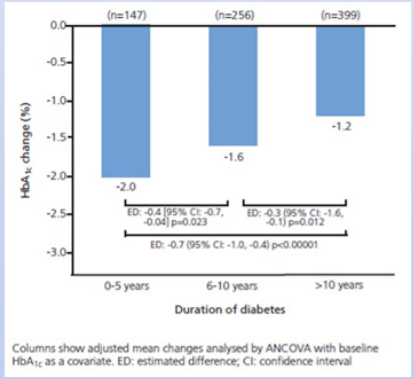

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Presented at ADA 79th Scientific Sessions, San Francisco, June, 2019

16 co-authors – the top contributors

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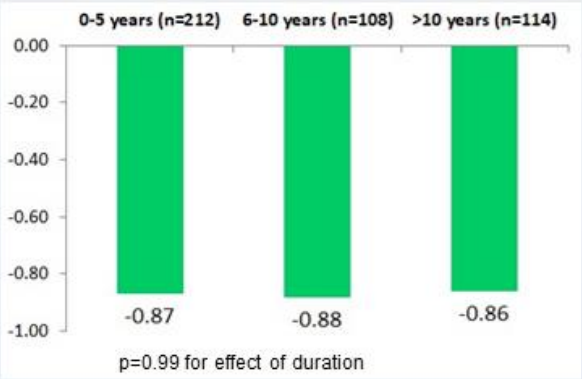

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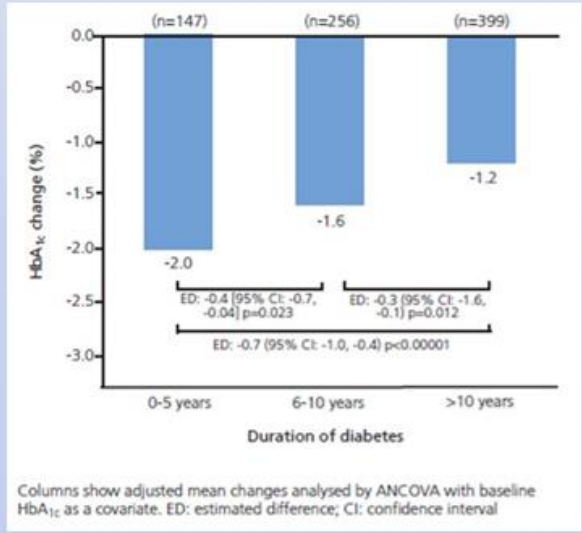

Columns show adjusted mean changes analysed by ANCOVA with baseline HbA_{1c} as a covariate. ED: estimated difference; CI: confidence interval

- Impact of canagliflozin on HbA1c the same regardless of diabetes duration
- Compared with findings from liraglutide audit – impact reduces with increasing duration

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ABCD nationwide audit of FreeStyle Libre

- **Headlines of presentation at DUK, Liverpool, March 2019**

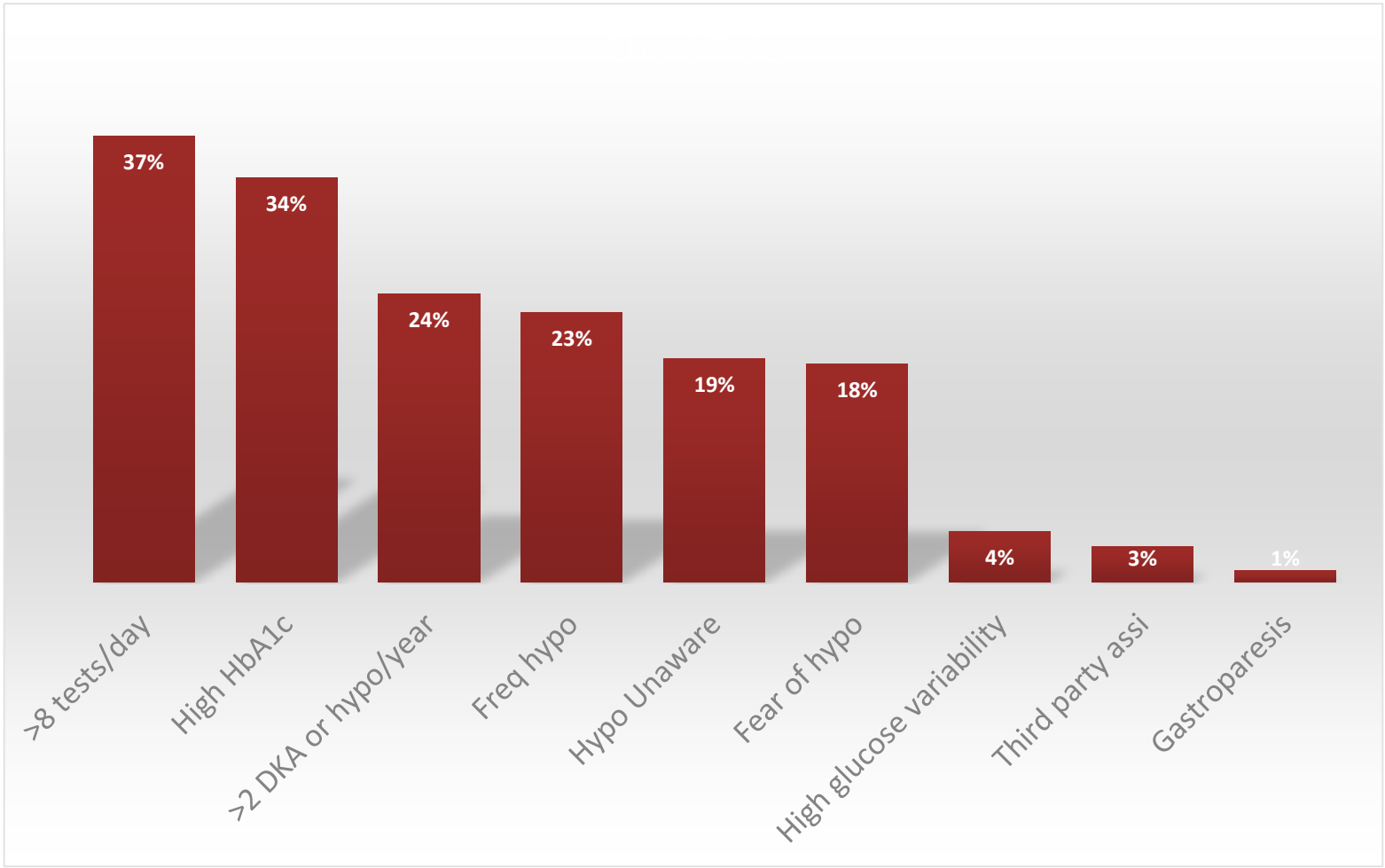
ABCD nationwide audit of FreeStyle Libre

Demographics and audit characteristics (n=3,382)

Age	34 (19-51)
Type 1 Diabetes	**96%**
Female (%)	54%
Duration of Diabetes (yrs)	14 (5-28)
BMI (kg/m2)	24 (21-28)
HbA1c (mmol/mol)	65 (56-76)
Patients with at least 1 follow-up	715
Median follow-up (months)	6 (1-5)

ABCD nationwide audit of FreeStyle Libre

Indications for FSL use in nation-wide FSL audit



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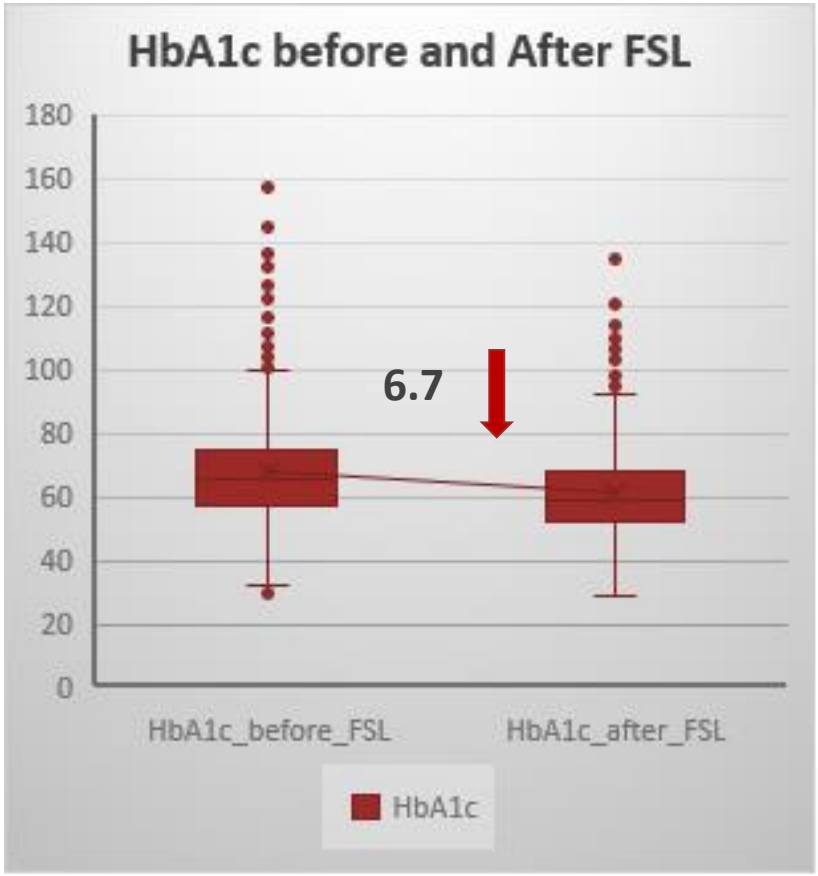
ABCD nationwide audit of FreeStyle Libre

Effect on HbA1c (mmol/mol)

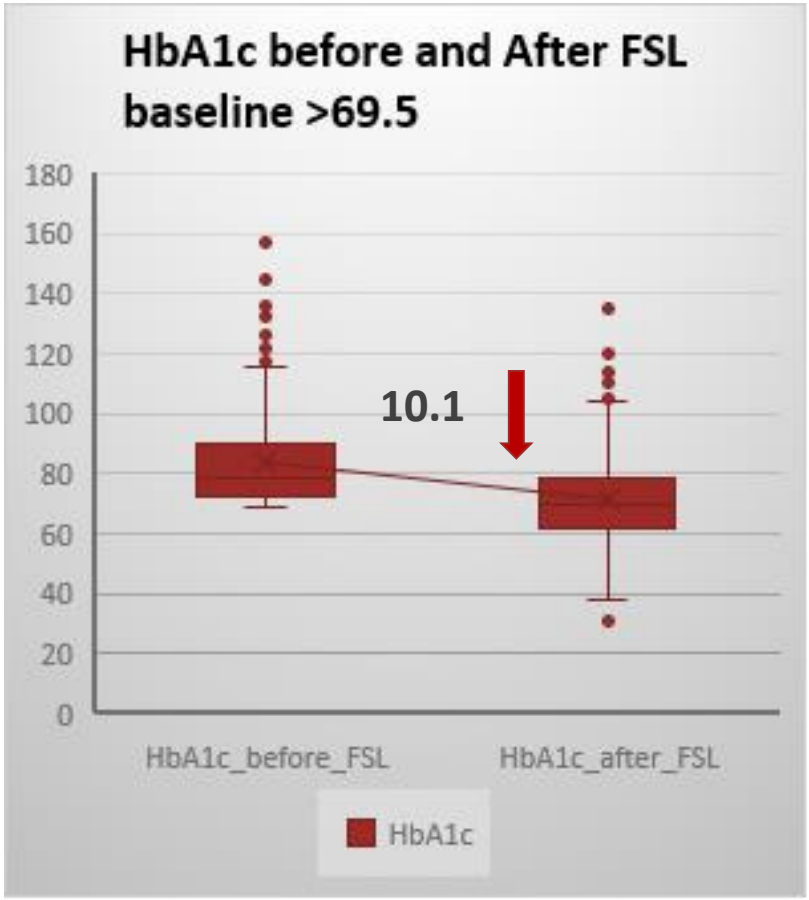
ABCD nationwide audit of FreeStyle Libre



Median pre-FSL HbA1c (IQR)	65.7 (17.1)
Median post FSL HbA1c (IQR)	59 (16)
P-value*	<0.0001

*P-value from Mann-Whitney U Test

ABCD nationwide audit of FreeStyle Libre



Median pre-FSL HbA1c (IQR)	80.1 (17)
Median post FSL HbA1c (IQR)	70 (17)
P-value*	<0.0001

*P-value from Mann-Whitney U Test

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Effect on Hypoglycaemia

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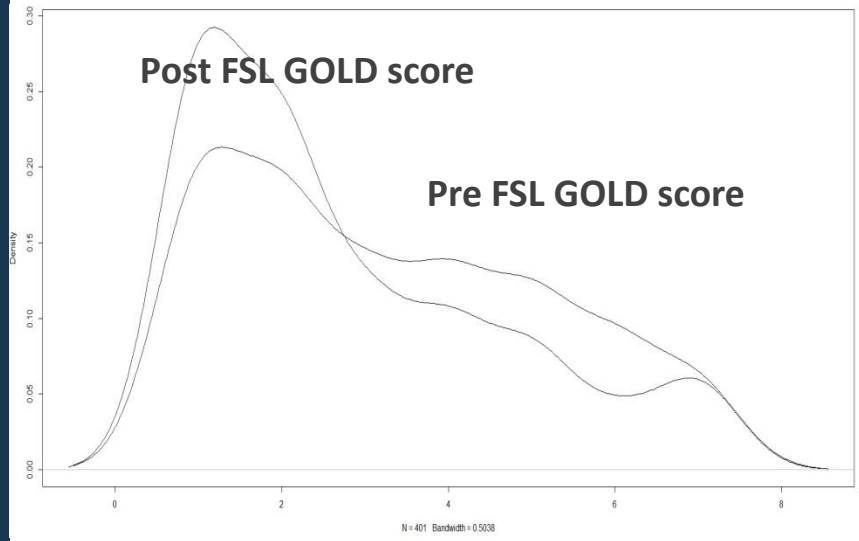
ABCD nationwide audit of FreeStyle Libre

Effect on Hypoglycaemia (GOLD Score*)

*Gold AE, MacLeod KM, Frier BM Diabetes Care 1994

ABCD nationwide audit of FreeStyle Libre

Effect on awareness of hypoglycaemia (GOLD Score)



Median pre-FSL GOLD (IQR)	3.29 (1.85)
Median post-treatment GOLD (IQR)	2.79 (1.91)
P-value	<0.0001

*P-value from Mann-Whitney U Test

More data needed to see if reversal of hypoglycaemia unawareness

ABCD nationwide audit of FreeStyle Libre

- **78%** reported that with use of FSL they were able to reduce the proportion of time in hypoglycaemia
- **33%** able to reduce rate of hypoglycaemia
- **32%** had reduced nocturnal hypoglycaemia

ABCD nationwide audit of FreeStyle Libre

Effect on Hospital Admissions & Diabetes Distress score

- Median Follow-up period of **6** months

- In the 12 months prior to FSL initiation, **5%** reported a hospital admission related to hyperglycaemia/diabetic ketoacidosis, hypoglycaemia; at follow-up this was **1%**

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Diabetes distress score Discontinuation

- Significant improvement in diabetes-related emotional score
- 3 (2-4) at baseline to 2 (1-3) at follow-up P<0.0001] in both components of brief DDSS
- 1% users had discontinued using FSL at 6 month follow-up majority of them because of lack of funding

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Conclusions

FSL use associated with

✓Significant improvement in HbA1c
✓Significant improvement in Gold Score
✓Possible reduction in hospital admissions due to DKA/Hypo and Hyperglycaemia (1 year f/u data awaited)
✓Improved diabetes related distress

Need for more follow-up data to see if beneficial effects are sustained

FreeStyle Libre May 2019

- Data presented at DUK March 2019based on
  - 3382 patients, 715 with follow up
- Yesterday (16 May 2019) data on
  - 5372 patients, 1483 with follow up
- Oral (HbA1c by Harshal Deshmukh) and poster (hypoglycaemia by Emma Wilmot) at ADA based on these bigger numbers
- First paper planned to be written after that

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FreeStyle Libre May 2019

- NB audit continues – we need hospital admission data ambulance callouts etc on big numbers over 1 year after starting FSL
- We need continued follow up data – more than one return visit

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ABCD NATIONWIDE AUDIT OF TESTOSTERONE DEFICIENCY IN MEN WITH TYPE 2 DIABETES

Questionnaire developed – audit tool being built

Lead – Professor Hugh Jones, Barnsley

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TESTOSTERONE DEFICIENCY IN MEN WITH TYPE 2 DIABETES

- Asking about erectile dysfunction should be part of routine annual review in all men with diabetes
- If present should measure testosterone and, if low, repeat with SHBG, LH, FSH

TESTOSTERONE DEFICIENCY IN MEN WITH TYPE 2 DIABETES

- High prevalence - 40% of men with type 2 diabetes have symptomatic testosterone deficiency
- Testosterone deficiency is associated with an adverse effect on cardiovascular risk factors, osteoporosis, reduced muscular strength (including frailty), anaemia and psychological well-being
- Testosterone deficiency is also associated with an increased mortality in type 2 diabetes and independently in cardiovascular disease
- Testosterone replacement has been shown to improve insulin resistance, lower HbA1c and cholesterol as well as reduce body weight and mortality

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New ABCD audit imminent

The ABCD Nationwide Testosterone Deficiency audit is an independent audit supported by an unrestricted grant from Besins Healthcare

ABCD NATIONWIDE AUDIT OF TESTOSTERONE DEFICIENCY IN MEN WITH TYPE 2 DIABETES

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FIRST VISIT DATA COLLECTION FORM

Date / (dd/mm/yyyy) /

Clinician | *Clinician's email* | *Centre ID*

PATIENT IDENTIFICATION

AFFIX PATIENT LABEL

FORENAME

SURNAME

DoB / / (dd/mm/yyyy)

NHS Number

Etnicity	☐ Afro-Carribean	☐ Asian
	☐ Oriental	☐ White
Marital Status	☐ Married/Civil	☐ Single
	☐ Separated/Divorced	☐ Widowed

DIAGNOSIS OF HYPOGONADISM MUST COMPRISE BOTH SYMPTOMS AND LOW TESTOSTERONE

PURPOSE OF THE AUDIT - 1

Testosterone replacement therapy is being used more commonly in men with hypogonadism and T2D

- TO DETERMINE THE CLINICAL BENEFITS OF TESTOSTERONE REPLACEMENT THERAPY

  Effect on symptoms of testosterone deficiency

  (a) Sexual (b) Physical (c) Psychological

  Glycaemic control, Lipid profile, body weight and change in diabetes medication.

  Effect of Testosterone therapy on Diabetes Distress

  and to assess normalisation of testosterone levels on treatment

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PURPOSE OF THE AUDIT - 2

- TO DETERMINE THE SAFETY OF TESTOSTERONE REPLACEMENT THERAPY
  - To determine how frequently hypoglycaemia is reported after initiation of testosterone therapy
  - Secondary polycythaemia – haematocrit >0.54
  - Cardiovascular events
  - Rate and cause of hospitalisation

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ABCD Nationwide Audit of Open Artificial Pancreas Systems

Funding agreed, research fellow appointed – starts August 2019

Dr Emma Wilmot lead - Derby

Association of British Clinical Diabetologists

Please be active in the current ABCD audits

Especially:

- FreeStyle Libre
- Semaglutide
- Testosterone – when it starts
- Open APS – start making a note of your patients ready to contact them – they are very enthusiastic and want to help!

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https://abcd.care/abcd-audits-n3
http://www.diabetologists-abcd.org.uk/n3/n3.htm