

ORAL SESSIONS

Oral Session I - Epidemiology, Genetics, Immunology and the Environment: T1D and T2D

O01

Degree of β -cell impairment and its translation to clinically meaningful alterations in glycemia in obese youth from normal glucose tolerance (NGT) to prediabetes to type 2 diabetes (T2D)

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Introduction: Impairment in β -cell function (BCF) relative to insulin sensitivity (IS) [disposition index (DI)] is the pathophysiological hallmark, and the strongest predictor of future T2D. However, it is not clear what degree of β -cell impairment it takes to impair glucose regulation.

Objective: We investigated the quantitative relationship between differences in clamp-measured DI and glucose area under the curve (G-AUC) during an oral glucose tolerance test (OGTT) in obese youth across the spectrum of glucose tolerance.

Methods: Study participants (age 14.9 ± 0.2 yrs.), 79 NGT, 49 impaired glucose tolerance (IGT), and 31 T2D, completed a 3-hr hyperinsulinemic ($80 \mu\text{U}/\text{m}^2/\text{min}$)-euglycemic clamp, to assess insulin sensitivity, a 2-hr hyperglycemic ($225 \text{ mg}/\text{dL}$) clamp, to assess insulin secretion, and a 2-hr OGTT to assess glycemia and G-AUC. The magnitude of differences in clamp DI ($\text{IS} \times 1^{\text{st}}$ -phase insulin) was compared with the degree of alterations in G-AUC, to provide a clinically meaningful translation of glycemic variations during a physiological test, the OGTT, imparted by changes in BCF.

Results: All groups were similar in age, sex, race and BMI (Table). In IGT vs. NGT, a lower DI of 33% corresponded to a 27% higher G-AUC, in T2D vs. IGT, 66% lower DI related to 25% higher G-AUC, and in T2D vs. NGT, 77% lower DI paralleled 59% higher G-AUC (Table).

Conclusions: A 25% deterioration in G-AUC from IGT and T2D is reflective of more than 50% impairment in BCF. We conclude that intervention trials that aim to reverse or improve BCF in obese youth at high risk for T2D, should not only focus on degree of improvement in BCF, rather its translation to clinically meaningful changes in glycemia which reflect recovery and conversion from T2D to IGT or from IGT to NGT. At least a 50% recovery in BCF might be needed to have a clinically meaningful improvement in G-AUC reflective of conversion to better glucose tolerance.

O02

State of the art metabolomics enables early detection, risk stratification and personalized follow-up in patients at increased risk for type 2 diabetes: study in 11896 young adults

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Objectives: Advances in metabolomics now allows for profiling of large-scale cohorts. We identified circulating blood biomarkers predictive of T2D. Also, metabolic signatures were generated for risk stratification and tracking the health of the individuals.

	NGT (34M/45F)	IGT (15M/34F)	T2D (14M/17F)	P
BMI (kg/m ²)	35.7 \pm 0.7	37.0 \pm 0.9	36.6 \pm 1.0	NS
Fasting glucose (mg/dL)	87.7 \pm 0.8	93.0 \pm 1.1	115.3 \pm 4.9	<0.0001
Fasting insulin ($\mu\text{U}/\text{mL}$)	32.2 \pm 2.1	43.6 \pm 3.5	62.5 \pm 10.1	<0.0001
2-hr glucose (mg/dL)	112.8 \pm 1.7	158.0 \pm 2.6	205.8 \pm 9.3	<0.0001
2-hr insulin ($\mu\text{U}/\text{mL}$)	163.0 \pm 16.6	360.9 \pm 30.0	200.2 \pm 31.0	<0.0001
Peripheral insulin sensitivity (mg/kg/min per $\mu\text{U}/\text{mL}$)	2.26 \pm 0.11	1.72 \pm 0.14	1.46 \pm 0.19	0.001
1st-phase insulin ($\mu\text{U}/\text{mL}$)	261.7 \pm 23.9	230.9 \pm 18.4	124.5 \pm 27.4	0.002
DI (mg/kg/min)	506.5 \pm 34.9	339.6 \pm 29.8	114.7 \pm 11.9	<0.0001
Glucose-AUC (mg·dL-1·h-1)	14,362.4 \pm 229.1	18,246.7 \pm 437.6	22,800.7 \pm 928.0	<0.0001

[Physical and metabolic characteristics of obese youth from NGT to IGT to T2D.]

Methods: NMR metabolomics was used to quantify 228 metabolic measures in 11,896 individuals from four Finnish cohorts (mean age 35 years, range 24-45).

Results: Associations between baseline metabolites and diabetes onset during the 7-15 years of follow-up (392 incident cases) were assessed by logistic regression. Altogether 113 metabolites were associated with incident diabetes ($P < 0.0009$; range of odds ratios (OR) per 1-SD: 0.59-1.50) after adjusting for sex, baseline age, glucose and BMI. Among the strongest predictors of increased risk of diabetes were higher concentrations of branched-chained and aromatic amino acids (OR: 1.33), triglycerides in very-low-density lipoproteins (VLDL; OR 1.50), and lower levels of omega-6 fatty acids (OR 0.75). A biomarker signature comprised of phenylalanine, free cholesterol in large HDL, and the ratio of cholesterol esters to total lipids in large VLDL was predictive of incident diabetes in an independent validation cohort after adjusting for baseline glucose and BMI (OR 10.1 comparing 5th vs 1st quintile of the biomarker score).

Conclusions: Individuals at risk for T2D display a distinct metabolic signature even years before the disease develops. Using the signature, both early risk stratification and personalized follow-up of the disease progression is enabled. High-throughput metabolomics therefore provides a powerful tool for population-wide diabetes prevention and control programs. Metabolomics is already used for health tracking in Finland.

O03

Size for gestational age affects the risk of type 1 diabetes in children and adolescents: a Swedish national case-control study

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The aim of this study was to investigate how size for gestational age affects the risk of type 1 diabetes (T1D), adjusting for maternal factors such as BMI, smoking habits and diabetes.

Using the Swedish Paediatric Diabetes Quality Registry (SWEDIABKIDS) and the Swedish medical birth register (MBR) we included all children who were diagnosed with T1D between 1982 and 2011 ($n=9376$) and four control children for each of them, matched for same sex, year and day of birth and birthplace in Sweden ($n=37504$). Small for gestational age (SGA) and large for gestational (LGA) age were defined according to the Swedish national standard. Data was initially analyzed using Person's Chi-square and thereafter by single and multiple logistic regression models.

An equal proportion of children were born appropriate for gestational age (AGA), but children with T1D were significantly more often born LGA and less often born SGA than control children (4.6% vs 3.5% and 2.7% vs 2.0%, $p < 0.001$). In the multiple logistic regression being born LGA significantly increased (OR 1.16, 95% CI 1.02,1.32) and SGA

significantly decreased (OR 0.79, 95% CI 0.65,0.96) the risk for T1D. In the subgroup analysis, LGA was an independent risk factor for T1D in the offspring and SGA was a protective factor regardless of maternal BMI and diabetes (see table).

Size for gestational age	SGA	0.79 (0.65 - 0.96)
	AGA	Ref
	LGA	1.16 (1.02-1.32)
Maternal BMI and maternal diabetes status	BMI <25 and no diabetes	Ref
	BMI ≥25 and no diabetes	1.19 (1.06-1.19)
	BMI <25 and diabetes	3.64 (2.79-4.74)
	BMI ≥25 and diabetes	3.51 (2.71-4.56)
Maternal smoking	Yes (Ref No)	0.86 (0.80-0.92)
Maternal age	≥30 years (Ref 13-29 years)	1.04 (0.99-1.10)
Gestational age	<37 weeks (Ref ≥37 weeks)	1.02 (0.91-1.14)

[Adjusted odds ratio, OR with 95% CI, for type 1 diabetes in children]

Size for gestational age affects the risk of T1D, with an increased risk if the child is born LGA and a decreased risk if the child is born SGA. To be born LGA is an independent risk factor for T1D irrespectively of maternal BMI and diabetes. This highlights the importance of preventive work to reduce risk factors for a child to be born LGA.

O04

The appearance, dynamics, and natural fate of diabetes-associated autoantibodies in children with increased HLA-conferred disease susceptibility to type 1 diabetes: a 15-year follow-up

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Objective: To assess the autoantibody signatures predictive for progression to type 1 diabetes (T1D).

Methods: HLA-predisposed children ($n=1006$, 53.0% boys) recruited from the general population in 1994-1997 were observed from birth

over a median time of 15.0 (range 1.9-15.0) years for islet cell (ICA), insulin (IAA), GAD (GADA), islet antigen-2 (IA-2A), and zinc transporter 8 autoantibodies (ZnT8A), and for T1D.

Results: By 15 years of age, 35 (3.5%) children had progressed to T1D. Altogether 272 (27%) tested positive for ≥ 1 autoantibody in ≥ 2 consecutive samples at a median age of 7.1 (0.2-15.0) years, including 32 progressors. The delay from seroconversion to diagnosis was shorter in progressors with multipositivity at seroconversion (≥ 1 positive sample) than in those with only one autoantibody (3.4 vs. 5.9 years; $P=0.03$). Transient IAA positivity associated with longer delay (8.1 vs. 3.4 years; $P=0.005$). Compared to 39 multipositive non-progressors, the progressors were younger (1.7 vs. 4.2 years; $P=0.008$), had higher frequency of IAA (59 vs. 28%; $P=0.008$), IA-2A (19 vs. 0%; $P=0.005$), ZnT8A (44 vs. 17%; $P=0.02$), and multipositivity (56 vs. 13%; $P<0.001$), and higher titres of ICA (13.5 vs. 5.0 JDFU; $P=0.005$) and IAA at initial seroconversion (9.8 vs. 7.1 RU; $P=0.04$). They had shorter delay to multipositivity (0.5 vs. 1.5 years; $P=0.005$). Within a year from seroconversion, a greater proportion of progressors were multipositive (93.8 vs. 48.7%; $P<0.001$). Among those with only one autoantibody at seroconversion, this was primarily IAA (43 vs. 27%; $P=0.27$) or ZnT8A (50 vs. 12%; $P=0.003$) among the progressors, and in multipositive non-progressors mainly GADA (0 vs. 38%; $P=0.007$).

Conclusions: Multipositivity at seroconversion and transient IAA positivity associate with progression rate to T1D. Multipositivity within a year from seroconversion is predictive for T1D. The first appearing autoantibody might reflect the events driving the disease process towards overt T1D.

O05

Low 25-hydroxyvitamin D is associated with increased risk of type 1 diabetes, younger age of onset and more severe presentation

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Objectives: To investigate the associations between blood 25-hydroxyvitamin D (25OHD) concentration and T1D risk, age of onset and severity of presentation, after adjustment for climatic variables, including ambient UV radiation.

Methods: A case-control design was used including a representative sample of 169 children aged 0-16 years newly diagnosed with T1D in Western Australia between 2011 and 2015 and 459 healthy controls. Demographic, clinical and 25(OH)D data from the Western Australian Children's Diabetes Database were individually linked with date- and location-specific data from NASA satellites and the Bureau of Meteorology for daily erythema-weighted UV radiation and temperature measurements, respectively. Climate data was calculated for the 91 days prior to venesection. Multiple regression analyses were performed using models adjusted for ethnicity, age, sex, body mass index, season, socio-economic status, UV radiation and temperature.

Results: Vitamin D deficiency (25(OH)D $< 50\text{nmol L}^{-1}$) was associated with an 8-fold increase in the odds of T1D (aOR=7.9, $p<0.01$, vs

$\geq 50\text{nmol L}^{-1}$). Among cases, vitamin D deficiency was associated with increased risk of diabetic ketoacidosis (DKA) at diagnosis (aOR 5.8, $p<0.01$). Lower 25(OH)D levels were associated with younger age of onset ($p=0.05$) and among cases with DKA, vitamin D deficiency was associated with a 2.7-year younger age of onset ($p=0.03$). There was no effect of UVR independent of 25(OH)D levels ($p=0.37$).

Conclusion: Children with T1D were more likely to be vitamin D deficient than controls. Vitamin D deficiency was associated with more severe presentation after adjustment for key demographic and climatic variables. Lower 25(OH)D levels resulted in significantly younger age of onset, which was more pronounced among those who presented with DKA. At time of diagnosis the evidence supports a determining effect of vitamin D.

O06

Association of prodromal type 1 diabetes with school absenteeism: a population-based case-control study

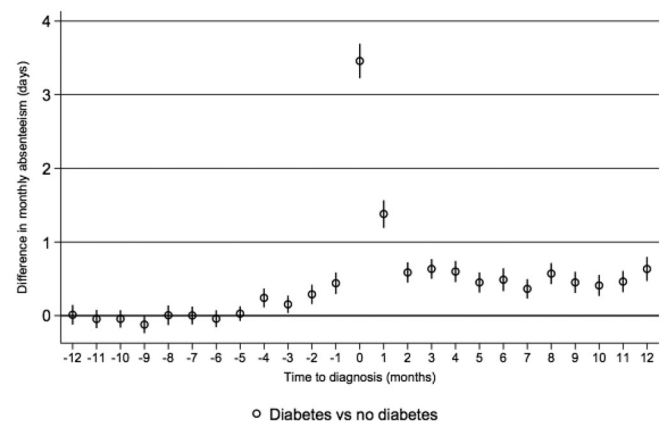
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Objectives: To examine if the prodromal phase of type 1 diabetes (T1DM) is associated with increased school absenteeism in Danish school children, and to investigate if T1DM is associated with increased school absenteeism post onset.

Methods: Population-based matched case-control study involving 1,338 Danish public-school children who developed T1DM from August 2010 to June 2017 matched to 6,690 children that did not develop T1DM. The children were matched 1:5 on date of birth and gender. The outcomes were school absenteeism (days) measured each month 12 months before and after the onset of T1DM. Linear regression was used to compare school absenteeism between children who did and did not develop T1DM. School absenteeism was compared between children who presented in diabetic ketoacidosis (DKA) vs those who did not present in DKA.

Results:



[Figure 1: Mean (95% CI) difference in school absenteeism (days) relative to onset-month, diabetes vs. control]

Age at Onset (years)	Total n (%)	Male n (%)	In DKA n (%)	Positive Family History in First Degree Relative: father; mother; sibling n (%)	Diagnosis at First Clinical Encounter n (%)
<2	170 (18)	97 (57)	122 (72)	10;10; 5 (15)	87 (51)
2 to 3.99	347 (36)	194 (56)	114 (33)	27; 8;12 (13)	226 (65)
4 to 6	438 (46)	221 (51)	82 (19)	30;13;10 (12)	333 (76)
Total	955	54%	318 (33)	67;31;27 (13)	68%

[Characteristics of 955 Children <6 years at Diagnosis of T1D 1990-2014]

Mean number of days absent per month for children without diabetes was 0.997 (SD 1.87). For children who developed T1DM in month 0, absenteeism was not statistically significantly different in months 12 to 5 before diabetes onset compared to children who did not develop T1DM. In month 4 before onset the mean difference was 0.24 (95% CI: 0.11 to 0.37, $p < 0.001$). In the month of onset, the difference was 3.46 (95% CI: 3.22 to 3.70, $p < 0.001$). Children who presented in DKA were only more absent in the month of onset: 1.03 more days (95% CI: 0.43 to 1.63, $p < 0.001$). In the other +/- 12 months absenteeism was similar to children diagnosed without DKA ($p = 0.30$ from joint test of significance in pre-months and $p = 0.20$ in post-months from joint test of significance).

Conclusion: School absenteeism was increased as early as 4 months prior to diabetes onset, suggesting that there is scope for earlier detection of T1DM. A year after onset, children with diabetes had around 50% more school absenteeism compared to their peers without diabetes.

O07

25 years of changing characteristics at diagnosis of type 1 diabetes (T1D) in children younger than 6 years

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Introduction: The increasing prevalence of T1D in young children was first reported in 1997 and subsequently corroborated. Diabetic ketoacidosis (DKA) at diagnosis remains at the forefront of institutional and national reports.

Objective: To assess trends in characteristics at diagnosis of T1D from 1/1/90 to 12/31/14 in children < 6 years presenting to Boston Children's Hospital (BCH).

Methods: We retrospectively reviewed medical records to obtain data at diagnosis.

The proportion of patients presenting in DKA within each 5-year epoch was characterized by univariate then multivariable logistic regression (LR) controlling for age, insurance, FH of T1D and diagnosis at first clinical encounter.

Results:

Over 25 years, the overall prevalence of DKA decreased by 3% per 5 year epoch.

Univariate predictors of DKA include age < 2 ($p < 0.0001$), age 2 and 3 years ($p < 0.004$), public insurance ($p < .0001$), FH of T1D in first degree relatives (FDR) ($p < 0.0001$), diagnosis without a clinical encounter within past 30 days ($p < 0.001$), calendar years 1990-1994 ($p < .0001$) and 2005-2009 ($p < 0.02$) and Non-Hispanic White ancestry ($p = 0.043$).

In the multivariable model, holding all other variables in the model constant, predictors of DKA include age < 2 ($p < 0.0001$), age 2 and 3 years ($p < 0.003$), public insurance ($p < 0.0001$) and a FH of T1D in FDR ($p < 0.0001$) with each subsequent year over 25 years associated with a 0.04 lesser odds of presenting in DKA. Using stepwise LR to identify predictors of DKA severity, while holding other variables in the model constant, only age < 2 years ($p = 0.0001$) and age 2 and 3 years ($p = 0.01$) were significant.

Conclusion: All family members, caregivers, teachers, and clinicians must be made aware of the hazard of presenting in DKA in pre-school age children.

Oral Session II - Acute and Chronic Complications and Associated Diseases

O08

Hypoglycemia leaves a persistent metabolomic fingerprint in children with type 1 diabetes

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Objectives: Insight into metabolic disturbances that persist after episodes of hypoglycemia and selection of biomarkers of those episodes.

Methods: Three groups of children with T1DM were recruited: after an episode of hypoglycemia (HG, n=10), with well-controlled diabetes (EDM, n=25) and with new onset diabetes without ketoacidosis group (NDM, n=15). All patients were matched based on sex and age at T1DM diagnosis. EDM and HG groups were matched based on age, duration of T1DM and recent HbA1c. Serum samples were collected at three time points: 0-12h-48h since hospital admission (HG group), 0-24h-72h for the NDM group and once for EDM patients. Metabolic fingerprinting was performed with LC-QTOF-MS (Agilent 6550 iFunnel). Metabolic features remaining after blank extraction and fulfilling quality control criteria entered statistical analysis.

Results: After filtering 359 out of 1006 (positive ionization) and 374 out of 763 m/z (negative ionization) values were suitable for between-group comparisons. Among those features we selected 6 metabolic features that persistently had higher level in HG than in

both EDM and NDM groups and 8 metabolic features with lowered levels in the HG group. Among the up-regulated features we identified three metabolites: two lysophosphatidylethanolamine (LPE) (18:2) and (20:3), and lysophosphatidylcholine (18:2). From down-regulated, we identified only oxy-phosphatidylcholine (34:4). LPE (20:3) showed the strongest discriminative capabilities in all timepoints analyzed together with AUC 0.813 (95%CI 0.729-0.989), sensitivity 100% (95%CI 85-100%), specificity 61,5% (95%CI 48.6-73.1%), second best was PC O(34:4) with AUC 0,720 (95%CI 0,619-0,821). In split analysis (0-12-48h) AUC values for LPE (20:3) were all >0.8.

Conclusions: Metabolic disturbances caused by hypoglycemia episode persist in the serum at least up to 48 hours after the occurrence of the episode.

The study was financially supported by Scientific Grant from Diabetes Poland.

O09

Nasal versus injected glucagon: User experience results of a simulated severe hypoglycemia study

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Objectives: Injectable glucagon (IG) is challenging to use for caregivers of a person with diabetes (PWD) in stressful severe hypoglycemia (SH) rescue. Success rates, administration time, and user preference

	PWD Trained (N=32) ^a				Untrained (N=33)			
	NG Successful	NG Unsuccessful	IG Successful	IG Unsuccessful	NG Successful	NG Unsuccessful	IG Successful	IG Unsuccessful
N (% of all device sims)	28 (90.3)	3 (9.7) ^b	5 (15.6)	27 (84.4)	30 (90.9)	3 (9.1)	0 (0)	31 (100) ^c
Ease of preparation ^{d,e}	26 (92.9)	1 (33.3)	4 (80.0)	23 (88.5)	24 (85.7)	3 (100.0)	N/A	27 (87.1)
Confidence that device will be used correctly ^{d,e}	22 (78.6)	1 (33.3)	3 (60.0)	20 (76.9)	27 (96.4)	3 (100.0)	N/A	30 (96.8)
Easy to use ^{d,e}	23 (82.1)	1 (33.3)	4 (80.0)	20 (76.9)	27 (96.4)	3 (100.0)	N/A	30 (96.8)
Overall satisfaction ^{d,e}	22 (78.6)	1 (33.3)	3 (60.0)	20 (76.9)	24 (85.7)	3 (100.0)	N/A	27 (87.1)
Overall preference ^{d,e,f,g}	24 (85.7)	1 (33.3)	4 (80.0)	21 (80.8)	26 (92.9)	3 (100.0)	N/A	29 (93.5)
PWDs who feel safer with NG ^{d,e}	25 (89.3)	3 (100.0)	5 (100.0)	23 (88.5)	-	-	-	-

^aOne additional participant did not find either device during sims. ^bOne participant was unsuccessful with IG, but did not attend the subsequent NG sim and did not complete the questionnaires. ^cTwo participants did not find the IG device. ^dStrongly prefer or prefer NG based on 5 point Likert scale (strongly prefer NG, prefer NG, no preference, prefer IG, strongly prefer IG). ^eData was analysed only for those who found the device and attempted administration at both visits, i.e. N=26 for PWD trained - IG unsuccessful. ^fNumber of PWD trained participants preferring IG: NG successful (2), NG unsuccessful (2), IG successful (0), IG unsuccessful (4). ^gNumber of untrained participants preferring IG: NG successful (1), NG unsuccessful (0), IG successful (N/A), IG unsuccessful (1). Abbreviations: IG = injectable glucagon, N = number, N/A = not applicable, NG = nasal glucagon, PWD = person with diabetes; sim = simulation.

[Proportion of successful versus unsuccessful administrations and user preference for NG over IG [N (%)]]

for nasal glucagon (NG) vs IG devices were evaluated after treating a simulation (sim) of SH.

Methods: Adult PWDs (N=33: 12 Type 1, 21 Type 2) were trained to use NG or IG and then trained their caregiver in its use; 1 wk later caregivers attempted administration to a manikin exhibiting SH in a simulated, real life setting. Untrained adults (N=33) not associated with a PWD (willing to assist, not trained), were shown the device pre-sim. After 1 wk the process repeated with the other device. Proportions of users successful with each device (complete dose+critical steps) and times to administer NG vs IG were studied. User/PWD perceptions were assessed by comparative questionnaires, completed after videos of both sims were viewed at the 2nd sim visit.

Results: Of PWD trained users, 90% (28/31) and 16% (5/32) were successful with NG and IG, respectively (McNemar $p < 0.0001$). Similarly, 91% (30/33) of untrained users were successful with NG, 0% with IG (McNemar $p < 0.0001$). Median time to successfully administer NG was 30 sec for both trained and untrained users; the 5 trained users successful with IG took 73 sec.

NG was rated preferred by those successful with either NG or IG; PWDs indicated they felt safer with NG even with successful IG dosing (Table). Untrained users were as successful as PWD trained in dosing NG, but there were no IG successes without training.

Conclusions: Both PWD-trained and untrained users were more successful and faster in administering NG vs IG. None of the few who preferred IG were successful with IG, while the few successful IG-users preferred NG or stated no preference. Being trained was not critical for success with NG and ease of preparation/use likely contribute to overall preference.

O10

Longitudinal determinants of cardiovascular risk in Australian and New Zealand youth with type 1 diabetes: the ADDN study

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Primary aim was to measure the impact of BMI in youth with type 1 diabetes on cardiovascular risk factors. We also identified other independent determinants of risk.

Methods: Inclusion criteria were youth with type 1 diabetes followed by the Australasian Diabetes Data Network (ADDN), aged 2 - 25 years at all visits, with at least (i) two measures of BMI (ii)two measures of blood pressure at rest and /or (iii) one measure of total and HDL cholesterol. Exclusion criteria were anti- hypertensive or statin medications. A two way random intercept model was fitted at the patient and centre level, and a random slope for BMI z-score. Outcomes in multivariate analyses were blood pressure z-score, non-HDL cholesterol, and urinary albumin /creatinine.

Results: An increase of 1 BMI z-score related independently to an increase in systolic (coefficient +0.26, 95% CI 0.24, 0.28, $p < 0.001$) and diastolic blood pressure z-scores (+0.13, 95% CI 0.11,0.14, $p < 0.001$) and higher non- HDL cholesterol (+0.16 mmol/L, 95% CI 0.13, 0.18, $p < 0.001$) and LDL cholesterol. Females had higher non-HDL cholesterol (coeff + 0.27 mmol/L, 95% CI 0.24- 0.31, $p < 0.001$) and higher ACR (coeff+0.63 mg/mmol, 95% CI 0.40, 0.86, $p < 0.001$). Indigenous Australians (1.8%) had higher non- HDL cholesterol (+0.21 mmol/L, 95% CI 0.04, 0.39, $p=0.02$) and markedly higher ACR (+ 2.37 mg/mmol, 95% CI 1.47, 3.27, $p < 0.001$). CSII participants had lower systolic and diastolic blood pressure z-scores ($p < 0.001$), lower ACR (-0.29 mg/mmol, 95%CI -0.53, -0.05, $p < 0.001$) and lower non-HDL cholesterol (-0.07mM, 95% CI-0.10,-0.03, $p < 0.001$), compared with MDI and independent of HbA1c's effect on non-HDL cholesterol (+0.13 mmol/L, 95% CI 0.12-0.14, $p < 0.001$).

n(male)	7061(3629)
Number of study visits per participant : median(IQR)	21(11,30)
Age at diagnosis - years : mean(SD)	7.9(4.1)
Followup(duration of diabetes) -years: median (IQR)	7.1(4.0,10.6)
Insulin regimen: CSII/MDI/BD	47.1%/43.2%/9.7%
BMIz over all visits: median(IQR)	0.7(0.1,1.2)
HbA1c % over all visits: median(IQR)	8(7.3,8.9)
Blood pressure mmHg over all visits: females, males: median(IQR)	110(100,119)/65(60,71); 110(100,120)/65(60,71)
Non-HDL cholesterol(total cholesterol-HDL cholesterol) mmol/L over all visits: median(IQR)	2.9(2.4,3.5)
Urinary albumin/creatinine(ACR) mg/mmol over all visits: median(IQR)	0.7(0.4,1.3)

[Table 1: Participant characteristics]

Conclusion: BMI had an independent adverse effect on cardiovascular risk. CSII had a modest independent benefit on cardiovascular risk profile. Females and indigenous Australians in particular had a more adverse risk profile.

O11

Angiotensin converting enzyme inhibitor (ACEi) and statin combination therapy reduces risk of 3-step retinopathy progression in youth with type 1 diabetes (T1D) in the adolescent cardio-renal protection intervention trial (AdDIT) - a post-hoc analysis based on diabetes duration

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Aim: We hypothesized that in adolescents with high levels of albumin excretion, ACEi (A) and /or statins (S) ameliorate risk of 3-step diabetic retinopathy (3DR) progression.

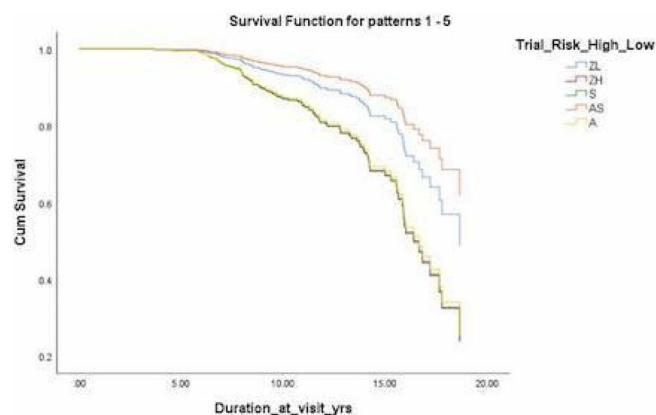
Methods: Annual digital retinal photography was performed in adolescents with T1D (n=978, age 14.3±1.6yrs, duration 6.6yrs) screened for participation in AdDIT. Participants were stratified according to Urinary Albumin Creatinine Ratio (ACR) into High-Risk (Upper ACR tertile: n=465) and Low-Risk (Lower ACR tertiles: n=512). 355 High-Risk adolescents were randomized to the AdDIT interventions: ACEi and/or statin, or placebo for 2-4 years. We performed post-hoc intention to treat analyses using multivariable cox regression with diabetes duration as the time dependent variable to evaluate whether intervention reduced risk of 3DR progression in the High-Risk group to risk in the Low-Risk group. 3DR progression was derived from the worst eye.

Results: The risk of 3DR progression was double in the High-Risk group compared with Low-Risk group. In the active treatment High-Risk group, ACEi+Statin reduced risk of 3DR progression to that of the Low-Risk group (Table). Higher HbA1c was also associated with greater risk of 3DR progression HR 1.3 (1.1,1.5) but neither blood pressure nor gender were significant in the model. Within the High-Risk group ACEi+Statin reduced risk to HR 0.33(0.12, 0.94).

	Hazard Ratio (95%CI)	P Value
High-Risk (including Placebo)	2.0 (1.3, 3.2)	0.003
Statin+Placebo	2.0(1.1, 3.7)	0.04
ACEi+Placebo	1.9 (1.0, 3.6)	0.046
ACEi+Statin	0.7 (0.2, 1.9)	0.4
Low-Risk	Reference	Reference

[Multivariable Cox Regression Model for 3-Step DR progression in AdDIT intervention and observational groups*]

Conclusions: ACEi and Statin combination therapy significantly ameliorated risk of 3-step DR progression in the High-Risk vs Low-Risk adolescents with T1D, while higher HbA1c increased risk. Long term follow-up of this cohort is necessary to elucidate possible long term legacy effects of such interventions.



[Risk of 3-step DR progression by treatment allocation group]

*Blood pressure and Sex were not statistically significant. HbA1c was significant.

O12

A comprehensive diabetes complications screening (DCAS) program: outcomes in a 20 year incident cohort

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Objectives: To examine (i) complication rates in an incident cohort of youth with type 1 diabetes (T1D); (ii) predictors of complications; and (iii) factors associated with uptake of the DCAS program.

Methods: The cohort consisted of 1832 youth aged < 16 yrs diagnosed with T1D at CHW between 1990-2009. Median age at diagnosis was 8.7 yrs [IQR 5.4-11.6]. 51% were female. From Apr 1991-2019, 1214 (68%) attended DCAS before age 20 yrs. Outcomes assessed at DCAS were retinopathy, quantitative sensory testing, cardiac autonomic function (heart rate variability) and nephropathy.

Retinopathy	369/1201 (31%)
Vision threatening diabetic retinopathy	4/1201 (0.3%)
Macular oedema	2/1201 (0.2%)
Albuminuria (elevated ACR or AER)	257/1180 (22%)
Cardiac autonomic nerve abnormality	297/621 (48%)
Peripheral nerve abnormality	452/1105 (41%)
Any complication	835/1214 (69%)

[Frequency of complications (at any visit)]

Predictors of complications analysed using multivariable generalized estimating equations were: duration, blood pressure SDS, BMI SDS, gender and HbA1c. Predictors of attendance at complications analysed using multivariable logistic regression were: socio-economic status (SES), lifetime HbA1c, gender, age at diagnosis and BMI SDS.

Results: Median DCAS visits per patient was 2 [1-4]. Age at last visit was 17.0 yrs [15.6 -18.4]. Those with complications (69%, see table) had higher lifetime HbA1c (8.4 v 8.2%, $p=0.004$) and longer diabetes duration (9.7 v 6.6 yrs, $p<0.0001$) The presence of any complication was associated with: T1D duration (OR 1.04, 95% CI 1.02-1.07, $p<0.0001$), systolic BP (OR 1.21, 1.12-1.31, $p<0.0001$), diastolic BP (OR 1.11, 1.01-1.21, $p=0.032$) and HbA1c (OR 1.17, 1.11-1.23, $p<0.0001$). Attendance at DCAS was associated with higher SES advantage (OR 2.12, 1.69-2.65 $p<0.0001$) and higher lifetime HbA1c (OR 1.21, 1.09-1.33 $p<0.0002$).

Conclusions: More than two thirds of this cohort had microvascular complications, most commonly cardiac autonomic and peripheral nerve abnormalities. Those who did not attend DCAS were more socially disadvantaged; this group should be targeted to ensure complications screening can be accessed by all young people with T1D. Our findings also highlight the need to address key risk factors - HbA1c and BP.

O13

Subclinical diabetic neuropathy and early endothelial dysfunction in youth with type 1 diabetes

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Objective: This study investigated the anomalies in peripheral nerve conduction in children with Type 1 Diabetes (T1D) and assessed its association with the presence of early endothelial dysfunction, as measured by means of reactive hyperemia, and with demographic and clinical factors.

Methods: The study included 41 patients (63% males), aged 15.9 ±3.6 years with T1D duration of 8.9±4.1 years, in intensive insulin treatment. All patients underwent bilateral motor and sensitive nerve conduction (NC) of median, ulnar, tibial, peroneal and sural nerves and performed the endopath test.

Results: None of the patients reported clinical signs/symptoms of neuropathy at the recruitment evaluation. However, 58.5% of patients presented a pathological NC in at least one nerve at baseline: 18 patients showed an altered motor NC and 15 patients an altered sensitive NC. Overall, 37% of the youth presented a polyneuropathy in at least 2 different nerves. The most common pathologic parameters were the peroneal nerve velocity (42% of patients) for motor nerves and the sural nerve velocity (27% of patients) for sensitive nerves. The mean conduction velocity for each nerve was not significantly different in patients with endothelial dysfunction (n=30), compared to patients with normal endopath test (n=11). Spearman test did not show significant correlations between nerves velocities and endopath values when considered continuously. Hemoglobin A1c and diabetes duration negatively impacted on peroneal nerve conduction, while there were no correlations with age, age at onset and insulin requirement.

Conclusions: Nerve conduction abnormalities are common in youth with T1D with no clinical signs of neuropathy. Glycemic control and diabetes duration are the most impacting risk factors for the development of neuropathy. Altered endothelial function did not associate with subclinical neuropathy.

O14

Narrow extended zone retinal calibre is associated with peripheral neuropathy in adolescents with type 1 diabetes

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Introduction: Early microvascular changes predict complications in type 1 diabetes. Association between retinal microvascular changes and diabetic complications including retinopathy and nephropathy is well established but not diabetic neuropathy (DN). We aim to investigate the association between retinal vascular calibre in the extended zone and DN in youth with type 1 diabetes.

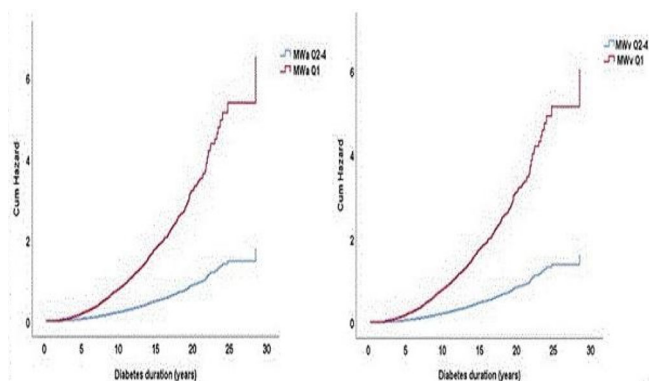
Research design and methods: Longitudinal study (median follow up 3.9 yrs) of 1158 youth with baseline mean ± SD age 14.0±1.5 yr, HbA1c 8.5±1.3 % (IFCC 69.4±14.1 mmol/mol), and median duration 4.6 yr [IQR 3.2-6.5]. DN was defined by ≥2 abnormalities in peripheral nerve function as measured by 2 thermal and 2 vibration threshold tests in the foot. Retinal vascular geometry (RVG) from baseline retinal photographs were comprehensively assessed using (Singapore I Vessel Assessment). "Extended zone" retinal vessel calibers are the mean width of arterioles and venules (MWa and MWv). Generalized estimating equations and cox regression were used to examine associations between vessel calibers and DN with covariates including HbA1C, height, gender, BMI, duration, BP and urinary albumin excretion rate.

	Mean (SD) z-score	95% Confidence Interval	p-value
DXA parameters (height z-score)			
Arms BMD	-0.43 (0.97)	-0.67 to -0.18	0.001
Femoral neck BMD	-0.46 (1.33)	-0.80 to -0.12	0.008
pQCT parameters (age z-score)			
4% tibial trabecular vBMD	-0.36 (0.76)	-0.55 to -0.17	<0.001
4% radial trabecular vBMD	-0.81 (1.35)	-1.14 to -0.47	<0.001
4% total BMC (radius)	-1.04 (1.27)	-1.36 to -0.72	<0.001
66% tibial cortical vBMD	0.50 (0.59)	0.36 to 0.65	<0.001
66% radial cortical vBMD	0.73 (1.46)	0.36 to 1.09	<0.001

[DXA and pQCT parameters in T1D adolescents]

Results: DN was present in 285 (26%). DN was associated with narrow retinal calibres (Q1vs Q2-4) MWa; OR 1.45 (95%CI 1.05, 1.9); MWv OR 1.55 (1.1, 2.1) after adjusting for covariates. DN was not associated with CRAE and CRVE. In Cox proportional hazard regression analysis, lowest quartiles (Q1 Vs Q2-4) MWa (HR 3.7 CI (2.8, 4.8)) and MWv (3.7(2.9, 4.9)) were associated with higher cumulative risk of DN (Figure 1).

Conclusions: Narrow extended zone vessels were associated with DN. Assessment of these vessels may identify young patients at greater risk for DN.



[Cumulative hazard curves for risk of diabetic neuropathy by quartiles of retinal vessel calibre]

O15

Association between childhood type 1 diabetes and bone mass and structure

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Objectives: 1. Describe fracture rate, bone mineral density (BMD) and bone structure in youth with type 1 diabetes (T1D) 2. Explore associations between complications, HbA1c and bone parameters.

Methods: Cross-sectional study of 64 youth (38 males) with >10y T1D duration, who had bone health and complications assessments including: Dual-energy X-ray absorptiometry (DXA), peripheral quantitative computed tomography (pQCT) and self-reported fracture survey. Age and height adjusted bone parameters were compared with population norms using 1 sample t-tests. Associations between T1D characteristics and bone parameters were assessed by 2 sample t-tests and Pearson correlation.

Results: 31/62(50%) youth had a positive fracture history and forearm was the commonest fracture site. Mean age was 16.6 ± 2.1 y, BMI z-score 0.62 ± 1.1, height z-score 0.11 ± 0.9, age at T1D diagnosis 3.8 ± 2.2 y, T1D duration 12.8 ± 2.2y and HbA1c at visit 8.9 ± 1.7%.

DXA (z-score): Total body, lumbar spine BMD and bone area were normal. Arm and femoral neck BMD were reduced; fat% (0.85, p< 0.001) and lean tissue mass (0.41, p=0.045) were increased.(Table)

pQCT (z-score): 4% tibial and radial trabecular volumetric BMD (vBMD), bone mineral content and bone cross sectional area (CSA) were reduced. Cortical vBMD was increased at 66% tibial and radial sites but muscle CSA was reduced in both limbs.(Table)

Total BMD was positively correlated with BMI and negatively correlated with age at T1D diagnosis. Retinopathy (23%) and abnormal resting heart rate (25%) were negatively associated with cortical and total bone CSA. HbA1c, T1D duration and fracture history were not associated with bone parameters.

Conclusion: Youth with T1D >10y duration had reduced trabecular vBMD and increased cortical vBMD suggesting increased material density. This may represent a low bone turnover state. Younger age at T1D diagnosis appears to have negative effect on BMD.

Oral Session III - Pumps, CGM and Automated insulin delivery

O16

Acceptability and effectiveness of a predictive hypoglycemia alert in children and adolescents

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Introduction: The “Urgent Low Soon” (ULS) alert introduced with the G6 continuous glucose monitoring (CGM) system (Dexcom, Inc., San Diego, CA) is activated when its estimated glucose value (EGV) is predicted to be ≤ 55 mg/dL within the next 20 minutes.

Objectives: We examined the extent to which the ULS alert was disabled and whether its enabled/disabled status was correlated with glycemic outcomes in pediatrics. We also examined the influence of age and device interactions.

Methods: EGVs from a convenience sample of pediatric patients (7910 children ages 2.0 to ≤ 12.0 and 7082 adolescents ages >12.0 to ≤ 18.0) in the United States who used the G6 CGM system and whose data were uploaded to the Dexcom Cloud were evaluated. ULS acceptability was estimated as the percentage of patients who maintained its default (enabled) setting. Efficacy is given as “hypoglycemia reduction” and was calculated as the between-groups difference in the minutes per day with EGVs < 70 mg/dL or < 54 mg/dL.

Results: The ULS was in its enabled (default) state among 92% of children and among 86% of adolescents. The ULS enabled/disabled status was not strongly related to the frequency at which CGM data were viewed or to the extent of system utilization (not shown). The Table shows statistically significant hypoglycemia reductions favoring ULS-enabled groups in both age groups and both hypoglycemia thresholds (all $p < 0.01$). ULS-disabled groups experienced >42 min/day with EGVs < 70 mg/dL and >10 min/day with EGVs < 54 mg/dL. By contrast, ULS-enabled groups experienced < 30 min/day with EGVs < 70 mg/dL and < 7 min/day with EGVs < 54 mg/dL. Efficacy tended to be higher among children than among adolescents.

Conclusions: The ULS was acceptable, and effectively mitigated hypoglycemia among children and adolescents.

O17

Continuous glucose monitoring alerts for existing or impending hypoglycemia among children and adolescents

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Introduction: Optimal use of continuous glucose monitoring (CGM) systems requires appropriate device settings and awareness of their likely impact on glycemic outcomes.

Objectives: We evaluated hypoglycemia in relation to use of threshold alerts for existing hypoglycemia and a new predictive “Urgent Low Soon” (ULS) alert for impending hypoglycemia among children and adolescents.

Methods: We examined estimated glucose values (EGVs) from an anonymized convenience sample of $n=1747$ pediatric patients who used the G5 Mobile CGM system and transitioned to the G6 system (both from Dexcom, Inc., San Diego, CA) between 5/1/2018 and 4/30/2019. Patients were included if they had uploaded one or more EGVs during each of the 30 days immediately before and after the transition to G6. Only patients using Internet-connected mobile devices were included. Data from users with a low threshold alert setting of 70 or 80 mg/dL (default) were analyzed separately. Data from patients who disabled the ULS alert on their G6 systems, or those from patients who varied their low threshold alert setting at any time during the study interval, were excluded. Hypoglycemia was calculated as the percentage of EGVs below either 54 or 70 mg/dL and converted to minutes per day.

Results: The Table shows higher mean EGVs and less time spent in hypoglycemia among cohorts using the 80 mg/dL threshold alert than among cohorts using the 70 mg/dL threshold alert. The Table also shows significant reductions in hypoglycemia after transitioning from G5 to G6 regardless of age range or threshold alert setting. Time in range (70-180 mg/dL) and with EGVs >180 mg/dL or >250 mg/dL did not change significantly after transitioning to G6 in any group (not shown).

Conclusions: The new ULS predictive alert works in conjunction with threshold alerts to mitigate hypoglycemia among children and adolescents using the new G6 CGM system.

Ages		ULS Disabled (n=669)	ULS Enabled (n=7241)	% Reduction	p-value
2.0 to ≤ 12.0 years	Time < 54 mg/dL (minutes/day)	10.5	6.2	40.7%	< 0.001
2.0 to ≤ 12.0 years	Time < 70 mg/dL (minutes/day)	48.5	29.2	39.9%	< 0.001
		ULS Disabled (n=966)	ULS Enabled (n=6116)	% Reduction	p-value
> 12.0 to ≤ 18.0 years	Time < 54 mg/dL (minutes/day)	10.1	6.7	34.3%	< 0.001
> 12 to ≤ 18.0 years	Time < 70 mg/dL (minutes/day)	42.8	29.4	31.2%	< 0.001

[Effectiveness of the Urgent Low Soon Alert]

Ages		Low Threshold Alert at 70 mg/dL				Low Threshold Alert at 80 mg/dL			
		G5	G6	% Reduction	p-value (G5 vs G6)	G5	G6	% Reduction	p-value (G5 vs G6)
2 to ≤12.0	n	380			-	645			-
2 to ≤12.0	Mean Glucose (mg/dL)	175.5	176.4	-0.5%	0.66	185.2	185.0	0.1%	0.92
2 to ≤12.0	Time <54 mg/dL (minutes/day)	13.8	8.9	35.3%	<0.001	8.4	5.6	33.7%	<0.001
2 to ≤12.0	Time <70 mg/dL (minutes/day)	50.7	41.2	18.8%	0.002	33.4	27.5	17.8%	<0.001
>12 to ≤18.0	n	325			-	397			-
>12.0 to ≤18.0	Mean Glucose (mg/dL)	173.4	176.3	-1.7%	0.19	180.5	183.5	-1.7%	0.18
>12.0 to ≤18.0	Time <54 mg/dL (minutes/day)	13.9	8.1	41.7%	<0.001	7.9	5.0	36.6%	<0.001
>12.0 to ≤18.0	Time <70 mg/dL (minutes/day)	47.9	37.7	21.4%	<0.001	32.9	26.3	20.2%	0.002

[CGM parameters according to device, device settings, and age range.]

O18

Successful CGM initiation early in the course of T1D results in persistence of use

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Objective: A majority of children and adolescents with type 1 diabetes (T1D) do not meet ISPAD hemoglobin A1c (HbA1c) targets. We have previously shown that after initial glycemic stabilization, there is a sharp rise in HbA1c between 5 and 6 months of T1D diagnosis. CGM has been shown to improve outcomes in T1D and may further improve outcomes if introduced early in T1D care. The purpose of this study is to understand the feasibility of CGM initiation early in the course of T1D.

Methods: Following routine diabetes education, patients with newly diagnosed T1D were offered the opportunity to start on the Dexcom G6. Participants received initial CGM education with a certified diabetes educator at the next visit followed by a nurse practitioner telehealth visit. We prospectively collected data to determine continued CGM use, HbA1c, time in range (TIR, 70-180 mg/dl) and time in hypoglycemia (< 70 mg/dl).

Results: Between July 2018 and May 2019, 44 new onset patients were approached to initiate CGM. 41 patients elected to start CGM (age = 9.7 ± 4.1 years at diagnosis and HbA1c = 12.2 ± 1.8%). Three adolescents declined CGM because they were not ready to wear a device. Time to CGM initiation was 9.0 ± 8.8 days post-diagnosis. At the most recent follow up visit (94.1 ± 64.3 days from CGM initiation), 38 continued on CGM. Two discontinued CGM due to a lack of insurance coverage and one stopped CGM use since he did not want to wear a device. The mean HbA1c was 7.2 ± 1.0%. Over a 2 week period, mean days of CGM wear was 13.2 ± 2.3 days with 69.6 ± 18.9% TIR and 3.4 ± 3.9% time in hypoglycemia.

Conclusions: Our data shows that initiation of CGM can successfully occur early in the course of T1D. Those who started on CGM have a high wear time. With the advent of factory calibrated CGM, CGM use should be a routine part of a new onset diabetes program. Further work needs to be done to understand long-term outcomes, psychosocial impacts, and universal access of early CGM use.

O19

Effect of fat on post prandial glucose excursions in young children while using a hybrid closed-loop system

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Objective: While it has been reported that fat content impacts the duration of glycemic excursions in persons with type 1 diabetes (T1D), there is no data describing this in youth with T1D under age 6. Dietary content of young kids may include higher fat meals. Utilizing data from a hybrid closed loop study (HCL) conducted in an outpatient transitional environment of a hotel or Airbnb, we sought to explore this issue.

Methods: Fourteen toddlers aged 2.5- 5.5 years (42% female) completed a supervised clinical trial of a HCL system. The carbohydrate (CHO), protein and fat content of each meal was recorded by the medical staff, using food labels. In the present analysis, data from 40 dinners were explored. Data from meals were excluded if: the pre-meal glucose was < 70 or >200 mg/dl; there was > 2 hrs of missing sensor data post-meal; no insulin bolus was provided for dinner; or if additional insulin boluses were given 1-hr after the meal or snacking occurred after dinner. Fifteen meals were included in the analysis. Variables explored included time to peak post dinner glucose, peak post dinner glucose, and time to return to target glucose (120 mg/dl) after dinner.

Results: The mean time to peak for the meals was 75±45 minutes, the mean peak was 200±31 mg/dl, and mean time to return to target glucose was 172±81 minutes. Using linear regression, there was no significant correlation between the amount of fat and time to peak, peak glucose or time to return to target glucose.

Conclusions: While limited to 38% of the dinnertime meals in the study, the present analysis did not demonstrate any impact of fat content. This could be due to the small sample size of meals analyzed or it may suggest benefits of dynamic automated insulin delivery system that works to mitigate the impact of fat content in meals. Additional data needs to be collected to verify/strengthen these findings as well as comparing this data to what occurs during open loop insulin therapy.

O20

Closed-loop insulin therapy in free-life shows better glucose control when used 24/7 versus overnight only in pre-pubertal children with type 1 diabetes: interim analysis of the Free-life Kid AP Study

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Introduction: Control of type 1 diabetes (T1D) is a daily challenge in children because of high glucose variability.

Objective: To assess the safety and the efficacy of closed-loop insulin therapy (CL) in free-life in pre-pubertal T1D children while used 24/7 vs. overnight (ON) only.

Methods: Free-life Kid AP Study is a multicentre, prospective, randomized trial comparing glucose control with the hybrid Tandem Control-IQ insulin delivery system using a control-to-range algorithm while used either 24/7 or ON only for 18 weeks in 120 T1D children using pumps. It is preceded by a 3-week run-in phase for Tandem X2 pump and Dexcom G6 CGM training. Primary outcome is %time spent in 70-180 mg/dl target range (%TIR); secondary outcomes include average CGM, %time below and above target range (%TBR and %TAR, respectively), and the same metrics on day-time and overnight.

Results: We present the results of a scheduled interim analysis performed in the first 30 included children (17F/13M, age: 8.8±1.7 yrs, diabetes duration: 6.0±2.0 yrs, HbA1c: 7.5±0.5%) after 12 weeks of system use. %Time in CL per day was: 97.1±1.5% (24/7) vs. 52.9±2.4% (ON) with no severe hypoglycemia or ketoacidosis. Results show significantly higher %TIR overall (71.8±4.0 vs. 67.5±6.5, p=0.035) and during daytime (66.4±7.8 vs. 60.3±8.8, p=0.023) with CL 24/7. At night-time %TIR exceeds 80%: 82.7±5.5 vs. 81.9±6.4(NS). This data was associated by trends to lower average CGM (150.2±7.4 vs. 156.7±10.5, p=0.06) and %TAR (25.4±4.8 vs. 29.6±6.7, p=0.054), while %TBR (hypoglycaemia exposure) did not differ (2.8±1.9 vs. 2.8±1.0, NS).

Conclusions: CL 24/7 for 12 weeks was achieved with safety and higher efficacy than ON only in the first subset of included children,

with participants able to maintain CL function 97% of the day. Hence, the trial will be followed by an 18-week extension with 24/7 use after the end of the comparative phase in order to confirm the sustained benefit of full-time CL in this population.

O21

Safety and performance of the omnipod hybrid closed-loop system in young children aged 2-6 years with Type 1 diabetes

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Introduction: T1D therapies must be proven safe for young children, who face unique diabetes management challenges.

Objectives: The safety and performance of the Omnipod[®] hybrid closed-loop (HCL) personalized model predictive control algorithm were assessed in those with T1D aged 2-5.9 y with A1C < 10% using an investigational device in a supervised hotel setting.

Methods: A 7-day at-home standard therapy (ST) phase with CGM use preceded the 48-72 h HCL phase. Meals during HCL were unrestricted, with boluses administered per usual routine. Exercise was performed for ≥30 min/d.

Results: The 14 participants were age 4.2 ± 0.9 y, T1D duration 2.4 ± 1.0 y, A1C 7.4 ± 1.0% (57 ± 11 mmol/mol), TDD 0.77 ± 0.13 U/kg (mean ± SD). Mean glucose was lower during HCL vs ST, 148 ± 16 mg/dL (8.2 ± 0.9 mmol/L) vs 172 ± 27 mg/dL (9.6 ± 1.5 mmol/L) overall and 135 ± 17 mg/dL (7.5 ± 0.9 mmol/L) vs 167 ± 28 mg/dL (9.3 ± 1.6 mmol/L) overnight. The percent time 70-180 mg/dL (3.9-10.0 mmol/L), was 32% higher during HCL vs ST overall, 72.6 ± 8.4% vs 55.2 ± 13.1%, respectively, and 47% higher overnight, 85.3 ± 9.4% vs 58.2 ± 16.4%. Percent time < 70 mg/dL (< 3.9 mmol/L) was reduced nearly 2-fold overall and overnight. Glycemic outcomes are reported in the Table. There was 1 severe hypoglycemic event after exercise which was treated with oral carbohydrates.

Glycemic outcomes (24-hr)	HCL	ST	P-Value
Mean glucose, mg/dL (mmol/L)	148 ± 16 (8.2 ± 0.9)	172 ± 27 (9.6 ± 1.5)	0.017*
Percent time <70 mg/dL (<3.9 mmol/L), %	2.9 ± 2.3	5.1 ± 5.3	0.24
Percent time 70-180 mg/dL (3.9 - 10.0 mmol/L), %	72.6 ± 8.4	55.2 ± 13.1	0.0002*
Percent time ≥250 mg/dL (≥13.9 mmol/L), %	6.0 ± 4.6	17.2 ± 13.2	0.002*
Overnight (11pm-6:59am)			
Mean glucose, mg/dL (mmol/L)	135 ± 17 (7.5 ± 0.9)	167 ± 28 (9.3 ± 1.6)	0.005*
Percent time <70 mg/dL (<3.9 mmol/L), %	2.0 ± 3.4	4.5 ± 5.6	0.15
Percent time 70-180 mg/dL (3.9 - 10.0 mmol/L), %	85.3 ± 9.4	58.2 ± 16.4	0.0002*
Percent time ≥250 mg/dL (≥13.9 mmol/L), %	0.5 ± 1.9	14.3 ± 13.7	0.001*

[Table. Glycemic Outcomes During Hybrid Closed-Loop (HCL) and Standard Therapy (ST) Phases]

Conclusions: The Omnipod HCL system was safe and performed well in these very young children in a supervised setting, similar to the performance previously observed in older pediatric, adolescent and adult participants.

O22

Pediatric real-world and pivotal trial glycemic outcomes during MiniMed™ 670G system use

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Background: Continuous subcutaneous insulin infusion systems integrated with continuous glucose monitoring have helped to improve glycemic control in the youngest individuals living with type 1 diabetes (T1D). Today, advanced integrated systems with closed-loop capability provide additional means by which to reduce time spent in hypoglycemic and hyperglycemic ranges. The glycemic control of children managing real-world T1D with the MiniMed™ 670G system across six months was compared to the pediatric MiniMed™ 670G system pivotal trial data from children aged 2-13 years.

Methods: CareLink™ data from N=475 children with T1D (0-15yrs of age, self-reported) were voluntarily uploaded from Mar 2017-Apr 2019 and retrospectively analyzed. MiniMed™ 670G system use and glycemic metrics (estimated HbA1c; sensor glucose [SG]; time spent below, within and above range; and SG variability) were evaluated during open-loop Manual Mode (~2wks) and up to six months after SmartGuard™ Auto Mode was enabled. Data were assessed relative to those of children (N=151, 2-13yrs) in the pediatric MiniMed™ 670G system pivotal trial and presented descriptively, herein.

Results: The table shows percentage of Auto Mode use and glycemic outcomes of the pivotal trial and real-world cohorts during open-loop and SmartGuard™ Auto Mode periods. All glycemic metrics improved except those of glycemic variability. Over the 6 months, the total daily dose of insulin increased in the real-world group, reflecting what occurred in the shorter pivotal trial. **Conclusions:** Data obtained over 6 months in 475 children with T1D compares favorably with the results of the much smaller and shorter pivotal trial. By confirming the results of the pivotal trial, these findings demonstrate robust real-world performance of the MiniMed™ 670G system and that the improved glycemic outcomes observed in the pivotal trial were not due to selection bias.

O23

Technology is more than the device: sustainable improvement of glycaemic control in type 1 diabetes through data-driven eHealth including patient-HCP contacts

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Objectives: Although diabetes technology (e.g. insulin pumps including integrated continuous glucose monitoring [CGM] and flash glucose monitoring [FGM]) can improve glycaemic control in controlled trials, better outcomes through increased use were not seen in recent real-world data from T1D Exchange. The Diabeter clinics deliver standardized, value-based, comprehensive T1D care. To try to explain outcome differences between Diabeter and T1D Exchange, we evaluated technology use and eHealth activities.

	Pivotal Trial Pediatric Cohort (2-13 years) (n=151)		Real-world Pediatric Cohort (0-13 years) (n=475)						
	Run-in Manual Mode (2 weeks)	Study Auto Mode (12 weeks)	Manual Mode (*2 weeks)	Post Auto Mode Start					
				1 st 30 days	2 nd 30 days	3 rd 30 days	4 th 30 days	5 th 30 days	6 th 30 days
Time in Auto Mode, %	--	80.4	--	85.4	82.6	80.6	79.5	79.2	78.2
HbA1c, %* (mmol/mol)	7.9±0.8 (82.7±9.0)	7.5±0.6 (58.8±6.4)	8.1±1.2 (64.6±13)	7.1±0.8 (53.7±8.5)	7.1±0.9 (54.2±9.6)	7.3±0.9 (55.7±9.9)	7.3±0.9 (55.8±10)	7.3±0.9 (56.1±10)	7.3±0.9 (56.0±9.8)
SG, mg/dL (mmol/L)	170.0	161.5	181.8	162.6	163.7	166.3	167.1	167.30	167.02
Percentage of time at sensor glucose ranges, mg/dL (mmol/L)**									
<50 (2.8)	0.7	0.5							
<54 (<3.0)	1.1	0.8	0.4	0.5	0.5	0.6	0.6	0.5	0.5
<70 (<3.9)	4.4	3.1	1.9	2.2	2.2	2.3	2.2	2.2	2.2
70-180 (3.9-10.0)	55.9	64.6	52.5	65.3	64.7	62.9	62.9	62.4	62.5
>180 (10.0)	39.7	32.3	45.7	32.6	33.1	34.8	35.0	35.4	35.2
>250 (13.9)	13.7	10.4	6.2	3.7	4.0	4.5	4.8	4.6	4.6
Overall SD of SG, mg/dL (mmol/L)	58.0 (3.2)	55.4 (3.1)	63.3 (3.5)	60.6 (3.4)	61.0 (3.4)	62.4 (3.5)	62.6 (3.5)	62.5 (3.5)	62.6 (3.5)
Overall CV of SG, %	34.6	34.2	34.9	37.1	37.1	37.3	37.4	37.3	37.4
TDD, units/day	29.5	31.7	31.3	33.8	34.9	35.4	36.2	37.5	37.8

*Estimated glycated hemoglobin (HbA1c) for the Real-world Pediatric Cohort is based on the following: TIR=12.762*HbA1c+155.4.

**The hypoglycemic ranges for the pivotal trial are ≤ versus <.

All data are shown as mean±SD or mean, excluding Time in Auto Mode (median).

SD=Standard deviation, SG=Sensor glucose, CV=Coefficient of variation, TDD=Total daily dose of insulin.

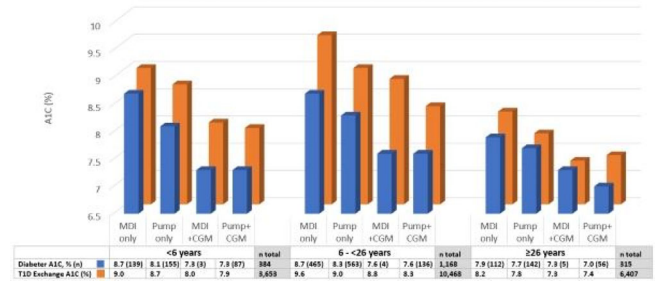
[Pediatric real-world and pivotal trial glycemic control during MiniMed 670G system Auto Mode use.]

Methods: Our disease management system Vcare collects patients' SMBG, pump and CGM data and automatically generates personalized treatment advice. We extracted cross-sectional data from 2018 on treatment modality (MDI/pump), uploads, glucose monitoring methods (SMBG/FGM/CGM) and A1C (last value of year). Data were analysed descriptively and compared with the T1D Exchange data. We used an individual net improvement score (NIS) to establish the overall improvement in care/outcome between 2017 and 2018 (range from -2 to +2).

Results: Age (mean±SD) of Diabeter patients (N=1,867) was 19.6 ±9.1 year (48% male); A1C 8.2±1.5%; 61% used pump and 16% CGM. Age of T1D Exchange patients (N=22,697) was 26±18 year (50% male); A1C 8.3%; 63% used pump and 30% CGM. Despite higher CGM use among T1D Exchange patients, the graph shows overall lower A1C by age and treatment modality for Diabeter patients. Percentage of patients who uploaded glucose data was considerable higher for Diabeter patients: 88% vs < 40% for T1D Exchange. Use of NIS also

shows improvement of A1C over time (56% improved [positive NIS], 28% were stable [NIS=0]).

Conclusions: These data indicate improvement in glycaemic control in patients receiving care according to our Value-based Healthcare (VBHC) model, combining technology use with frequent uploads and contacts between patient and team. This model facilitates improved glycaemic control compared with standard care.



[DIABETER vs T1D Exchange data]

Oral Session IV - Diabetes Care-Clinical Care Delivery

O24

Adolescent and parent perspectives on the use of financial incentives to promote diabetes self-care adherence in adolescents with type 1 diabetes

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Introduction: A majority of adolescents with type 1 diabetes (T1D) are not meeting recommended targets for glycemic control. Pilot studies of financial incentive (FI) programs for adolescents with T1D have demonstrated that FIs have the potential to promote improved diabetes self-care. Given that leveraging FIs to influence health behavior change is controversial, an understanding of family receptivity to FI programs is critical to ensure real-world uptake of FI interventions.

Objective: To explore adolescent and parent perspectives on using FI to promote diabetes self-care adherence in adolescents with T1D.

Methods: Focus groups with 46 adolescents with T1D (12-17 years old) and 39 parents of adolescents with T1D were conducted in the Seattle metropolitan area. Semi-structured questions addressed participants' current use of incentives to promote change in diabetes self-care and receptivity to a theoretical incentive program that would be administered by a third-party. Qualitative data were analyzed and emergent themes identified.

Results: Factors influencing adolescent and a parent willingness for FI program participation fell into three thematic categories: 1) Perceived potential for incentives to improve T1D self-care; 2) Acceptability of using incentives in the context of diabetes management; and 3) Threat of both short and long-term health consequences creating urgency to improve self-care (Table). These three factors together led most parents and adolescents to be open to participation in a FI program.

Conclusions: Our qualitative results suggest that well-designed FI programs offer a potential strategy for adolescents struggling with T1D management. Additionally, the use of FIs may support adolescents with T1D in developing strong self-care habits and ease the often-turbulent transition to independent self-care.

O25

The type 1 diabetes care index: a novel metric to assess delivery of optimal type 1 diabetes care

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Introduction/Objectives: The International Society for Pediatric and Adolescent Diabetes (ISPAD) has outlined standards for best practices in providing optimal diabetes care to children with type 1 diabetes (T1D). Our objectives were to design and test a metric that evaluated delivery of optimal diabetes care and to use this metric to drive improvement within our diabetes program.

Methods: Using ISPAD guidelines, we identified 11 elements of optimal diabetes care that should be reliably delivered at our institution as standard-of-care across three domains: 1) Patient-centered care 2) Preventative Screening, and 3) Psycho-social support. We utilized our electronic medical record to aid in data collection, and to help notify staff of when to deliver specific care elements (e.g. annual assessment with dietitian, lipid collection, depression screening, etc.). We designed the Type 1 Diabetes Care Index (T1DCI), a metric which aggregates missed opportunities to deliver optimal diabetes care over

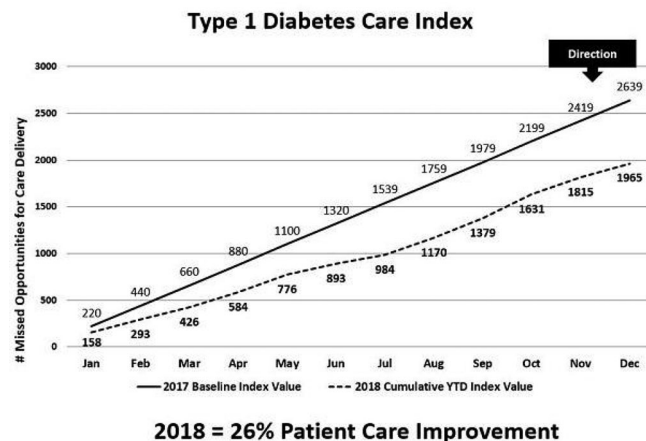
Themes	Adolescent and Parent Quotes
Perceived potential for incentives to improve T1D self-care	"[Getting incentives] keeps you more motivated [about your self-care] because you're actually getting a reward, you're not just working for nothing." - Adolescent
	"Over the six-month period [in an FI program, my child would] realize...'Wow, I can do this.' And after a while, the financial piece will fade away. 'Cause they'll see, 'I feel good. My numbers are better, I'm healthier, and Dad or Mom don't have to remind me all the time to do something.' So, I think there's more benefits to it in the long run." - Parent
Acceptability of using incentives in the context of diabetes management	"My mom she usually gives a prize for every appointment if we bring down our A1C." - Adolescent
	"We said, 'Look, your father gets paid for doing what is expected of him. How is [paying for diabetes self-care] any different? We compensate people for doing what we expect.'" - Parent
Threat of both short and long-term health consequences creating urgency to improve self-care	"I'm approaching the age where I will hopefully be leaving for college...if I can't do it on my own now, knowing the rate at which things change in my life, I won't be able to do it then and then that will be bad." - Adolescent
	"Anything's worth a try you know, cause it's their life. If you don't realize it when they're young, they're gonna have limbs missing and be blind, and so I'm all for [the use of FI]." - Parent

[Themes and Representative Quotes from Adolescents and Parents Describing Factors Influencing Family Willingness for FI Program Participation]

a given period into a cumulative score. A lower T1DCI reflects better care delivery and overall improved diabetes program performance.

Results: The T1DCI was easy to track and implement. The T1DCI progressively decreased from 2,639 at baseline to 1,965 after 12 months of utilization, a 26% reduction. This reduction translates to 1.8 missed care opportunities/patient during the baseline period to an improvement of 1.3 missed care opportunities/patient during the intervention period. Tracking the T1DCI allowed us to recognize areas for focusing improvement efforts, which led to the refinement of existing processes for care delivery.

Conclusions: The T1DCI is a useful metric to evaluate the ability of our diabetes program to standardize, quantify, and monitor delivery of optimal diabetes care to children with T1D, and to drive our program towards zero missed opportunities for care delivery.



[Type 1 Diabetes Care Index]

O26

Novel application of artificial intelligence and machine learning methods to predict deterioration in long-term glycemic control in youth with type 1 diabetes

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Objective: To develop a supervised machine learning-based model to predict 3-month changes in glycemic control (HbA1c) among youth with type 1 diabetes (T1D).

Methods: Youth with T1D ages 9-17 years of age with HbA1c < 12% were evaluated. Model inputs included discrete and free text clinical data from the electronic health record (EHR) and diabetes device data (blood glucose meters, insulin pumps, and continuous glucose monitors). Predicted change in HbA1c was modeled 70-110 days following the most recent diabetes clinic visit. Ensemble machine learning

methods were applied to all available data. The clinical sample was randomly divided into 3 folds; 3-fold model development and out-of-sample validation was performed. Average root mean squared error (RMSE) for the 3-fold cross-validation was used to define model performance.

Results: Clinical data from 1743 youth with T1D (9643 visit intervals between 70-110 days) were available for development and validation of the predictive models. A total of 17,466 features were considered for the predictive model; 1630 features improved model performance for at least 1 of 3 training:validation dataset pairs, and 305 features improved model performance for all 3 training:validation dataset pairs. Average RMSE was 0.88. Diabetes device data were available for between 1853-2130 visit intervals among 663-704 youth for 2-week intervals over an 8-week period prior to the subsequent clinic visit; RMSE decreased from 0.76 to 0.69 from 8- to 2-wks prior to the next visit with the addition of device data.

Conclusions: Supervised machine learning applied to routinely collected EHR and diabetes device data can predict significant rises in HbA1c three months following a clinical encounter. Such models could inform interventions aimed at preventing deteriorating glycemic control between clinical visits. Predictive performance of the model might be improved with further study including the addition of patient reported outcome measures.

O27

Driving better paediatric diabetes care in England and Wales - a decade of continuous improvement

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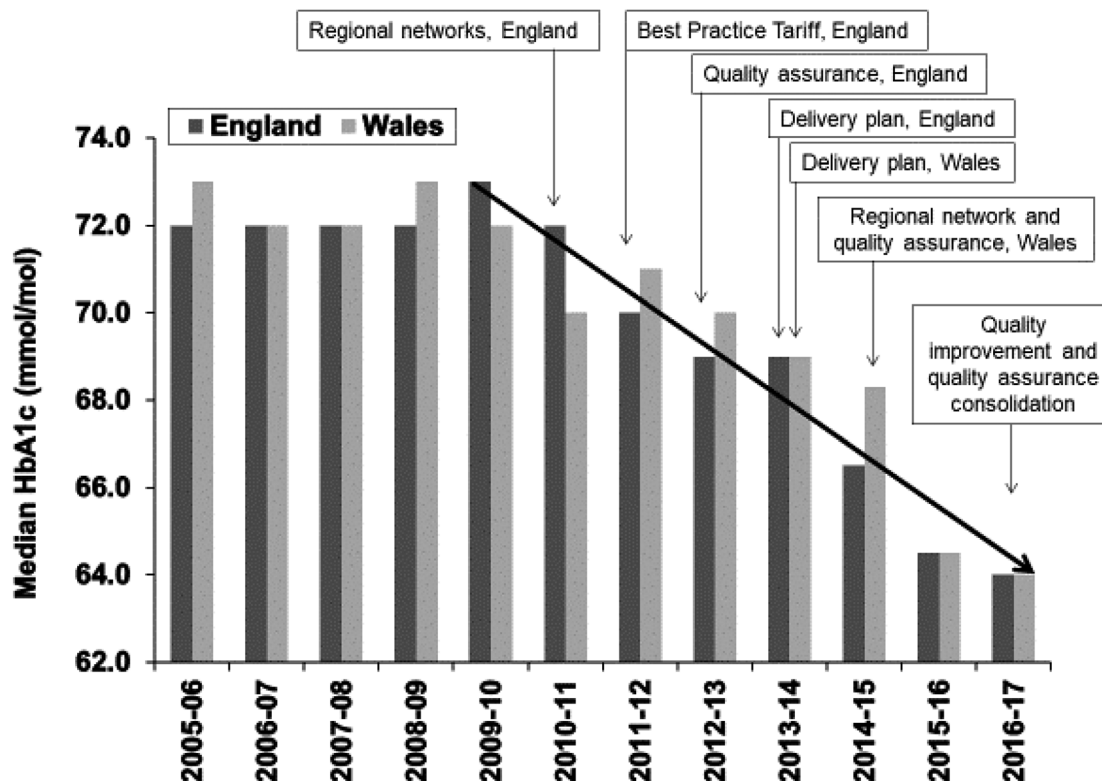
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When benchmarked against other European countries of similar economic status, there was a recognised delay in improvement of diabetes outcomes in England and Wales in the last decade. A co-ordinated framework of support for the 173 multidisciplinary teams that care for almost 30,000 children and young people with diabetes and their families was introduced from 2009 to drive improvement that would be comparable to international results and meet optimal standards of care set out by the National Institute for Health and Care Excellence.

In 2009, 10 regional networks were established in England. Each region has been overseen by a named Network Manager who works alongside local clinical leads within an overarching National Children and Young People's Diabetes Network. In 2012, a tariff-based payment for care, named the Best Practice Tariff, was initiated by the Department of Health in England with a quality assurance process in 2012 and 2015. The regional network structure and quality assurance were then introduced in Wales in 2014.

Since 2009, there has been a clear trajectory of improved outcomes for children and young people with diabetes as measured by a consistent year on year reduction of median HbA1c levels by the National Paediatric Diabetes Audit (NPDA). The NPDA has demonstrated this reduction in national median HbA1c levels from 73mmol/mol in 2009

MEDIAN HbA1c ENGLAND & WALES



[National median HbA1c levels in England and Wales from 2005 to 2017.]

to 64mmol/mol in 2017. Engaging teams and their host organisations to improve further is required to maintain momentum of the existing improvement and prevent the risk of plateauing. The combined approach of national audit data, quality assurance and quality improvement underpinned by a subscription model of financial support in the form of a National Children and Young People's Diabetes Quality Programme was launched in 2018. It is hoped that this will be the impetus for an accelerated rate of improvement over the next decade ahead.

O28

Significant reduction of ketoacidosis at diabetes onset in children and adolescents with type 1 diabetes - results of the diabetes awareness campaign of children hospital and public health department of Stuttgart, Germany

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Introduction: To prevent the potentially life-threatening complication (diabetic ketoacidosis, DKA) at type 1 diabetes onset in children and adolescents awareness campaigns about the typical clinical symptoms of type 1 diabetes can be effective, as consistently demonstrated by several campaigns.

In Germany the incidence of DKA at diabetes onset is still between 20 - 26% and shows no change over the last 15 years. As increasingly very young children suffering type 1 diabetes with increased risk for DKA we perform our Stuttgarter Ketoacidosis Prevention-Campaign. **Method:** The Campaign occurred stepwise during 3 years (2015-2017) with information flyers and posters about the diabetes-typical symptoms within school entry health examinations, in day-care facilities, in pediatric practices and by public relation activities at regular intervals. Data were collected at Olgahospital, the only children hospital in Stuttgart. 2011 - 2013 was selected as reference period.

Results: As part of the school entry health examinations we informed 17.174 children and their families (median age 4.5 years). One child showing the typical diabetes symptoms was diagnosed directly without DKA.

During Campaign 118 children and adolescents were treated with newly diagnosed type 1 diabetes compared to 127 during reference period. During Campaign DKA incidence was significant decreased (n = 19 (16.1 %) vs. n = 36 (28 %), p = 0.02).

The Campaign was fully accepted from participating institutions and persons involved. No need for additional informations and further clarification was required.

Conclusion: Awareness Campaigns like our Stuttgarter Ketoacidosis Prevention-Campaign about the typical clinical symptoms of type 1 diabetes can reduce the risk for DKA at diabetes onset significantly. This Campaign can be a model for other urban and rural districts.

O29

Use of insulin pumps combined with continuous glucose monitoring (CGM) in type 1 diabetes has similar impact on HbA1c as living in the least deprived areas of England and Wales: outcomes from the National Paediatric Diabetes Audit (NPDA) 2017-18

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Objectives: The use of insulin pumps & CGM is increasing throughout the world. Although evidence from trials suggests improved diabetes control, whole population monitoring from national audit/registries provides a better understanding of the impact that such technology may have and the effect of other patient level influences on outcomes.

Methods: Data from the NPDA collected from 173 centres providing children's diabetes care in England and Wales, between April 2017 and March 2018, was analysed. A multiple regression model, taking into account the effect of age, gender, duration and ethnicity was used to estimate the difference in mean HbA1c among patients using multiple daily injections (MDI) vs insulin pump therapy with or without added CGM. Deprivation quintiles were derived by matching postcode to indices of multiple deprivation.

Results: There were 19,932 with Type 1 diabetes (11,685 MDI, 449 MDI & CGM, 6,319 insulin pump and 1,479 insulin pump & CGM); mean (SD) age of 11.9(4.0) and mean duration of 4.3(3.8) years. Mean (SD) HbA1c for the cohort was 67.3(17.0) mmol/mol. Compared to MDI alone, the addition of CGM was associated with a decrease in mean (95% CI) HbA1c of 2.6(1.1- 4.1 p=0.001), insulin pump alone of 4.9(4.4- 5.4, p< 0.000) and insulin pump with CGM of 6.4(5.5-7.2, p< 0.000) mmol/mol after taking into account gender, age and duration of diabetes (adjusted R²=14.4%, p< 0.000). A similar difference of 5.7(5.0-6.4) was seen between those living in the least deprived compared to most deprived areas.

Conclusion: In this large observational cohort of children with Type 1 diabetes, insulin pump use, combined with CGM, was associated with improved diabetes control of a similar magnitude to the difference between living in the most and least deprived areas. Only 14.4% of the variability in HbA1c was explained by the model. Unobservable factors such as clinic organisation, consistent educational messages and environmental factors are also likely to have an effect on outcome.

O30

Effect of exercise intensity on glucose requirements to maintain euglycaemia at high insulin levels in type 1 diabetes

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We have shown that there is an inverted U relationship between exercise intensity and the exogenous glucose requirements to maintain stable blood glucose levels under basal insulin levels, with no glucose being required during high intensity exercise (1). Our aim was to test the hypothesis that this inverted U relationship also holds under hyperinsulinaemic conditions, but with extra glucose being required at all exercise intensities.

Nine young adults with T1D (mean±SD age, 22.6±4.7 y; duration of disease, 12.9±5.1 y; glycated haemoglobin, 61±14 mmol/mol [7.7±0.9%]; body mass index, 24.0±3.3 kg/m²; V̇O_{2peak}, 36.6±8.0 ml kg⁻¹ min⁻¹) were subjected to a hyperinsulinaemic-euglycaemic clamp (5-6 mmol/l), and exercised for 40 minutes at 4 intensities (35%, 50%, 65% and 80% V̇O_{2peak}) on separate days following a randomised counterbalanced design. Glucose infusion rate (GIR) and glucoregulatory hormones levels were compared between conditions.

GIR (± SEM) to maintain euglycaemia was 4.4 ± 0.4 mg kg⁻¹ min⁻¹ prior to exercise, and increased significantly by an extra GIR of 1.8 ± 0.4, 3.0 ± 0.4, 4.2 ± 0.7, and 3.5 ± 0.7 mg kg⁻¹ min⁻¹ during exercise at 35, 50, 65, and 80% V̇O_{2peak}, respectively, with no significant differences between the two highest exercise intensities (p= 0.145). Nor-epinephrine and growth hormone levels increased during the two higher exercise intensities, with highest levels attained in response to exercise at 80% V̇O_{2peak} (P < 0.05).

The relationship between exercise intensity and the glucose requirements to maintain euglycaemia under hyperinsulinaemic conditions follows a hyperbolic rather than an inverted U relationship during exercise. Further research is required to translate our findings to clinical practice.

1. Vinutha B Shetty, Fournier PA, Davey RJ, Retterath AJ, Paramalingam N, Roby HC, Cooper MN, Davis EA, Jones TW. Effects of Exercise Intensity on Glucose Requirements to Maintain Euglycaemia during Exercise in Type 1 Diabetes. JCEM; 2016.

Oral Session V - Behavioral Health and Young Adulthood

O31

Psychosocial screening in routine clinical care of youth with diabetes

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Objectives: Research indicates that youth with diabetes have high rates of psychological disorders that can interfere with successful diabetes management. Clinical practice guidelines recommend routine, preventive psychosocial screening across a variety of domains. This study reports on the results of universal, comprehensive psychosocial screening in an integrated pediatric diabetes clinic.

Methods: Pediatric patients with diabetes 12 years and older were screened for depression and suicidal risk, anxiety, life satisfaction, diabetes stress, disordered eating, family conflict, regimen adherence, and motivation for adherence. The screeners were completed on tablets in the waiting room before the appointment. If patients scored above a pre-determined cutoff on any measure, the psychology team conducted a consultation and developed a follow-up plan.

Results: 281 youth (M age=14.9 years, 56% female, 86% with type 1 diabetes) completed the screener over a 12-month period. The following percentages screened positive: depression, 23.5%; suicidal risk, 6.8%; anxiety, 19.1%; life satisfaction, 7.1%; diabetes stress, 21.1%; disordered eating, 6.9%; family conflict, 11.2%; regimen adherence, 38.1%; and motivation, 52.8%. Patients who screened positive in at least one domain were more likely to have higher A1c (M=9.2%, SD=2.5) than patients who did not screen positive (M=7.7, SD=1.5; $t=4.7$, $p < .001$). A higher number of total elevations was also significantly related to higher A1c ($r=.37$, $p < .001$). Females were more likely to have at least one elevation ($\chi^2=.03$, $p < .05$) and had a greater total number of elevations ($r=.13$, $p < .05$).

Conclusions: These findings indicate that psychosocial screening can be integrated into routine clinical care. The high percentage of youth screening positive and the association with poorer glycemic control supports the need for routine psychosocial screening so that these youth can be identified and provided appropriate interventions.

O32

Diagnostic accuracy of depression screening tools for adolescents with type 1 diabetes

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Objectives: Examine diagnostic accuracy and optimal cut-offs for common depression screening measures in adolescents with type 1 diabetes (T1D).

Methods: One hundred adolescents with T1D (Mean Age = 15.0 \pm 1.7 years; Age at Diagnosis = 8.9 \pm 4.1 years; 60% Male; 87% White; Mean HbA1c = 8.9 \pm 1.8%; 72% Pump) completed the Patient Health Questionnaire for Adolescents (PHQ-9), Children's Depression Inventory, 2nd edition (CDI-2), and Center for Epidemiological Studies Depression Scale Revised (CESDR). A researcher administered the Kiddie Schedule for Schizophrenia and Affective Disorders (KSADS) for DSM-5 to diagnose concurrent depressive disorders. We calculated sensitivity and specificity for measure total scores, including pre-existing cut-offs (i.e., ≥ 10 on the PHQ-9, ≥ 20 on the CDI-2, and ≥ 16 on the CESDR), as compared against KSADS diagnoses.

Results: On the KSADS, 15% of adolescents met criteria for a current depressive disorder (e.g., Major Depression, Dysthymia, Bipolar). Average depression measure scores were 3.3 \pm 3.6 (range 0-17), 8.6 \pm 7.4 (range 0-35), and 7.2 \pm 8.3 (range 0-34) on the PHQ-9, CDI-2, and CESDR, respectively. Using pre-existing cut-offs, 6% of adolescents reported clinically elevated depressive symptoms on the PHQ-9, 11% on the CDI-2, and 14% on the CESDR. Sensitivity and specificity for all total scores are included in **Table 1**. Empirically derived cut-offs that may increase sensitivity are ≥ 5 on the PHQ-9, ≥ 11 on the CDI-2, and ≥ 8 on the CESDR. Using these new cut-offs, 30-33% of adolescents would screen positive across measures.

Conclusions: Depression screening measures demonstrated poor sensitivity but high specificity to detect depressed adolescents with T1D using pre-existing cut-off scores. Findings may indicate an advantage to lowering cut-off scores on the PHQ-9, CDI-2, and CESDR despite reduced specificity. New techniques that more accurately predict depression should be developed.

Cut-Off Score	Sensitivity (true positive/ total positive screens)	Specificity (true negative/ total negative screens)
PHQ-9		
≥ 10	.33 (5/15)	.99 (84/85)
≥ 5	.87 (13/15)	.80 (68/85)
CDI-2		
≥ 20	.53 (8/15)	.96 (82/85)
≥ 11	.80 (12/15)	.76 (65/85)
CESDR		
≥ 16	.60 (9/15)	.94 (80/85)
≥ 8	.80 (12/15)	.75 (64/85)

[Sensitivity and specificity of the PHQ-9, CDI-2, and CESDR in adolescents with T1D.]

O33

Pre-empting challenges of adolescence: effects and theoretical frameworks of psychosocial interventions targeting pre-teens with type 1 diabetes

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Objectives: In people with type 1 diabetes, adolescence is particularly challenging, and a focus on pre-teens (9-12 years old) with type 1 diabetes has been recognized as key to improving outcomes. The aim of this study was to explore 1) the outcomes of psychosocial interventions targeting pre-teens with type 1 diabetes, and 2) the theories informing these interventions.

Methods: We conducted a systematic literature review of intervention studies targeting pre-teens with type 1 diabetes. Seven databases across different scientific disciplines were searched for papers published between 1995 and 2018. The quality of interventions was evaluated using the ISPAD recommendations.

Results: 12 studies covering 10 interventions were included for the review of intervention effects, and 24 studies were included in the review of theories informing interventions. The most frequently applied outcomes were self-management (n=7) and glycemic control (n=6). Effect sizes for self-management and glycemic control ranged from -2.37-0.14 and -0.17-0.38, respectively. Mixed programs met more quality criteria (n=14.7) compared to programs focusing on self-care (n=10.75) or psychosocial aspects (n=13) alone. Of the 24 studies included in the review of theories, 14 were categorized as theory-inspired and 10 as theory related. Social Cognitive Theory appeared most frequently. Most studies did not provide a rationale for their choice and application of theory. The studies were characterized by use of adult-centric theories, and a focus on the relationships between children and their parents.

Conclusions: Most interventions had small effect sizes and were based on individual level change theories. We suggest that interventions might benefit from using approaches that are centred on the needs and experiences of children, family dynamics, and the relationship between interventions and the social context in which they are implemented.

O34

Characteristics and metabolic outcome of children and adolescents with type 1 diabetes supported by psychological care in a real-world setting

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Introduction: Children and adolescents with type 1 diabetes appear to have a higher risk of psychological problems compared to healthy peers. International guidelines recommend provision of psychological care.

Objectives: To characterize children and adolescents with type 1 diabetes supported by psychological care in a real-world setting.

Methods: Data from children with type 1 diabetes under the age of 18 years with a diabetes duration of more than one year from 199 diabetes care centres participating in the nationwide German diabetes survey DPV were included. Short-term psychological care and continued psychological care (e.g psychotherapy) were distinguished. Clinical parameters, HbA1c, and rates of severe hypoglycaemia and diabetic ketoacidosis were analysed.

Results: Overall, out of 31,861 children with type 1 diabetes 12,326 received psychological care. Children with psychological care had higher HbA1c (8.0% vs 7.7%, $p < 0.001$) and higher rates of DKA (0.032 vs 0.021 per patient-year, $p < 0.001$) compared to children without psychological care. In age-, sex-, diabetes-duration-, and migratory background-matched children HbA1c was higher but stayed stable in children with continued psychological care during follow-up (HbA1c 8.5% one year before psychological care started vs 8.4% after two years, $p = 1.0$), whereas HbA1c was lower but increased significantly by 0.3% in children without psychological care (HbA1c 7.5% vs 7.8% after two years, $p < 0.001$). Analysis of HbA1c-matched children showed that HbA1c did not change during follow-up in either group but the percentage of children with severe hypoglycaemia decreased in children receiving continued psychological care compared to children without psychological care ($p = 0.009$).

Conclusions: This survey in a real-world-setting showed that psychological care was preferably given to children with worse glycaemic control and a higher rate of DKA. Continued psychological care was associated with stable glycaemic control.

O35

The association of mindfulness with depression, diabetes distress, and diabetes-related outcomes in adolescents with type 1 diabetes (T1D)

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Introduction: Adolescents with T1D are at increased risk for depression and diabetes distress (DD), which is associated with poor self-care (SC) and glycemic control (A1c). Mindfulness is a protective factor against stress and has been associated with better mental and physical health in adults with diabetes. Yet, little is known about mindfulness in adolescents with T1D.

Objective: To examine the association of trait mindfulness with depression, DD, SC, and A1c among adolescents with T1D.

Methods: Adolescents (age=12-18 years) with T1D were recruited during routine clinic appointment. Participants completed validated measures on mindfulness (Child and Adolescent Mindfulness Measure), depression (PHQ9), DD (Problem Area in Diabetes Questionnaire-Teen), and SC (SC Inventory) using electronic tablet. A1c was obtained from medical record. Descriptive statistics and Pearson product-moment correlations were used to describe the sample and examine the association of mindfulness with depression, DD, SC, and A1c.

Results: Adolescents (n=43) were 63% male, 86% white, on average 14.9±1.8 years of age, and a mean diabetes duration of 7.2±3.8 years and A1c of 8.5±1.6%. Participants had moderate levels of mindfulness (28.6±8.7; range=10-40); 19% had at least moderate-to-severe depression (cut-off point ≥10) and 40% had elevated levels of DD (cut-off point ≥44). Sample had moderate levels of SC (57.2±9.0; range=15-75). Mindfulness was significantly negatively associated with depression ($r=-.82$; $P<.001$) and DD ($r=-.70$, $P<.001$) but not associated with SC ($r=.21$, $P=.18$) or A1c ($r=-.18$, $P=.26$).

Conclusion: Mindfulness was negatively associated with depression and DD, but not with SC behavior or A1c. Our findings support that mindfulness can be helpful for the mental health of teens with T1D and show the need to establish mindfulness-based intervention to improve their health.

O36

Illness identity and diabetes-specific functioning across adolescence and emerging adulthood: a four-wave longitudinal study

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Objectives: Prior research has demonstrated the importance of illness identity - or the extent to which patients succeed in integrating their illness into their identity - for diabetes-specific functioning. Four illness identity dimensions have been identified: engulfment, rejection, acceptance, and enrichment. Unfortunately, longitudinal research on this topic is scarce. The present study adds to the literature by examining developmental trajectories of illness identity and linking these trajectories to diabetes-specific functioning over time.

Methods. Adolescents and emerging adults with type 1 diabetes, aged 14 to 25 ($M_{age}=19$; 54% girls) participated in a four-wave longitudinal study spanning 3 years ($N=559$ at T1). Patients filled out questionnaires on illness identity, treatment adherence, and diabetes-specific distress. HbA_{1c} values were obtained from patients' medical records. To chart the development of illness identity across the four measurement waves, we performed latent growth curve modeling (LGCM). Multivariate LGCM was used to examine the co-development of illness identity and diabetes-specific functioning over time.

Results. Overall, we observed linear increases in acceptance and engulfment and a linear decrease in rejection across waves. Decreases in engulfment and rejection and increases in acceptance were associated with decreases in diabetes-specific distress over time. In addition, decreases in rejection and increases in acceptance were associated with increases in treatment adherence across waves.

Conclusions. Over the course of adolescence and emerging adulthood, patients tend to be more accepting of their diabetes and show less rejection. However, at the same time, patients feel increasingly engulfed by their diabetes. Interestingly, these changes in illness identity were found to go hand in hand with changes in treatment adherence and diabetes-specific distress, which may have important implications for clinical practice.

O37

Financial stress characteristics in emerging adults with type 1 diabetes

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Introduction: Emerging adults, ages 18-25 years, with T1D are at high risk for financial stress and self-management barriers as they grapple with the developmental milestone of financial independence and endure health insurance changes and costs of diabetes care. Additionally, the amount of money one is willing to pay per month for diabetes care to achieve or maintain optimal glycemic control, or willingness to pay (WTP), has not been explored in the emerging adult population. Costs exceeding one's WTP and financial stress may lead to insulin rationing, suboptimal HbA1c, and acute and long-term diabetes complications.

Objectives: The purpose of this study was to describe financial stress factors in emerging adults with T1D.

Methods: This secondary data analysis was part of a larger descriptive, correlational study. Emerging adults with T1D ($N=500$) were recruited via email by the T1D Exchange Clinic Registry and completed online REDCap surveys. The Perceived Stress Scale, Personal Financial Well-Being Scale, Financial Independence Visual Analog Scale, and the investigator developed Diabetes Cost Survey, and WTP scales were administered. Descriptive statistics were analyzed.

Results: The mean patient cost was \$399.74/month while WTP was \$268.18/month. A total of 76.6% experienced high perceived stress, 45.2% had high financial stress, and 68.1% reported low financial independence.

Conclusions: The majority of emerging adults with T1D reported high perceived stress, high financial stress, and low financial independence despite having private health insurance. While emerging adults find it important to pay for diabetes care each month to achieve optimal glycemic control, the direct patient cost was significantly higher than the WTP. Findings suggest that emerging adults with T1D may be at increased risk for financial stress related barriers to optimal T1D self-management.

	N	Mean	SD	Median	Min	Max
Disease Duration	405	13.21	4.41	12.00	3	24
HbA1c	410	8.11	1.61	7.90	4.6	15.0
	n	%				
Insurance Type Private Private, high-deductible Private, no high-deductible Uninsured Medicaid	275 154 121 72 66	66.6 37.3 29.3 17.4 16.0				
Insulin Pump Usage Yes No	288 125	69.7 30.3				
CGM Usage Yes No	231 182	55.9 44.1				

[Diabetes-Related Characteristics (N=500)]

O38

Is there an association between celiac disease and depression in children and young adults with type 1 diabetes? A multicentre approach

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Objectives: Type 1 diabetes (T1D) has been independently linked to celiac disease (CD) and to depression. However, little is known about the co-existence of both CD and depression in T1D. We compared T1D patients with and without CD to examine whether depression is more common in T1D with CD compared to T1D patients without CD.

Methods: T1D patients 6-25 years of age from the multicentre diabetes patient follow-up registry (DPV) were studied. Demographic and clinical data of the most recent treatment year were aggregated. CD

diagnosis was gathered from medical records within DPV, presence of CD autoantibodies (CD-AB) or biopsy. Diagnosis of depression was extracted from medical records or from the use of respective medication. We used multivariable logistic regression models adjusting for sex, age, diabetes duration and migration background to examine the association between CD and depression.

Results: 85,433 T1D patients were identified with a median age of 16.6 years (Q1 13.2, Q3 18.0 years) and 52.9% being males. CD was present in 12,912 (15.1%) T1D patients and depression was diagnosed in 1,945 (2.3%) patients. CD-AB were found in 11,861 (91.9%) patients with CD and 2,035 (15.8%) had a biopsy-confirmed CD diagnosis. CD was significantly associated with depression in children and young adults with T1D (OR 1.3 (95%-confidence interval: 1.2-1.5)). The association between depression and CD was consistent and ORs were comparable between the different CD diagnosis categories (medical records only 1.4 (1.1-1.7), CD-AB 1.3 (1.2-1.5), biopsy-confirmed CD 1.4 (1.0-1.8)).

Conclusions: CD was associated with depression in children and young adults with T1D. The association was independent of whether CD diagnosis was gathered from medical records only, presence of CD-AB or biopsy-confirmed. Screening of CD is important in T1D in order to enable early treatment and to prevent further comorbidities.

Oral Session VI - Diabetes Education and Psychosocial issues

O39

Socioeconomic disparities in pump uptake among Canadian children and adolescents with type 1 diabetes: findings from two provincial programs

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Objectives: Within universal healthcare settings, previous studies have shown socioeconomic status (SES) disparities exist in uptake of insulin pump therapy (or continuous subcutaneous insulin infusion (CSII)). We hypothesized that SES disparities would be reduced in Quebec, Canada, where CSII and all associated supplies are fully funded, but not in Manitoba, Canada, where additional supplies are uncovered.

Methods: We conducted a cross-sectional study using multiple linked health administrative data in Quebec and Manitoba. We identified children aged 1-16 years who were diagnosed with type 1 diabetes between 1996 and 2016 using a validated definition. Our cohort was followed from April 1, 2011 to March 31, 2017 or age 18 years. Our primary outcome was pump uptake as identified by CSII specific physician billing codes. Our primary exposure was SES using a validated area-based deprivation index to assign material and social deprivation quintiles. We used logistic regression analysis to determine association of SES with CSII uptake, adjusted for age, rural/urban status, and sex.

Results: In both provinces, children in the most deprived material and social quintiles had reduced odds of initiating CSII therapy. In Quebec, for those in the most deprived material and social quintiles, the odds of starting CSII therapy were 42% lower (odds ratio (OR) 0.58, 95% confidence interval (95% CI) 0.45-0.75) and 34% lower (OR 0.66, 95% CI 0.51-0.86), respectively, compared to those in the most advantaged quintile. In Manitoba, the odds of pump uptake were 74% lower (OR 0.26; 95% CI 0.11-0.62) and 61% lower (OR 0.39, 95% CI 0.19-0.84) for children in the most deprived material and social quintiles, respectively, as compared to those least deprived.

Conclusions: Despite comprehensive government financial support for CSII in Quebec, SES disparities still exist in CSII use. Further efforts should focus on exploring other drivers of SES disparities in CSII therapy uptake.

O40

Community health workers improve outcomes in high-risk children with type 1 diabetes

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Introduction: Adverse social determinants of health (SDOH) are associated with poor glycemic control and worse outcomes in children with type 1 diabetes (T1D). Community health workers (CHWs) are community members who do not have healthcare training, but are ideally placed to help identify and strategize around addressing SDOHs.

Objective: The aim of this study was to determine if adding a CHW to the care team of high-risk children with T1D for 6 months improves glycemic control, parent quality of life (QOL) and diabetes self-efficacy (DSE).

Methods: Children with T1D for ≥ 1 year, aged < 18 years with either hemoglobin A1c (HbA1c) concentration $\geq 9.5\%$ or increased healthcare utilization (defined as ≥ 2 ED presentations, hospitalizations or missed appointments over the prior year) were eligible to receive a CHW. The CHW performed home visits and focused on addressing SDOH for 6 months. HbA1c, QOL (PedsQL for parents of children with chronic disease), DSE (parental self-efficacy in diabetes scale) and SDOH (Health Leads USA) were measured at baseline and 6-months.

Results: Twenty-one patients (9 male) received support from a CHW over 6-months. Patients had a median (IQR) age of 13.7 (12.2, 15.9) years, and T1D duration of 6.2 (4.9, 8.2) years. The CHW performed a median (IQR) of 7 (5, 10) home visits. The most common SDOH challenges improved at 6 months: food insecurity (43%, to 29%, $p=0.002$); utility bills (38% to 24%, $p=0.047$); and accommodation stability (29% to 19%, $p=0.05$). Median (IQR) QOL scores improved from 63.2 (44.1, 79.2) to 75 (58.3, 87.1), $p=0.047$. DSE was not significantly affected (63 (44, 65.5) to 58 (50.5, 66.5), $p=0.6$), but HbA1c improved from 11.5(10,12.4) to 11 (9.1, 12.2), $p=0.047$.

Conclusions: Addressing SDOH in high-risk families of children with T1D can have a significant impact on diabetes control and QOL. Further study is required to determine if these improvements are sustainable.

O41

Understanding Fear of hypoglycemia as a barrier to administering recommended insulin dose using objective insulin pump data

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Objective: To demonstrate the relation between self-management behaviors, via objective data downloaded from insulin pumps, and fear of hypoglycemia (FOH) in adolescents with T1D and their parents.

Methods: 107 caregiver-adolescent dyads participated (M age=13.86 \pm 2.26 yrs; M T1D duration=6.45 \pm 3.53 yrs; M A1C=8.76 \pm 1.50%; 45.8% male) in a RCT to improve self-management behaviors (DKO91558). Adolescents used Medtronic insulin pumps and had T1D \geq 1 year. The Hypoglycemia Fear Surveys were completed (Parent, HFS-P; Child, HFS-C). Pumps were downloaded at routine T1D clinic visits prior to beginning intervention.

Results: Caregiver and adolescents scores on the Maintain High BG subscale were significantly correlated ($r=0.265$, $p=0.009$). Caregiver HFS-P Maintain High BG scores significantly predicted percentage of time that insulin boluses administered equaled pump calculator recommendations ($F(1,100)=9.67$, $p=0.002$; $R^2=0.091$) and percentage of time pump calculator recommendation was overridden in favor of administering less insulin ($F(1, 80)=6.24$, $p=0.015$; $R^2=0.072$). Adolescent HFS-C Maintain High BG scores also significantly predicted percentage of time insulin boluses delivered equaled pump calculator recommendations ($F(1,99)=7.39$, $p=0.008$; $R^2=0.069$). When included in the same model, both parent and adolescent scores on Maintain High BG significantly predicted percentage of time insulin boluses administered equaled pump calculator recommendations ($F(2,93)=6.44$, $p=0.002$; $R^2=0.112$). Age did not predict percentage of time insulin bolus delivered equaled pump calculator recommendations.

Conclusions: This is the first study to use downloaded insulin pump data to objectively demonstrate how FOH affects self-management behaviors. Objective data from insulin pumps provides unique information that is difficult to obtain from self-report questionnaires. These results clearly illustrate that intervention is warranted to address FOH - a clear barrier to T1D adherence.

O42

Socio-demographic and clinical correlates of fear of hypoglycemia among parents of children with type 1 diabetes: results from an Italian survey

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Introduction: A cross-sectional, nationwide survey about parental fear of hypoglycemia (PFH) and use of technology, was carried out in Italy during September-November 2018.

Objectives: To evaluate socio-demographic and clinical factors, including technologies for diabetes, associated with PFH.

Methods: The survey was conducted among parents of children with T1D through SurveyMonkey[®]. It consisted in two parts; the first had the aim to assess PFH using the Behaviour and the Worry subscales of the Hypoglycaemia Fear Survey-Parent (HFS-P), the second collected socio-demographic and clinic characteristics of patients.

Quantile regression models were performed to estimate factors associated with HFS-P Behaviour and Worry subscales.

Results: 1450 questionnaires were obtained, 1106 (861 Mothers) reported a complete HFS-P in both the worry and behavior subscales. Children median age was 11 years (IQR: 8-14), median HbA1c 7.2% (IQR: 6.7-7.8). Glucose Sensor (including CGM and FGM) was used in 77% of patients and insulin pump in 44%. Median HFS-P behavior score was 29 (IQR: 24-33), HFS-P worry score was 36 (IQR: 29-46). Residence in South Italy, higher level of parent's education, female child, shorter diabetes duration, use of glucose sensor, occurrence of severe hypoglycemia in the past 12 months, were associated with a significant increase of HFS-P Behaviour score. Younger age of parents, residence in South Italy, higher level of parent's education, occurrence of severe hypoglycemia in the past 12 months, were associated with a significant increased of HFS-P Worry score.

Conclusions: Parental fear of hypoglycemia was associated with modifiable and non-modifiable factors. The use of insulin pump does not seem to affect neither worries nor behaviors, while glucose sensor does influence parental behaviors.

O43

Sleep habits of a well-controlled group of youths with type 1 diabetes mellitus

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Objective: A high prevalence of sleep disturbances have been previously reported in individuals with type 1 diabetes mellitus (T1DM). The aim of the present study was to assess sleep habits in a group of youths with T1DM and to explore potential associations with glycaemic control and quality of life (QOL).

Methods: Young adults (17-29 years) with T1DM attending a diabetes outpatient clinic were consecutively enrolled and cross-sectionally evaluated. Sleep habits were assessed with Athens Insomnia Scale (AIS) (score 0-24, values \geq 6 diagnosing insomnia) and QOL with the SF-36 (higher scores reflecting better health and QOL), both validated in the Greek population.

Results: In total 37 youths with T1DM (age: 22.6 \pm 3.5 years, BMI: 24.5 \pm 4.2 kg/m²) and good glycaemic control [median HbA1c 7.1 (6.8, 8.1)%] were enrolled. The median AIS score was 4 (2.5, 6.0), while the median duration of night-time sleep was 7 (6.0, 8.0) hours. Neither AIS nor night sleep duration were significantly correlated with HbA1c (both $p>0.05$). Total AIS score was negatively correlated with mental component of SF-36. The sample was further divided in 23 youths wearing insulin pump and 15 under multiple daily injections (MDI) therapy. The subgroups didn't differ regarding age, BMI and HbA1c. Nevertheless, 47.8% of the pump users and 7.1% of participants on MDI had insomnia ($p=0.01$). Pump users compared to MDI users reported lower sleep quality ($p=0.001$), lower night sleep duration ($p=0.03$), problems regarding sleep induction ($p=0.02$) and lower total mental component summary ($p=0.028$). In both groups total AIS score

was negatively correlated with social functioning, role limitations due to mental health and total mental component summary (all $P < 0.05$).

Conclusions: In a group of well-controlled youths with T1DM, lower sleep quality was associated with lower quality of mental health. Individuals on insulin pump therapy reported shorter duration and lower quality of night sleep compared to those on MDI therapy.

O44

The link between externalizing behavior and HbA1c in youth with type 1 diabetes is mediated by executive function: novel insights for interventions

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Objective: Externalizing Behavior and Executive Function (EF) problems in youth with type 1 diabetes (T1D) have been associated with worse diabetes-related and psychosocial outcomes. Specific dynamics between both factors and their relationship to HbA1c seem understudied. In this study we aimed to examine whether Externalizing Behavior is associated with HbA1c and whether this relationship is mediated by EF problems, specifically Metacognition (i.e., the ability to initiate, plan, organize and monitor behavior - important skills for T1D self-management).

Methods: A cohort of Belgian and Dutch parents of children with T1D filled out questionnaires. Externalizing Behavior was assessed by the Strengths and Difficulties Questionnaire (SDQ) subscale. Mediation variable Metacognition was assessed by the Behavior Rating Inventory of Executive Function (BRIEF) composite scale. Treating physicians were contacted to collect HbA1c values. Mediation

analyses were performed for the composite Metacognition scale correcting for age, gender and diabetes duration.

Results: 335 parents of youth (6-18 years) with T1D (mean age 12.3 \pm 2.8 SD; mean HbA1c 7.6% \pm 1.1 SD (60 mmol/mol \pm 12.0 SD); mean diabetes duration 5.3 \pm 3.6 SD; 49.6% female) participated. Analyses showed that the association between Externalizing Behavior and HbA1c is mediated through Metacognition (*ab* path Point estimate = 0.05 BCa CI 95% .02-.08, see Figure).

Conclusions: Results uncovered the impact EF problems may have on the association between Externalizing Behavior and HbA1c. This emphasizes the importance to be mindful of EF problems in the Metacognition domain when working with youth who display externalizing behavior. Therefore, interventions should not only target behavioral components but also cognitive processes involved in Metacognition.

O45

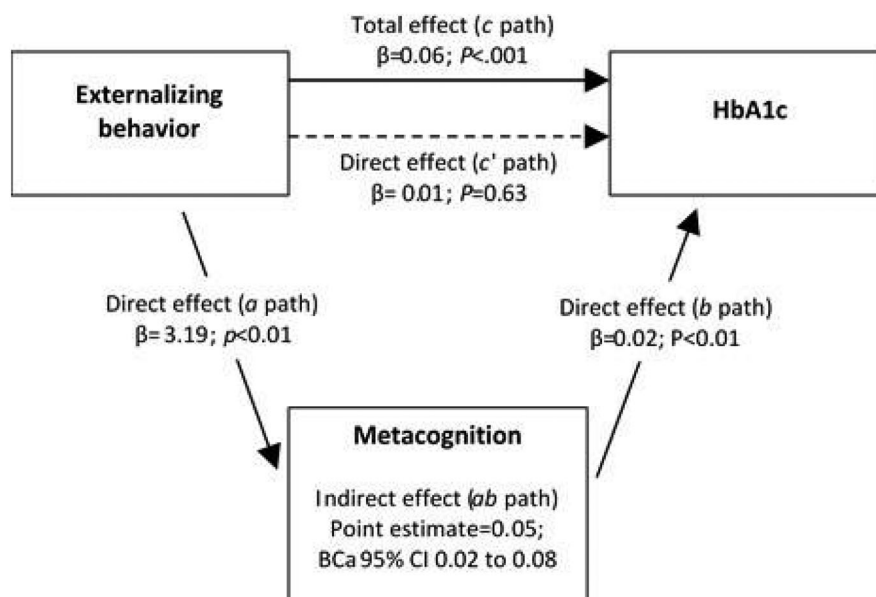
Changing the conversation: addressing emotional wellbeing and mental health in adolescents living with type 1 diabetes

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Objectives: We aimed to improve emotional wellbeing and quality of life (QoL) for adolescents with type 1 diabetes.

Methods: In 2016, we launched a collaborative, integrated model of care in a pediatric diabetes clinic at Trillium Health Partners in Mississauga, Canada. Adolescents ages 13 - 17 years old were engaged in conversations every 9 months about emotional wellbeing and QoL using the Mind Youth Questionnaire (MY-Q). Those who were experiencing significant difficulties with their emotional wellbeing were screened for depressive symptoms with the Patient Health



[Figure: Graphic Representation of mediation model (Preacher & Hayes, 2008)]



[Model of Care]

Questionnaire (PHQ-A), and then offered a psychiatric assessment and joint medical and mental health supports if needed. A program evaluation approach was taken. Outcome measurements included MY-Q scores, overall QoL, and hemoglobin A1c (HbA1c).

Results: 95 adolescents were screened twice; at baseline and within 6 - 9 months. Mean age was 14.5±4.8 years old; 57% were female. N=23 (24%) of the patients were found to be struggling with their emotional well-being; N=10 (10%) underwent a psychiatric assessment and were diagnosed with a psychiatric disorder. At follow-up, there was a significant reduction in the mean (SD) number of difficulties reported on the MY-Q [4.2(3.6) vs 3.3(3.3); $p < 0.01$]. Mean fewer difficulties related to social functioning and responsibility were reported ($p < 0.01$ and $p < 0.04$ respectively). Overall, mean QoL rating stayed the same (7.8(1.6) vs 7.9(1.3); $p = 0.49$) and mean (SD) HbA1c increased [8.1(1.9)% to 8.9(1.9)% or 67(16) mmol/mol to 73(18) mmol/mol; $p < 0.01$].

Conclusions: Engaging adolescents in conversations about emotional well-being and quality of life is found to be acceptable and feasible for patients, families, and healthcare providers. Although HbA1c did not improve, adolescents reported improvements in numerous QoL domains. Future studies will examine if improvements in QoL can be sustained.

O46

Diabetes related knowledge and attitude towards diabetes among final-year medical students from different worldwide centers - preliminary results

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Objectives: This multinational study investigated knowledge regarding diabetes (DM) of final-year medical students.

Methods: Students from Poland, Jordan, Italy, Slovenia, Taiwan, and India answered a 25-question survey regarding basic knowledge of DM and attitude related to it (1091 surveys handed out, response rate 86%).

Results: Responders: 58% - females, 90% attended diabetology classes, 11% planned to specialize in diabetology. Total rate of correct answers was 73%, with significant differences between countries - median results ranged from 10/25 to 22/25. Only 80% of students knew that type 1 DM is incurable and 75% that people with it require insulin even when fasting. Knowledge about monogenic DM had 83% of students. Most students were familiar with hyperglycemia symptoms (75%) and causes (80%). 82% of students knew that insulin is not appropriate for treating hypoglycaemia, but only 53% of them distinguished the correct blood glucose level to diagnose it. Diabetic ketoacidosis treatment and basic facts regarding technologies (insulin pumps, continuous glucose monitoring) had, respectively, 83% and 71% of students. Questions regarding type 2 DM treatment were answered correctly by about 75% of students.

Attending DM classes (20 vs 13/25, $p < 0.0001$) was the strongest factor associated with the greatest knowledge about DM. Students with

higher total scores (by 1-2 points) were more likely to be female ($p=.003$), with no familiar/personal experience of DM ($p=.009$), and not interested to specialize in diabetology ($p=.0002$). Students who declared to be not prepared to take care of people with DM (20%) had the lowest score (14/25), compared to those describing

themselves as afraid (21/25), quite comfortable (20/25) or prepared (18/25) for DM management ($p< 000.1$).

Conclusions: Basic knowledge about DM remains a challenge worldwide. Participating in classes concerning DM contributed the most to the DM knowledge among final-year medical students. SUT 02/010/BK-18/0102

Oral Session VII - Nutrition and the Gut

O47

Effect of prebiotic intake on glycemic control and intestinal permeability in children with type 1 diabetes

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Background: Patients with type 1 diabetes (DM1) have distinct gut microbiota that has been linked to changes in intestinal permeability, inflammation and insulin resistance. Prebiotics are non-digestible carbohydrates that alter gut microbiota and could potentially improve glycemic control in DM1 by improving intestinal permeability and thereby insulin sensitivity.

Objective: Our aim was to determine the effect of prebiotics on glycemic control and intestinal permeability in children with DM1.

Methods: Children aged 8-17 years with DM1 for at least one year were randomized to placebo or a prebiotic for 12 weeks. Baseline, 3 month, and 6 month (3 month post end of intervention) assessments included: HbA1c, C-peptide, inflammatory markers, frequency of diabetic ketoacidosis (DKA) and severe hypoglycemia, intestinal permeability (measured by the relative renal excretion of lactulose to mannitol), and gut microbiota.

Results: 43 were recruited. 38 completed the study. The groups were similar at baseline: prebiotic (N=17), age 12.5 years, A1c 8.02%; placebo (N=21), age 12.0 years, A1c 8.08%. No significant differences were found in frequency of DKA or severe hypoglycemia between the two groups throughout the trial. At the end of the 12-week intervention, the prebiotic group had a better preservation of C-peptide and an improvement in intestinal permeability in comparison to the placebo group. There was also a significant increase in the relative abundance of *Bifidobacterium* with the prebiotic group at 3-month. At 3 month, A1C was significantly and positively correlated with intestinal permeability.

Conclusion: Prebiotics are a potentially novel, inexpensive, low-risk treatment addition for T1D that may improve glycemic control. Further larger scale trials are needed.

O48

Effect of high-dose oral probiotic intake on glycaemic control in children with type 1 diabetes mellitus: a randomised, double-blind placebo control trial

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Background: Studies in animal models and humans with Type 1 Diabetes (T1D) have shown that high dose multi-strain probiotic supplementation leads to decreased pro-inflammatory cytokines (responsible for damaging β - cells of pancreas), improved gut barrier function and induction of immune tolerance.

Objectives: To study the effect of supplementation of high dose multi-strain probiotic in children with T1D on glycemic control, insulin dose and plasma C-peptide levels.

Methods: A single-centre, double-blinded randomized placebo-controlled trial was conducted in 96 children (2-12 years) with new-onset T1D (Clinical Trial Registry-India:2017/06/008725). A total of 90 patients (45 each in Placebo and Intervention group) were eventually analysed for outcome parameters. The intervention was high dose (112.5 billion viable lyophilized bacteria per capsule) multi-strain probiotic product VSL3 (manufactured by Danisco-Dupont) currently sold as Vivomixx[®] [MENDES, S.A., Lugano, Switzerland]. Probiotic was supplemented for a period of 3 months and HbA1c, C-peptide, blood sugar records (over previous 7 days) and insulin dose were recorded at baseline and at 3 months.

Results: We found a significantly more reduction (delta change) in HbA1c (baseline to 3 months), higher decline in total and bolus insulin

Outcome parameters	Intervention group (n=45)	Placebo group (n=45)	p-value
Change in HbA1c (%) (Mean \pm SD)	5.11 \pm 2.89	3.57 \pm 3.40	0.021
Change in C-Peptide (ng/ml) (Mean \pm SD)	0.19 \pm 0.58	0.21 \pm 0.58	0.901
Decline in Total Insulin (U/Kg/Day) (Mean \pm SD)	0.41 \pm 0.42	0.22 \pm 0.41	0.037
Decline in Basal Insulin (U/Kg/Day) (Mean \pm SD)	0.08 \pm 0.15	0.07 \pm 0.23	0.736
Decline in Bolus Insulin (U/Kg/Day) (Mean \pm SD)	0.34 \pm 0.38	0.15 \pm 0.35	0.018
Mean variability in FBS over 7 days at 3 months (gm/dl)(Mean \pm SD)	72.28 \pm 8.46	48.56 \pm 9.48	0.0001
Mean variability in blood glucose over 7 days at 3 months (gm/dl)(Mean \pm SD)	71.69 \pm 12.73	41.91 \pm 5.65	0.0001
Honeymoon Phase achieved	12 (26.6%)	4 (8.8%)	0.023

[Table 1. Outcome parameters in two groups after 3 months of intervention.]

dose (U/kg/day) in Intervention group when compared with placebo group after 3 months. A significantly higher number of children achieved honeymoon in treatment group (Table 1). Use of high dose multi-strain probiotics was safe in children with no significant adverse effects.

Conclusion: A high dose probiotic supplementation over short term can lead to more fall in HbA1c, a significant decrease in total and bolus insulin dose, decreased glycemic variability and more chances of achieving honeymoon in children with new onset T1D.

O49

Impact of diet on the gut microbiome and short chain fatty acids in children with and without type 1 diabetes

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Introduction: Gut microbiomes of at-risk children, who do not develop islet autoimmunity (IA) or type 1 diabetes (T1D), support increased production of short chain fatty acids (SCFAs) which regulate metabolism and immunity, in comparison with those who develop T1D/IA. Diet modifies the infant gut microbiome, but less is known of its impact in older children.

Objectives: We aimed to characterise and compare the effect of diet on the gut microbiome and SCFA in children with IA or T1D, and controls.

Methods: 81 participants (25 T1D, 17 IA, 39 controls) from the Australian T1D Gut Study prospective cohort were studied (median [IQR] age 10.9 [8.3-13.5] years, 42% female). Dietary intake was measured using the Australian Child and Adolescent Eating Survey. 16S rRNA gene sequencing was performed on stool samples. The anti-inflammatory SCFA, plasma acetate, was measured by gas chromatography. Relationships between dietary measures and microbiome diversity and plasma acetate were explored using linear mixed models and PERMANOVA.

Results: The impact of diet on the gut microbiome was similar in IA or T1D and controls. Greater gut microbiome richness and evenness did

not correlate with higher intake of nutrient-dense foods. Greater diversity of microbial composition related to higher Australian Recommended Food Scores in controls [$p=0.001$] but not in T1D and IA [$p=0.4$]. Higher total fat intake, particularly saturated fats, related to lower plasma acetate, and higher carbohydrate intake, but not fibre, related to higher plasma acetate (Table 1). Breast feeding history did not differ across groups or have a detectable impact on the microbial composition.

Conclusion: In conclusion, diet impacted the gut microbiome similarly in children with IA, T1D and controls, but higher scores of diet quality support increased diversity of microbial composition only in controls. Carbohydrate and fat intake impacted plasma acetate levels substantially in all groups.

O50

A standardized approach for management of pediatric patients with type 1 diabetes following low carbohydrate or ketogenic diets

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Objectives: Limited data exists regarding the risks or benefits of children with type 1 diabetes (T1D) consuming a low carbohydrate (CHO) or ketogenic diet, and guidelines for managing children following ketogenic diets are chiefly for treatment of epilepsy. We aimed to create a standardized approach to medical management of pediatric T1D patients following a low CHO or ketogenic diet in order to monitor for and identify risks associated with CHO restriction.

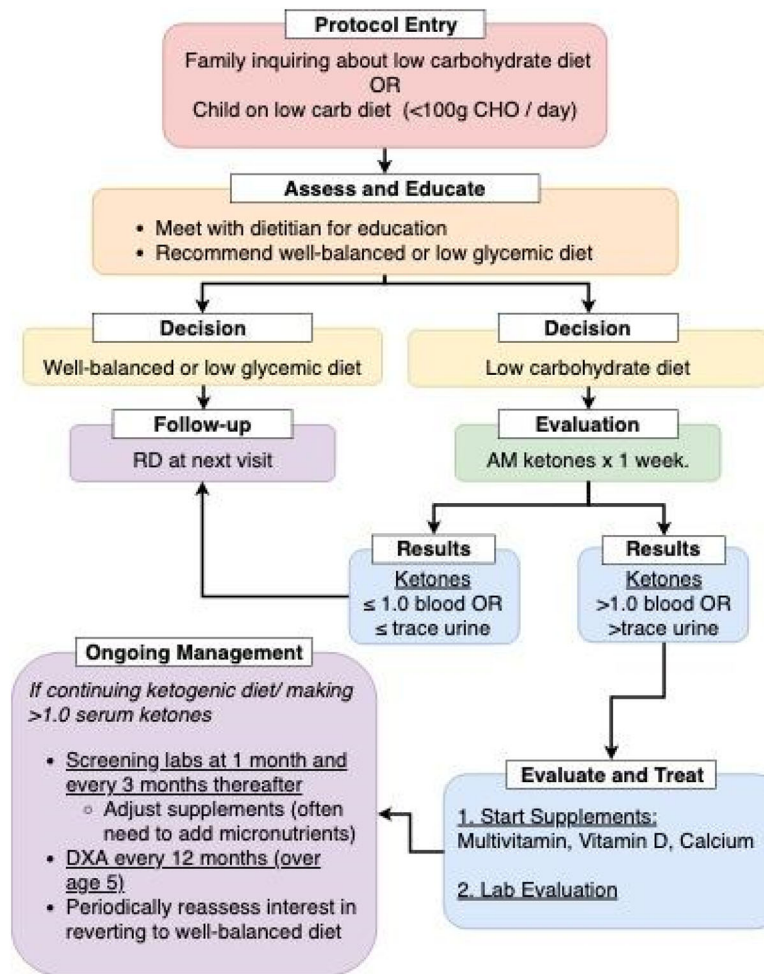
Methods: A comprehensive search of PubMed was performed to identify papers reporting the use of low CHO or ketogenic diets in patients with T1D. RCTs do not exist in children with T1D. In children with seizure disorders, ketogenic diets can negatively impact nutrition, growth, puberty and bone health. We developed a protocol for medical management of children with T1D following CHO restricted diets. (FIGURE).

Results: Conservatively, we defined a low CHO diet as < 100g CHO/day. Children consuming a low CHO diet are referred to a Registered Dietitian to discuss potential risks and recommendations for

	DIETARY MEASURE	Adjusted Estimate* (95% CI)	Adjusted p
Fibre	10 g increase in control; 10 g increase in T1D/IA	11.81 (-11.53, 35.16) 17.89 (-3.22, 39.00)	controls = 0.3; T1D/IA = 0.1
Carbohydrate	100g increase in control; 100g increase in T1D/IA	41.13(1.74, 80.53) 51.81 (11.16, 92.46)	controls = 0.04; T1D/IA = 0.01
Total Fat	50 g increase in control; 50 g increase in T1D/IA	-96.32(-158.73,-33.92) -72.04(-119.28,-24.81)	controls = <0.01; T1D/IA = <0.01
Saturated Fat	10 g increase in control; 10 g increase in T1D/IA	-31.86 (-53.85, -9.88) -24.92 (-40.96, -8.87)	controls = <0.01; T1D/IA = <0.01
Unsaturated Fat	10 g increase in control; 10 g increase in T1D/IA	-36.29 (-61.86, -10.72) -26.99 (-47.08, -6.91)	controls = <0.01; T1D/IA = <0.01

* Estimates represent change in plasma acetate (uM) corresponding to the increase in the dietary variable, adjusted for age, gender and % energy intake

[Table 1: Associations between diet and plasma acetate in type 1 diabetes, islet autoimmunity and controls]



[Protocol for pediatric patients following low CHO or ketogenic diet]

a well-balanced diet. Families choosing a CHO restricted diet are instructed to monitor ketones. If ketones are elevated, screening for underlying metabolic disorders, micronutrient deficiencies and bone health is completed. Recommendations are made for vitamin/mineral supplementation. Children have routine repeated laboratory assessments and a yearly DEXA scan if ≥ 6 years.

Conclusion: The risks and benefits of a CHO restricted diet in the pediatric T1D population are not well understood. Pending further study, children need to be carefully monitored for nutritional deficiencies, growth abnormalities and poor bone health. Standardizing the medical management of patients following a CHO restricted diet will ensure medical safety, and following these patients over time will help to determine the degree of risk associated with a low CHO or ketogenic diet in children.

O51

Youth with more severe type 1 diabetes are slower to process healthiness of food

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Objectives: Severity of T1DM has been associated with differences in cognitive outcomes in youth with Type 1 Diabetes (T1D). The objective of this study is to examine dietary decision-making in youth with T1D utilizing a neurocomputational task, and how severity of disease is associated with food choice.

Methods: 35 youth with T1D (age 10.9 ± 1.6 y, male 63%, Tanner 2.2 ± 1.4 , HbA1c $7.7 \pm 1.3\%$, BMI percentile 74.4 ± 24.7) performed a food choice task with computer mouse-tracking (MATLAB), rating 60 food cues (30 high-calorie, 30 low-calorie) for tastiness and healthiness, then choosing between 100 food choice pairs that were generated based on individual participant ratings. Cursor-trajectory analyses pinpointed when food attributes of tastiness and healthiness influenced the choice process. Participants were categorized as low HbA1c ($\leq 7.5\%$) vs. high HbA1c ($\geq 8.5\%$), history of DKA vs. no DKA, and earlier age at diagnosis (< 7 years) vs. later age at diagnosis (> 7 years).

Results: In all groups, the tastiness of food items significantly influenced dietary choice earlier than healthiness. In youth with low

HbA1c, both tastiness and healthiness significantly influenced the final dietary decision, in contrast to youth with higher HbA1c where only tastiness significantly influenced dietary decision. Both tastiness and healthiness influenced dietary decision in youth with or without history of DKA, and earlier or later age at diagnosis. However, there was a larger difference between the processing speed of tastiness and healthiness in participants with a history of DKA (471 msec) vs. those without DKA (130 msec), and in participants with earlier age at diagnosis (439 msec) vs. later age at diagnosis (294 msec).

Conclusions: Severity of disease may impact dietary decision-making in youth with T1DM, with increased severity associated with slower processing of food healthiness. Group differences may be due to effects of DKA and prolonged hyperglycemia on the brain and cognition.

O52

Household food insecurity in high-risk youth with type 1 diabetes: associations with glycemic control, diabetes distress and general stress

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Introduction: Previous studies of youth with type 1 diabetes (T1D) have produced conflicting evidence on the association between household food insecurity (HFI) and glycemic control. The link between HFI and perceptions of general stress and diabetes distress in youth with T1D is unknown.

Objectives: To examine the association of HFI with

- 1) glycemic control;
- 2) diabetes distress and;
- 3) general stress in youth with T1D with suboptimal glycemic control and their parents.

Methods: Youth with T1D (aged 3-19 years) from the Seattle metropolitan area with a T1D duration ≥ 12 months and suboptimal glycemic control (HbA1C $\geq 8.5\%$) were enrolled. Parents reported HFI using the 18-item U.S. Household Food Security Survey Module; ≥ 3 affirmations were considered indicative of HFI. Parents and youth ≥ 10 years old completed the Problem Areas in Diabetes (PAID) and the

Perceived Stress Scale (PSS). Linear regression was used to compare mean HbA1C, PAID and PSS scores.

Results: Of 159 adult-youth dyads enrolled, 145 parents and 110 youth completed surveys (youth age 12.8 ± 3.3 years, T1D duration $6.2 \text{ years} \pm 3.8 \text{ years}$, 34% Medicaid). Youth with HFI had an adjusted mean HbA1C that was 0.88% (95% CI: 0.29, 1.48) higher than youth without HFI. Parents and youth with HFI reported higher diabetes distress and general stress scores compared to participants from food secure households (Table).

Conclusions: Among a sample of youth with T1D and suboptimal glycemic control, those who experienced HFI had higher HbA1C than peers who did not experience HFI. Moreover, parents and youth who experienced HFI reported higher levels of diabetes distress and general stress than food secure peers, which may be potential mediators for suboptimal glycemic control. Our findings underscore the potential value in screening youth with T1D for HFI in clinical settings to identify those at increased risk for poor diabetes outcomes and who might benefit from tailored support.

O53

Prevalence and sociodemographic correlates of household food insecurity in youth and young adults with diabetes: the SEARCH for diabetes in youth study

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Introduction: Recent diabetes practice guidelines recommend assessing patients' household food insecurity (HFI). The prevalence of HFI in youth and young adults (YYAs) with diabetes in the U.S. is not known.

Objectives: To assess the prevalence of HFI in YYAs with type 1 diabetes (T1D) and type 2 diabetes (T2D) overall and by diabetes type and sociodemographics.

	PARENTS (n=145)		YOUTH (n=110)	
	Mean Score \pm SD	Adjusted* Mean Difference (95% CI)	Mean Score \pm SD	Adjusted* Mean Difference (95% CI)
DIABETES DISTRESS (PAID)				
No HFI	39.1 \pm 17.7	REF	22.8 \pm 14.7	REF
HFI	49.9 \pm 17.3	8.46 (0.64, 16.27)	24.7 \pm 16.6	8.31 (0.68, 15.94)
GENERAL STRESS (PSS)				
No HFI	4.5 \pm 2.8	REF	5.4 \pm 2.8	REF
HFI	6.3 \pm 2.6	1.26 (0.08, 2.44)	7.1 \pm 3.5	1.19 (-0.36, 2.73)

*Models adjusted for age at enrollment, duration of diabetes, and insurance (Medicaid vs non-Medicaid)

Methods: The study included participants from SEARCH for Diabetes in Youth with T1D and T2D recruited in 2016-2019. HFI was assessed using the 10-item U.S. Household Food Security Survey Module; 3 or more affirmations were considered indicative of HFI. The prevalence of HFI was estimated as a simple proportion with 95% confidence intervals. Chi-square tests were used to assess whether the prevalence of HFI is associated with diabetes type and participant characteristics.

Results: Of 2189 respondents (age range 10-35 years; 80.6% ≤ 25 years), 1849 had T1D (mean age 20.8 ± 5.0 years, 70% non-Hispanic white) and 340 had T2D (mean age 25.2 ± 3.8 years, 18.5% non-Hispanic white). The overall prevalence of HFI was 18.3% (95% CI: 16.7, 19.9). YYAs with T2D had a higher prevalence of HFI than those with T1D (29.1% vs. 16.3%, $p < 0.01$). Prevalence of HFI overall varied by age (10-17 years: 14.5%, 18-25 years: 18.4%, >25 years: 23.6%; $p < 0.01$). Prevalence of HFI was higher among females, ($p < 0.01$), non-Hispanic Blacks ($p < 0.01$), lower parental education ($p < 0.01$), lower income ($p < 0.01$), and Medicaid/Medicare and uninsured individuals ($p < 0.01$).

Conclusions: Almost 1 in 5 YYAs with diabetes experienced HFI in the past year (more than 1 in 4 with T2D), a prevalence that is higher than in the general U.S. population (11.8% in 2017). This study reinforces the need for widespread implementation of routine HFI screening in clinical practice of all YYAs with diabetes. Knowledge of a patient's food security status will allow diabetes care teams to tailor management and facilitate referral to food assistance programs

O54

Differences in celiac disease screening rates between children, adolescents and adult type 1 diabetes patients evaluated as part of the CD-DIET study

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Introduction: As shared autoimmune conditions, Celiac Disease (CD) is diagnosed at higher rates in individuals with Type 1 Diabetes. The Celiac Disease and Diabetes Dietary Intervention and Evaluation Trial (CD-DIET) conducted a large scale, centralized serological testing program for CD using tissue trans-glutaminase (TTG) antibody with biopsy confirmation alongside assessment of CD symptoms in a mixed adult and pediatric cohort of patients with type 1 diabetes.

Objectives: To describe the celiac disease screening and confirmation in a large, pediatric and adult, type 1 diabetes population with regards to gastrointestinal (GI) symptomatology and asymptomatic CD status.

Methods: Data from subjects with type 1 diabetes screened as part of the CD-DIET study at multiple sites in Ontario, Canada were analyzed to describe the characteristics of the screening population with respects to demographic data, symptoms and CD status.

Results: 2353 subjects completed serological testing for CD, encompassing 389 children (8-12years), 670 adolescents (13-18years) and 1294 adults (19-45 years). Symptomatic patients tended to be older, female and had higher HbA1c with 34.1% of adults reporting at least one GI symptom compared to 21.7% of children and adolescents ($p < 0.0001$). Serologic positivity rates were 4.6% in children, 4.5% in adolescents and 6.8% in adults ($p = 0.05$). Celiac disease was confirmed in 82 subjects who underwent biopsy, with adults having significantly higher rates of CD (4.2%) compared to pediatric subjects (2.6%) ($P = 0.03$).

Conclusions: Significant differences were observed in CD serologic and biopsy positivity between and type 1 diabetes children and adults which may be due to increasing risk of autoimmune comorbidities with age and many adults being naïve to celiac disease screening.

Oral Session VIII - Diabetes Care-Health Outcomes

O55

Most preschool children with T1D in Sweden reach ISPAD target HbA1c

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Introduction: Early onset T1D gives high risk of cardiovascular complications. Lower HbA1c reduces the risk. As treatment options has improved, HbA1c targets have been changed.

Prevalence of overweight (including obesity) was 12% and the prevalence of obesity was 2.3 % in the general population of 4-year old children in Sweden 2017.

Objective: To describe the treatment and treatment outcome in children younger than 7 years with T1D in Sweden.

Methods: Data was retrieved from Swediabkids, The Swedish Paediatric Diabetes Quality Registry. All paediatric diabetes teams in Sweden report to Swediabkids. Data from children with diabetes duration < 3 months were excluded from the analyses. CGM (rtCGM and isCGM) usage was reported to Swediabkids from year 2016. Overweight and obesity were defined as ISO-BMI >25 and >30. Significance was tested with Chi-square test.

Results: The proportion of children reaching current ISPAD HbA1c target (≤ 52 mmol/mol; < 7%) increased from 46% to 61% between year 2015 and 2018. The proportion of children reaching the Swedish treatment target HbA1c (≤ 48 mmol/mol; < 6.5 %) has increased from 30% to 45% during the same period. Usage of CGM has increased from 82% in 2016 to 97% in 2018 while the usage of CSII only increased slightly during this period. The prevalence of overweight (including obesity) in children younger than 7 years with T1D was 25% in 2015 and 29% in 2018. The prevalence of obesity was 5.5 % in 2015 and 7.2 % in 2018.

Conclusions: Sixty-one percent of children younger than 7 years with T1D in Sweden reach ISPAD HbA1c target. The proportion of children reaching HbA1c target and CGM use increased simultaneously. Standard paediatric T1D care in Sweden includes CGM and increased experience in CGM usage might be an important factor contributing to better glycaemic control. The high frequency of overweight and obesity in young children with T1D warrants attention.

O56

Identifying HbA1c trajectories in 5-9-year-olds across the recent-onset period of type 1 diabetes (T1D)

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Objective: To determine whether there are distinct HbA1c trajectories in children across the first 24-months following a new T1D diagnosis.

Measures: In the longitudinal TACKLE T1D study of 5-9-year-olds recently diagnosed, we tracked HbA1c levels for up to 24-months in 123 youth (child baseline age: 7.35 ± 1.34 years; T1D duration at baseline: 4.56 ± 3.26 months; 86% Non-Hispanic White). We used latent class analyses to derive distinct trajectories of child HbA1c. Using AIC and BIC measures, as well as clinical judgment, a 3-class solution provided the best fit.

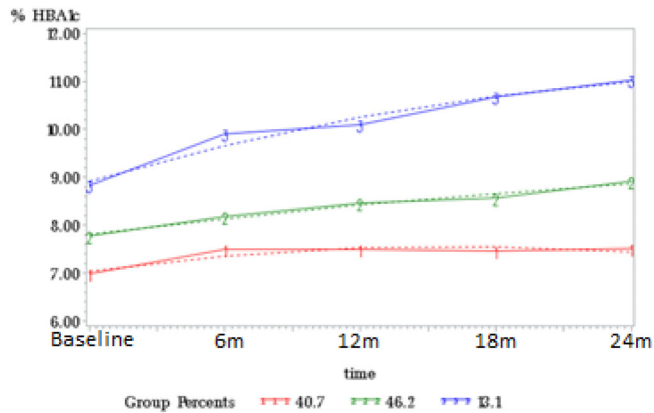
Results: All 3 trajectory groups show significant increases in child HbA1c over time ($p < 0.005$). However, group 1 (41% of children) describes children with an HbA1c trajectory that approximates the clinical target and slowly increases across the new-onset period (M change= 0.11%), while groups 2 and 3 (59% of children) describe trajectories that are above the clinical target and more rapidly increase over time. Group 2 (46% of children) increases at an average rate of 0.26% resulting in a final HbA1c estimate that is 1.0% higher than their baseline estimate. Group 3 (13% of

Year	2015	2016	2017	2018
Number of children	897	917	889	863
Age (years)	4.8	4.8	4.9	4.8
% treated with CSII	71.9 (68.9-74.9)*	76.8 (74.0-79.6)	75.7 (72.8-78.6)	78.7 (76.0-81.4)*
% using CGM (rtCGM or isCGM)		81.8 (79.3-84.3)*	96.3 (95.0-97.6)	96.6 (95.4-97.8)*
HbA1c (mmol/mol)	52.8 (49.2-56.4)	52.5 (48.9-56.1)	52.2 (48.6-55.8)	50.3 (46.8-53.8)
HbA1c (%DCCT)	7.0 (6.7-7.3)	7.0 (6.6-7.3)	6.9 (6.6-7.3)	6.8 (6.4-7.1)
% of children reaching HbA1c ≤ 48 mmol/mol (6.5% DCCT)	29.9 (26.8-33.0)*	31.1 (28.0-34.2)	31.8 (28.6-35.0)	44.8 (41.4-48.2)*
% of children reaching HbA1c ≤ 52 mmol/mol (<7% DCCT)	45.7 (42.3-49.1)*	47.1 (43.7-50.5)	48.8 (45.3-52.3)	60.6 (57.2-64.0)*
% of children being overweight or obese	25.1 (22.2-28.0)	25.3 (22.4-28.2)	26.6 (23.6-29.6)	28.5 (25.6-33.0)

[Treatment and treatment outcome in children younger than 7 years with T1D in Sweden. Data are presented as mean (confidence interval, CI). * $p < 0.05$]

children) increases at an average rate of 0.53% resulting in a final HbA1c estimate that is 2.1% higher than their baseline estimate.

Conclusions: We found 3 distinct HbA1c trajectories in our sample of 5-9-year-olds with recent-onset T1D. Notably, all 3 trajectories show a significant increase in HbA1c, but groups 2 and 3 describe children who start with levels above the clinical target and increase at a more rapid rate over time. Next steps should involve identifying psychosocial and behavioral factors early in T1D that may predict a child's HbA1c trajectory to inform potential preventative interventions.



[HbA1c trajectories in 5-9-year-olds with recent onset T1D]

O57

Glycemic control of adolescents and young adults with type 1 diabetes across Australia and New Zealand

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Introduction: Many adolescents and young adults with type 1 diabetes (T1D) move away from supportive parental homes, have less structure in their lives and engage in behaviors which may be detrimental to their diabetes care.

Objectives: We examined the glycemic control of young people with T1D across Australasia, on whom there is a paucity of published data.

Methods: We used data from ADDN (addn.org.au), a collaboration among pediatric and adult diabetes centers across Australasia. Longitudinal data were extracted on all healthcare visits attended by young people with T1D who were aged 16-25 yrs at their last visit. Clinical data were extracted from 1st Jan 2014-31st Dec 2018 inclusive.

Results: A cohort of 4651 young people attending 17 diabetes centers across Australasia met the inclusion criteria; 2433 (52%) were male. Mean±SD T1D duration was 8.6±4.9 yrs (range 0-24); BMI SDS 0.61±0.97; mean aggregated HbA1c from all visits in the 5-yr period was 8.7±1.8% (71.9±19 mmol/L); only 530 (11%) achieved an aggregated HbA1c< 7.0% (53mmol/mol). At their last visit, mean HbA1c was 8.8±1.9% (72.6±20.7 mmol/L); 569 (13%) had HbA1c< 7.0%; 54% (n=2,231) used multiple-daily injections (MDI), 39% (n=1,606) CSII and 8% (n=335) twice-daily (BD) injections. HbA1c was slightly higher in females vs males (8.9 vs 8.7%, 73.3 vs 71.9mmol/mol, p=0.02) and in those diagnosed < age 10 yrs vs >10 yrs (8.9 vs 8.7%, 73.3 vs 71.9mmol/mol, p< 0.001). In multivariable linear regression, higher HbA1c was associated with younger age at T1D diagnosis (p< 0.001), female gender (p=0.03) and BD therapy vs MDI/CSII (p< 0.001).

Conclusions: The glycemic control of adolescents and young adults with T1D across Australasia is persistently sub-optimal across this age range, particularly among those with young onset of T1D. There is a need to better understand factors that contribute to these observations, and how healthcare services can support achievement of improved glycemic control in this population.

O58

Lowering HbA1c during the first 2 years predicts a lower long-term HbA1c on a clinic level

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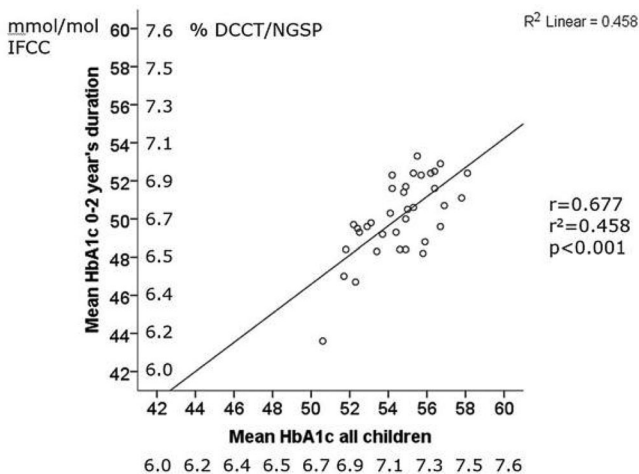
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Background: Mean HbA1c in children and adolescents varies between countries, but there is a considerable variation also between clinics within the same country. It has been difficult to characterize factors that contribute to this difference. We aimed to compare early metabolic control with long-term mean HbA1c in clinics within Sweden.

Methods: The Swedish pediatric diabetes quality registry (SWEDIABKIDS) covers 98% of children and adolescents < 18 years in Sweden. We captured overall mean HbA1c for 36/42 clinics (6 had less than 20 patients with < 2 years' duration) and compared with HbA1c over the first 2 years of diabetes. Values with < 3 months' duration were not included as these are affected by glucose levels before diagnosis.

Results: Mean overall HbA_{1c} for all 42 clinics was 54.6 (95% CI 53.3-55.9) mmol/mol (7.1%, 95% CI 7.0-7.3) and over the first 2 years for the 36 clinics 50.1 (95% CI 48.0-52.2) mmol/mol (6.7%, 95% CI 6.5-6.9). The correlation for the 36 clinics was $r=0.677$ ($p < 0.001$). R^2 was 0.458, i.e. 45.8% of the variation in overall HbA_{1c} was explained by HbA_{1c} during the first 2 years of diabetes.

Conclusions: An intensive education program at the onset of diabetes resulting in a low HbA_{1c} early on is a good investment for the long-term metabolic control. Mean HbA_{1c} during the first 2 years will be a good variable to measure the effectiveness and success on a clinic level of new implementations in diabetes treatments.



[Mean clinic HbA_{1c} during the first 2 years vs. mean HbA_{1c} of all children]

O59

Analysis of continuous glucose monitoring data reveals vacation-associated deterioration of glycemic control in pediatric type 1 diabetes

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Introduction: Continuous Glucose Monitoring (CGM) metrics have advantages over glycated hemoglobin (A1c) in assessing glycemic control on brief time scales.

Objectives: We sought to leverage CGM data to test the effect of school vacation in a pediatric type 1 diabetes (T1D) cohort.

Methods: From >1000 T1D Dexcom CGM users at Boston Children's Hospital, we identified N=97 consistent users (>=100 weeks of >=50% sufficient data since 1/2016), aged 5-20 years. The cohort (53% females, 81% white, median age 13 years) had a median (IQR) glucose of 176 mg/dL (129, 231) based on >18 million CGM glucose measurements during the study period (8/2016-2018) spanning 2 school years. Users were randomly divided into Test (N=79) and Replication Cohorts (N=18), which showed directionally consistent results.

Results: The median glucose and percentage of time out of range (TOR) throughout the year had three peaks, and these overlapped with December, February, and April school vacations. Paired t-tests

comparing the baseline week to the week including the first vacation weekend and to the full vacation week (the peak) were conducted for each user-week pair. An increase in both metrics was statistically significant (Bonferroni $p < 0.05/12$) for the full vacation week in February (median glucose $p=4.4e-4$ and TOR $p=2.9e-4$) and April (median glucose $p=1.1e-6$ and TOR $p=4.2e-7$). Glycemic deterioration was worst among 15-20 year-olds during these vacations, when the median glucose rose above 200 mg/dL.

Conclusions: Our findings point to school vacations as being high risk periods for pediatric T1D, especially for adolescents who may have less support and may have higher baseline risk of diabetic ketoacidosis. Vacation-associated glycemic deterioration would not be apparent using A1c trends alone. Because adherent CGM users may be more adherent in other ways, we may have underestimated the risk. Here we provide evidence for how CGM can inform time- and age-specific T1D anticipatory guidance.

O60

Occurrence of hypoglycemia with fast-acting insulin aspart versus insulin aspart according to baseline HbA_{1c} in children and adolescents with type 1 diabetes: a post hoc analysis

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Objectives: Balancing the risk of hypoglycemia with glycemic goals is a challenge in pediatric type 1 diabetes (T1D). This *post hoc* analysis of a large, randomized trial (onset 7) compared the rates of hypoglycemia with fast-acting insulin aspart (faster aspart) vs insulin aspart (IAsp) in children and adolescents with T1D according to baseline glycemic control with HbA_{1c} < or ≥7.5% (58 mmol/mol).

Methods: onset 7 was a 26-week, phase 3 trial in which participants (1-< 18 years old) with T1D were randomized to double-blind mealtime faster aspart (n=260) or mealtime IAsp (n=258), or open-label post-meal faster aspart (n=259), all with insulin degludec. In this *post hoc* analysis, rates of severe or blood glucose (BG)-confirmed hypoglycemia (ISPAD 2014 classification and/or < 3.1 mmol/L [56 mg/dL]) during the 26-week period were compared between treatment arms according to baseline HbA_{1c} < or ≥7.5% (58 mmol/mol).

Results: Respectively, participants with a baseline HbA_{1c} < 7.5% were of similar age to those with HbA_{1c} ≥7.5% (11.8 vs 11.6 years), but had a shorter T1D duration (3.9 vs 4.8 years). There were no statistically significant differences in rates of severe or BG-confirmed hypoglycemia between faster aspart (mealtime or post-meal) and mealtime IAsp, which were comparable regardless of baseline HbA_{1c} group (Table). Overall, across both baseline HbA_{1c} < 7.5% and ≥7.5% groups, there were few severe hypoglycemic events (7 vs 8 events, respectively). Furthermore, there were no statistically significant differences in total daily insulin dose (U/kg) at week 26 between faster aspart (mealtime or post-meal) and mealtime IAsp for those < or ≥7.5% (Table).

Severe or BG-confirmed hypoglycemia and insulin dose after 26 weeks of faster aspart versus IAsp for all participants according to baseline HbA_{1c}

	Baseline HbA _{1c}	Faster aspart (meal-time)	Faster aspart (post-meal)	IAsp (meal-time)	Estimated treatment ratio [95% CI]			
					Faster aspart (mealtime) / IAsp	P-value*	Faster aspart (post-meal) / IAsp	P-value*
Severe or BG-confirmed hypoglycemia rates, events/PYE*	<7.5%	26.94	30.94	25.57	1.08 [0.80;1.47]	0.85	1.20 [0.89;1.64]	0.48
	≥7.5%	28.69	25.97	25.75	1.13 [0.84;1.51]		1.03 [0.77;1.38]	
Median total daily insulin dose, U/kg†	<7.5%	0.81	0.79	0.81	1.02 [0.93;1.11]	0.76	1.00 [0.92;1.10]	0.31
	≥7.5%	0.87	0.87	0.83	1.04 [0.95;1.13]		1.07 [0.98;1.16]	

*Hypoglycemia rates were analyzed using a negative binomial model for hypoglycemia episode count with a log link function, and the logarithm of the exposure time as offset. †Doses were analyzed on a log-scale using a mixed effects model for repeated measures, with back-transformation to express results as dose ratios. *P-values for homogeneity of treatment differences were calculated using a Wald test. Values at 'week 26' are the last 'on-treatment' values recorded. In total, 116/113/129 participants receiving mealtime faster aspart/post-meal faster aspart/mealtime IAsp, respectively, had a baseline HbA_{1c} <7.5%, and 144/146/129 had a baseline HbA_{1c} ≥7.5%, respectively. BG, blood glucose; CI, confidence interval; faster aspart, fast-acting insulin aspart; IAsp, insulin aspart; PYE, patient-year of exposure.

[Table]

Conclusions: In children and adolescents with T1D, rates of hypoglycemia, as well as similar insulin doses, were comparable between faster aspart and IAsp irrespective of whether participants had a baseline HbA_{1c} < or ≥7.5% (58 mmol/mol).

O61

10-year follow-up of the SWEET type 1 diabetes registry: improvement of metabolic control in all age groups

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Objective: The SWEET registry was initiated in 2008. A 10-year follow up from eligible clinics gives the option to study a time trend of HbA_{1c} over time on a background of increasing pump use in children and adolescents with type 1 diabetes (T1D).

Methods: Data on subjects with T1D below 25 years of age from the international diabetes registry SWEET were analyzed. Centers with data in the first (2008 - 2010) and second (2016 -2019) observation period with documented HbA_{1c} values in at least 15 subjects were included. In each observation period, data were aggregated per patient. Linear and logistic regression models were applied (adjusted mean with 95% CI).

Models were adjusted for gender, age- and diabetes duration-groups with pump usage as explanatory variable. The outcome metabolic control was measured as HbA_{1c}, and analyzed for differences over time.

Results: The cohort from the first observation period included 4772 patients from 21 centers, 51 % male, median age 11.3 y [Q1;Q3: 7.9; 14.5] and median T1D duration 2.89 y [0.78; 6.38]. The second time cohort included 12750 patients, 52 % male, age 13.20 y [9.6; 16.3] and duration 4.27 y [1.45; 7.45]. HbA_{1c} was higher in the first time period (8.2% (8.15; 8.23)) compared to the second time period (7.8% (7.76; 7.81)), p < 0.0001. All age-groups showed decreased HbA_{1c} for the two time periods (< 6y: 7.9% (7.8; 8.0) to 7.4% (7.37; 7.52); >6 - ≤12 y: 8.0% (7.90; 8.01) to 7.5% (7.47; 7.55); >12 - ≤16 y: 8.3% (8.21; 8.38) to 7.9% (7.85; 7.95); >16 y: 8.4% (8.32; 8.56) to 8.2% (8.21; 8.24), all p < 0.001). Insulin pump use increased between the two periods from 38 % (36; 40) to 46 % (45; 46), p < 0.0001.

Conclusions: Data from the SWEET registry in these selected 21 centers from Europe, Australia, Canada and India comparing two observational time periods over 10 years demonstrated that the HbA_{1c} has significantly decreased over time and that the use of insulin pumps in young with type 1 diabetes has increased.

O62

Costs and outcomes of intermediate versus minimal care for youth-onset type 1 diabetes in six countries

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30y country data - expressed as minimal care/intermediate care

	Mali	Tanzania	Pakistan	Sri Lanka	Bolivia	Azerbaijan
30y survival rate	8.5%/50.1%	10.1%/52.7%	39.4%/76.7%	45.5%/79.9%	25.8%/68.1%	62.1%/89.2%
HLYs per individual	12.4/21.1	14.0/22.0	19.3/24.9	20.3/25.3	17.1/23.8	22.5/26.5
Cost of HLYs gained as % GDP/capita	146.2%	78.5%	72.2%	23.9%	19.9%	18.4%

Prevalence of selected complications after 30y duration T1D

Mean HbA1c	Proliferative retinopathy	Blindness	Overt nephropathy	Renal failure	Column intentionally blank	Column intentionally blank
8.5% (69 mmol/mol)	45.2%	7.0%	26.7%	2.4%		
9.0% (75 mmol/mol)	49.6%	9.2%	31.8%	3.9%		
12.5% (113 mmol/mol)	86.1%	51.3%	90.7%	68.1%		

[Results table]

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Objective: Data is needed to demonstrate that providing an intermediate level of type 1 diabetes (T1D) care is cost-effective compared to minimal care in less-resourced countries.¹We studied these two care scenarios in six countries.

Methods: We modelled the complications/costs/mortality/Healthy Life Years (HLYs) associated with intermediate care (mean HbA1c 8.5% (69 mmol/mol) (Azerbaijan only) or 9.0% (75 mmol/mol) (all other countries) compared to minimal care (12.5% (113 mmol/mol)).¹A discrete time Markov illness-death model with age and calendar-year-dependent transition probabilities was developed in R 3.3.1 with R Stu-

dio integrated development environment. 30 years (y) of complications and Standardized Mortality Rate data from the youth cohort in the Pittsburgh Epidemiology of Diabetes Complications Study (with follow-up commencing in 1980s-1990s) were used in the model. Background mortality was obtained from the Global Health Observatory. Costs were determined from international and local prices.

Results: Key results are shown in the table below.

Conclusions: Marked reductions in complications rates and mortality are achievable with intermediate care. This is also cost-effective, and the increase in HLYs is not an expensive intervention according to the WHO 'Fair Choices' approach.²

References:

1. Ogle et al. Pediatric Diabetes 2019;20(1):93-98
2. WHO 2014. www.who.int/choice/documents/making_fair_choices/