

Psychosocial Impact of New Diabetes Technologies

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Disclosure

☐	No, nothing to disclose
☒	Yes, please specify:

<i>Company Name</i>	<i>Honoraria/ Expenses</i>	<i>Consulting/ Advisory Board</i>	<i>Funded Research</i>	<i>Royalties/ Patent</i>	<i>Stock Options</i>	<i>Ownership/ Equity Position</i>	<i>Employee</i>	<i>Other (please specify)</i>
Roche	X	X	X					
Animas	X	X						
Novo Nordisk	X	X	X					
Sanofi	X	X						
Astra Zeneca	X							
AbbVie	X							
Lifescan	X							
Janssen	X							

Overview

- Why Psychosocial Assessment is Crucial
- Uptake of Diabetes Tech
- What Does Psychosocial Assessment Tell Us?
- Artificial Pancreas Psych Research
- Next Steps

Why Assess Psychosocial Outcomes?

“Health is not defined by only the absence of disease and infirmity, but also by the presence of physical, mental and social well-being”

WHO (1948, 1952)

The Whole is $>$ the Sum of Its Parts

Engineering and biomedical excellence are taken as ‘a given’ by people with diabetes

Devices must be ‘discreet, small, accurate, effective, reliable, flexible, easy to use’

- ‘Allows me to have a normal life’
- ‘Gives me freedom in my life’
- ‘Lets me not have to think about diabetes all the time’
- ‘Gives me a better quality of life, makes me happier, less exhausted with diabetes’

Uptake and Continuation of Db Tech

- <50% of PWD (T1) eligible for insulin pump use one (USA)
- 7% adults (T1), 19% kids (T1) in the UK use insulin pump
- 15% PWD (T1) in Germany and Norway
- 6.5% of PWD use CGM consistently
- Marked geographical variation in uptake of CSII
- Significant variation across age groups of CGM
- May suggest different interpretations of the value and experience of the technology

What Users Say

Positives:

- CSII: Increased independence, improved QoL (for user and family members), greater flexibility with timing and content of food
- CGM: additional information, empowering, greater control

Negatives:

- CSII: Increased visibility of disease state, cost, occlusions
- CGM: Alarms (false), lack of accuracy, unable to trust it

What Should We Measure?

- Quality of Life
- Psychosocial Functioning
- Functional Health Status
- Well-being
- Treatment Satisfaction
- Depression / anxiety / distress
- Treatment / device related burden

What Will It Tell Us About Tech Impact?

- Whether a person can/will live with the device every day
- Perceived benefit / downside associated with device
- Acceptance / trust / usability
- Impact on social relationships
- Impact on family members
- Impact on perceived burden of disease

Informing Clinical Practice

Predictors of perceived QoL benefits equal:

- Greater confidence in using device
- Perceived control over diabetes (> glycaemic control)
- Satisfaction with device accuracy
- Usability and acceptability
- Trust

All factors influencing ability to self-manage effectively

What About HCPs?

- How do HCPs incorporate tech into routine care?
- How many devices / software systems etc should HCPs be knowledgeable about?
- How do you keep up with a ‘moving target’ of new tech?
- Whose responsibility is it when devices fail?
- How will you manage the ever-increasing data download?
- What happens when devices don’t download? How do you manage that frustration (yours and your patients)?

Impact of Diabetes Tech Survey

- 100 parents of children with T1D and 74 partners of adults with T1D
- 85% children / 77% adults use CSII
- 72% children / 70% adults use CGM
- 82% parents report easier to achieve bg targets
- 51% parents reported reduction in frequency of hypos
- 55% parents reported reduction in severity of hypos
- Challenge of supporting child with T1D is a large/very large burden (45%)

Artificial Pancreas Research

- Significant progress over recent years in technology
- Completely game-changing in db management
- Important to manage and understand expectations and psychosocial implications of technology
- Confidence, trust in device, perceived burden of technology and effort required to manage it all important factors
- Achievement of desired goals versus potential loss of personal control

AP Research

- No routine psychosocial assessment in clinical trials
- Psych Impact: attitudes, beliefs and emotions of users currently under-evaluated
- Yet, robust, evidence-based psychosocial assessment is required by regulatory approvals bodies e.g. FDA, NICE
- AP specific measures are necessary to address the potential impact of devices on everyday living
- Guidelines are required to support research teams to identify and select appropriate measures

AP Research – INSPIRE Study

Development and validation of new psychosocial self-report measures for use in AP clinical research for:

- Children
- Adolescents
- Parents of children and adolescents
- Adults
- Significant other/partner of adults

To support uptake and continued use of AP when available

Methods

- Focus groups and semi-structured, qualitative interviews – to explore participants' perceptions of the impact of the closed loop technology on their lived experience
- HCP survey
- Stakeholder engagement – regulatory approvals bodies, payers/reimbursement agencies, industry, advocacy groups, charities, PWD, academia, HCPs etc
- Linked with all AP research teams globally – they will all use these measures

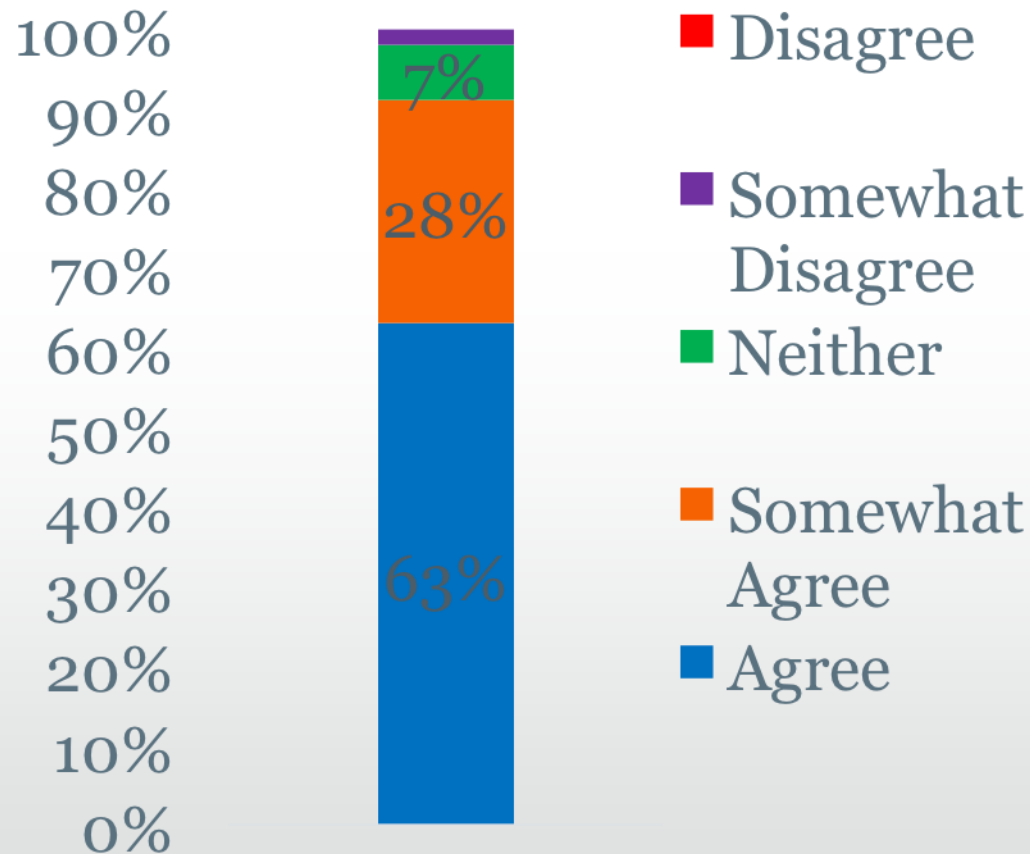
Results To Date - PWD

59 focus groups and 88 1:1 interviews across 4 centres –
Bournemouth, Stanford, Joslin, Chicago

Key Themes:

- Reassurance/peace of mind; improved bg control; better informed to manage db; better start to the day; improved sleep; 'time off diabetes'; fewer complications later on
- Equipment (too many devices); alarms; technical difficulties; connectivity; increased visibility of disease state; cost

I believe AID will optimize diabetes control for patients with T1D



Results To Date – HCP Survey Data

- 32% believe they will have sufficient time to implement and manage AID in T1D
- 39% believe AID will require more professional time than previous insulin delivery approaches
- 78% believe additional trainers/educators will be required to support AID in T1D
- 7% believe that PWD will be willing to share the cost of AID systems
- 5% believe that AID will require less self-care effort by PWD

Comments from Previous Research

- “It was brilliant! ‘we know what’s happening at night” (001)
- “I didn’t realise how much better I could feel” (003)
- “My sugars were a lot better in the morning ... it does what it says on the tin” (008)
- “When it [*the trial*] finished I was really sad” (012)
- “I would pretty much always wake up with a perfect blood sugar which was then a really good way to start your day” (021)

Results – Closed Loop Specific

- “The concept .. moving towards an artificial pancreas optimizing people’s sugar controls to improve the levels to avoid high readings. It was generally doing at least as good if not a better job than I would be doing myself”. (002)
- “My sugars were a lot better in the morning ... it does what it says on the tin. The technology is coming forward and research is coming forward There will be solutions to the issues”. (008)

Results – Closed Loop Specific

- “You could wake up, look at this diagram of the profile of your blood sugar and it would be dead level, erm absolutely constant throughout the night and that makes you feel better”. (006)
- “It was pretty good It was the best I have had for several years. I didn’t go to sleep worrying about having a hypo or not waking up. I knew that it would correct this, it was like a break”. (014)

Results – Closed Loop Specific

- “The calibration at night. So much equipment you need to be using for the closed loop” (011)
- “It got a bit confused .. it bleeped at night a couple of times and kept losing contact”. (012)
- “There were so many times when for a variety of reasons it kept me awake all night because it was alerting or it didn’t seem to work”. (009)
- “You feel a bit battered by the end of it ... fit your whole life around a machine that isn’t working that well”. (019)

Comments

- “The worst thing for me was not knowing whether what was happening was down to operator incompetence or the technology” (009)
- “The terrible row ...” (005)
- “Absolutely dreadful ... The whole thing overwhelmed me I have to say (018).

Results – Closed Loop Specific

- “It was awful ... it wasn’t for me at all. The inconvenience in the evening, the bleeping just going off ... its sleep deprivation for me” (020)
- “Absolutely dreadful. I was really angry by the end of it ... I had a lot of problems with the hardware. The whole thing overwhelmed me I have to say. You couldn’t image what was going to go wrong next, I found it made me really anxious” (018)
- “They made out it was my fault ... I must have done something if they said everything was alright and it just happened but why? ... I feel it was my fault.” (017)

Conclusions

- Automated insulin delivery technology represents cutting edge research
- It shows promising potential that is exciting for many participants
- Technical difficulties with pump and CGM were common and influenced negative experience by some participants
- Participation demands a lot from people, over prolonged periods of time, physically and emotionally
- Questions about self-identity, relationship with diabetes and 'back-up' requirements need to be addressed

Questions / Comments?

Thank You

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