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Diabetes Technological Revolution: Winners and Losers?

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Abstract

Over recent years there has been an explosion in availability of technical devices to support diabetes self-management. But with this technology revolution comes new hurdles. On paper, the available diabetes technologies should mean that the vast majority of people with type 1 diabetes have optimal glycemic control and are using their preferred therapy choices. Yet, it does not appear to be universally the case. In parallel, suboptimal glycemic control remains stubbornly widespread. Barriers to improvement include access to technology, access to expert diabetes health care professionals, and prohibitive insurance costs. Until access can be improved to ensure the technologies are available and usable by those that need them, there are many people with diabetes who are still losing out.

Keywords

diabetes technology, winners, losers, access, inequality

Over recent years there has been an explosion in availability of technical devices to support diabetes self-management. The blood glucose meter market has been flooded with new brands and models, insulin pumps now come with ever increasing functionality such as bolus calculators, low glucose suspend, or even automated insulin delivery (artificial pancreas). Continuous glucose monitoring systems have undergone something of a transformation in terms of accuracy, reliability and functionality with data sharing functionalities, data presentation (AGP), and more recently factory calibration (complete replacement for self-monitoring of blood glucose, SMBG, at least in nominal conditions). Data platforms are appearing that strive to combine all available information generated by our patients (CGM, SMBG, insulin, meals, physical activity), and are moving from data presentation, to insight generation, and eventually full-fledged advisory systems.

But with this technology revolution comes new hurdles:

- Novel, often lower price and lower accuracy blood glucose monitors may affect the glucose monitoring industry, people with diabetes, and eventually health systems themselves—with the commoditization of critical medical devices still used for more than 95% of glucose measurements leading to insulin dosing[1] come decaying clinical outcomes,[2,3] and potentially increased overall health costs.[4,5]
- Start-up tech companies are aggressively moving into the marketplace, spurring dynamic innovations and technology development, some with strong clinical trial data[6-11]—but important questions about technology access (for who?), cost premium (at what cost?) remain to be answered, especially as socioeconomic status and availability of health care have been identified as barriers to access to these technologies
- The increasing prevalence of data, and data presentation widens the burden of diabetes, it is now "shared" (literally), however for others it means greater interference (often for teenagers) and unwanted attention to diabetes rather than identification of self as a person first (not a broken pancreas). These psychobehavioral hurdles are far from understood and may again exclude significant segments of people with diabetes.
- Finally, regulatory bodies (eg, FDA)[12-14] are rethinking their processes for approval and regulation of these new advances. On one hand, the regulatory approval process is by nature rigorous and slow compared to technology innovation: approvals must be based on evidence, often clinical, which are not easy or quick to develop. Safety—do no harm—must prevail. But classification of these new tools may have significant impact on how, when, and even if, these tools become available to patients. The regulatory bodies' capacity to understand and characterize the risk profile of each system, and therefore their level of regulation, may very well encourage or suppress beneficial innovations, and impact people with diabetes' health and well-being.

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So, who are the winners and losers in this technological revolution?

On paper, the available diabetes technologies including connected/smart self-monitoring of blood glucose, insulin pumps, flash glucose meter, continuous glucose meters, data-driven expert systems, and closed-loop automated insulin delivery should mean that the vast majority of people with type 1 diabetes have optimal glycemic control and are using their preferred therapy choices. Surely, then people with diabetes should come out as overall winners? Yet, it does not appear to be universally the case. Uptake of technology varies considerably, with prevalence of insulin pump use for example in the USA at 40-62% of adults with type 1 diabetes, as compared with 5-15% in Europe.[15] Furthermore, age group and socioeconomic status differences show further disparity in uptake and availability.

In parallel, suboptimal glycemic control remains stubbornly widespread, with for example UK data showing the percentage of people with type one diabetes achieving their treatment targets for HbA1c at 30.2% (2016-2017) and people with type two diabetes at 66.8% (2016-2017).[16] These figures have remained largely unchanged over recent years with 2013-2014 percentages at 29.4% and 66.8% respectively.[17] It seems that, despite the increasing use of latest diabetes technologies, and despite their proven benefits in randomized clinical trials, this is insufficient in itself to support optimal glycemic control over our patient populations.

Self-Monitoring of Blood Glucose

To start understanding the factors leading to this bleak conclusion, we must acknowledge the broad variety of performances and availability of medical devices, even when all use similar technologies. For example, the variability in accuracy of self-monitoring of blood glucose meters has been well documented.[18] ISO standard 15197:2013 specifies that $\geqslant$95% of SMBG results must be $\pm$15 mg/dl ($\pm$0.8 mmol/L) of the reference result for samples with blood glucose concentrations $<$100 mg/dL ($<$5.6 mmol/L) and $\pm$15% for samples with blood glucose concentrations $\geqslant$100 mg/dL ($\geqslant$5.6 mmol/L).[19] There have been several studies demonstrating high levels of accuracy of some blood glucose meters, for example Jendrike et al[20] and Christiansen et al.[21] But a review by Klonoff and Prahalad, examining 11 studies presenting data about clinical performance of SMBG systems, found that only 15 out of 31 (48.3%) of SMBG systems met the ISO15197 2013 criteria in all of the studies in which they were evaluated.[22] A commentary by Parkin[23] goes on to state that these findings "concur with several earlier studies that revealed significant inaccuracy and lot-to-lot variability in up to 45% of SMBG systems currently marketed."

while ISO standards aim at improved accuracy for users, they will do little to change the rationing of test strips that remains a problem for many according to UK Charity Diabetes UK.[24] In a recent survey conducted from March to May 2016, it was found that 27% of the 1000 respondents had, in the past 12 months, been refused a prescription for blood glucose test strips or had the number of test strips on their prescription restricted. Of these, over half (52%) had type 1 diabetes. Reasons for refusals and restrictions included "budget constraints" and "excessive testing." In addition, 66% of respondents were given no choice of blood glucose meter. Of these, one in four (25%) were not happy with the meter provided. Diabetes UK argue that rationing is unsafe and potentially puts the health of people with diabetes at risk.

Continuous Glucose Monitoring

But variability in technology access is not always driven by extraneous factors such as reimbursement, and often are the results of a combination of these with design decisions, ease of use, and how well people can integrate the devices in their usual care. As a case in point, continuous knowledge of glucose levels with an accurate, discrete device has been cited as a research priority by people with T1D,[25] however access to and uptake of CGM systems remains low. It is also well established that diabetes and its treatment can impact the lives of people living with somebody with T1D in both positive and negative ways.[26] As such, CGM has been shown to be beneficial for self-management and sometimes to have been limited in its impact or problematic for family members. Alarms and alerts being the most complained about aspects for partners, particularly overnight.

Specifically, improvements in glucose control are dependent on consistent CGM use however this can be expensive and not always reimbursed by insurance or other health care providers. Furthermore, alarm fatigue, technical failure, and accuracy problems limit ongoing engagement, with lack of trust in the devices and irritation with technological failure cited as primary reasons by people with T1D. A negative psychosocial impact of CGM use has been described,[27] and despite a high proportion of pump use, CGM use in the T1D Exchange cohort remains low with 6% of children $<$13 years old, 4% of adolescents 13 to $<$18 years, 6% of young adults 18 to $<$26 years, and 21% of adults $\geqslant$26 years using CGM. Discontinuation rates are high, however, at 41% of users having discontinued use by 1 year.[28]

So, while CGM systems are credited with optimization of A1c and avoidance of hypoglycemia, more needs to be done to support effective onboarding and managing expectations of daily experience. Borges and Kubiak[29] report that for many the feeling of "information overload" represented a major barrier to the sustained use of CGM. Data downloads—how to make sense of the overload of data and what to do with it can be challenging. Balancing the expectations of health care professionals with those of people with diabetes requires careful navigation. HCPs' focus on A1c as primary outcome, whereas people with diabetes having a greater focus on how to implement the device in everyday life while managing other daily tasks, creates potential for frustration for all. Furthermore, lack

of understanding of the benefits of technology[30] and lack of ability to incorporate technologies into everyday living without unreasonable interference or distress compound the problem.

Stigma

Wider holistic barriers to optimal diabetes self-management may go some way to explaining this challenge. Self-reported stigma associated with diabetes is high with a 2017 DiaTribe survey of people with diabetes in the USA highlighting that 76% of people with type 1 diabetes report feeling stigmatized, as well as 52% of people with type 2 diabetes.[31] In the same survey, 72% of participants reported feeling that others saw their diabetes as a "failure of personal responsibility," 65% as a "burden on the health care system," and 52% as "having a character flaw or fault." It is perhaps unsurprising that diabetes related distress, burden and psychological morbidity such as depression and anxiety disorders remain prevalent.

Barriers to Optimal Usage

Barriers to improvement include access to technology, access to expert diabetes health care professionals, prohibitive insurance costs, and potentially inappropriate "gate-keeping" by health care professions as demonstrated in the REPOSE trial.[31] In this study, staff described how "alongside clinical criteria, they had tended to select individuals for CSII in routine clinical practice based on their perceptions about whether they possessed the personal and psychological attributes needed to make optimal use of pump technology." They also noted, however, how those assumptions about personal and psychological suitability had been challenged by "observing individuals make effective use of CSII who they would not have recommended for this type of therapy in routine clinical practice." Furthermore, the lack of dedicated, validated, and industry-independent education for novel technologies makes it difficult for HCPs and people with diabetes to fully understand the benefits and challenges the technologies present.

Mobile Apps

The ever-growing smartphone app market creates further benefits and challenges. The ability to access evidence-based, theory-driven advice via your phone provides greater opportunities for individuals to access help quickly and easily. We should be careful though not to overestimate the numbers of people who have access to smartphones or are willing to use them in this way. Factors such as age, comfort with technology, and socioeconomic status, for example, exclude some people from these benefits. Furthermore, despite the plethora of apps available, it can be very difficult to identify those that are efficacious or safe. Many apps may be poorly designed and or implemented, lack clinical evidence to support their use, and are only available in English. How much does/should such medical interventions cost? and who reaps any real benefit in terms of improved glycemic control or reduced diabetes burden remain largely unanswered but important questions.

Closed Loop

Finally, in the advent of closed-loop technologies, novel questions will need to be addressed to ensure people are able to gain maximum benefit from these new systems. Perceptions of disease, visibility of disease state, trust and longevity of use are areas requiring greater exploration as systems become increasingly available to people with diabetes.

Conclusion

Who are the winners and losers of this diabetes technology revolution? Several multifactorial challenges remain unaddressed, for example, faster funding processes for research, faster regulatory approvals processes, greater considerable of integration of novel devices into routine clinical and greater understanding by HCPs and people with diabetes about the strengths and limitations of technologies present barriers to implementation and adoption of technologies. Ultimately people with diabetes and their families are the winners. Until access can be improved to ensure the technologies are available and usable by those that need them, there are many people with diabetes who are still losing out.

Abbreviations

AGP, ambulatory glucose profile; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; FDA, US Food and Drug Administration; HbA1c, hemoglobin A1c; HCPs, health care professionals; ISO, International Organization for Standardization; Mmol/L, millimoles per liter; NICE, National Institute for Health and Care Excellence; REPOSE, relative effectiveness of pumps over structured education; SMBG, self-monitoring of blood glucose; T1D, type 1 diabetes.

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References

1. Miller KM, Foster NC, Beck RW, et al. Current state of type 1 diabetes treatment in the US: updated data from the T1D Exchange clinic registry. *Diabetes Care*. 2015;38:971-978.

2. Campos-Náñez E, Fortwaengler K, Breton MD. Clinical impact of blood glucose monitoring accuracy: an in-silico study. *J Diabetes Sci Technol*. 2017;11:1187-1195.
3. Boettcher C, Dost A, Wudy SA, et al. German/Austrian Diabetes Prospective Documentation Initiative. Accuracy of blood glucose meters for self-monitoring affects glucose control and hypoglycemia rate in children and adolescents with type 1 diabetes. *Diabetes Technol Ther*. 2015;17:275-282.
4. McQueen RB, Breton MD, Ott M, Koa H, Beamer B, Campbell JD. Economic value of improved accuracy for self-monitoring of blood glucose devices for type 1 diabetes in Canada. *J Diabetes Sci Technol*. 2016;10:366-377.
5. Fortwaengler K, Campos-Náñez E, Parkin CG, Breton MD. The financial impact of inaccurate blood glucose monitoring systems. *J Diabetes Sci Technol*. 2017;12:318-324.
6. Grifantini K. Advances in management technology for diabetes: from personal reminders to digital doctors. *IEEE Pulse*. 2014;5:40-44.
7. Hompesch M, Kalcher K, Debong F. High risk population using mobile logging application shows significant reduction in LBGI. *Diabetes* 2017;66:A245-A245.
8. Salber P, Niksch A. Digital health tools for diabetes. *J Ambul Care Manage*. 2015;38:196-199.
9. Quinn CC, Clough SS, Minor JM, Lender D, Okafor MC, Gruber-Baldini A. WellDoc™ mobile diabetes management randomized controlled trial: change in clinical and behavioral outcomes and patient and physician satisfaction. *Diabetes Technol Ther*. 2008;10:160-168.
10. Bollyky JB, Bravata D, Yang J, Williamson M, Schneider J. Remote lifestyle coaching plus a connected glucose meter with certified diabetes educator support improves glucose and weight loss for people with type 2 diabetes. *J Diabetes Res*. 2018;2018:3961730.
11. Kovatchev B, Tamborlane WV, Cefalu WT, Cobelli C. The artificial pancreas in 2016: a digital treatment ecosystem for diabetes. *Diabetes Care*. 2016;39:1123-1126.
12. Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff. Available at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf.
13. FDA authorizes first fully interoperable continuous glucose monitoring system, streamlines review pathway for similar devices. Available at: https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm602870.htm.
14. Artificial Pancreas Device System: FDA's Role. Available at: https://www.fda.gov/medicaldevices/productsandmedicalprocedures/homehealthandconsumer/consumerproducts/artificialpancreas/ucm259561.htm.
15. Naranjo D, Tanenbaum ML, Iturralde E, Hood KK. Diabetes technology: uptake, outcomes, barriers and the intersection with distress. *J Diabetes Sci Technol*. 2016;10:852-858.
16. National Diabetes Audit 2016-17 Short Report Care Processes and Treatment Targets. Available at: https://www.hqip.org.uk/resource/national-diabetes-audit-2016-2017-full-report-care-processes-and-treatment-targets/#.W0Xhm9JKiUk Accessed January 11, 2018.
17. Miller KM, Foster NC, Beck RW, et al. Current state of type 1 diabetes treatment in the US: updated data from the T1D Exchange clinic registry. *Diabetes Care*. 2015;38:971-978.
18. Klonoff DC, Prahalad P. Performance of Cleared Blood Glucose Monitors. *J Diabetes Sci Technol*. 2015;9:895-910.
19. International Organization for Standardization. ISO 15197: 2013(e). *In Vitro Diagnostic Test Systems—Requirements for Blood-Glucose Monitoring Systems for Self-Testing in Managing Diabetes Mellitus*. Geneva, Switzerland: International Organization for Standardization; 2013.
20. Jendrike N, Baumstark A, Kamecke U, Haug C, Freckmann G. ISO 15197: 2013 evaluation of a blood glucose monitoring system's measurement accuracy. *J Diabetes Sci Technol*. 2017;11:1275-1276.
21. Christiansen MP, Garg SK, Brazg R, et al. Accuracy of a fourth-generation subcutaneous glucose sensor. *Diabetes Technol Ther*. 2017;19:446-456.
22. Klonoff DC, Prahalad P. Performance of cleared blood glucose monitors. *J Diabetes Sci Technol*. 2015;9:895-910.
23. Parkin CG. If SMBG accuracy is critical to patient safety, why are inaccurate meters still on the market? *J Diabetes Sci Technol*. 2017;11:574-576.
24. Diabetes UK. Testing times: restrictions accessing test strips and meters for people with diabetes. Available at: https://diabetes-resources-production.s3-eu-west-1.amazonaws.com/diabetes-storage/migration/pdf/1092_Testing%2520times_test%2520strips%2520and%2520meters%2520report%2520WEB%2520final.pdf. Accessed January 9, 2018.
25. Gadsby R, Snow R, Daly AC, et al. Setting research priorities for type 1 diabetes. *Diabet Med*. 2012;29:1321-1326.
26. Barnard K, Skinner TC. Qualitative study into quality of life issues surrounding insulin pump use in type 1 diabetes. *Pract Diabetes Int*. 2007;24:143-148.
27. Markowitz JT, Pratt K, Aggarwal J, et al. Psychosocial correlates of continuous glucose monitoring use in youth and adults with type 1 diabetes and parents/caregivers of youth. *Diabetes Technol Ther*. 2012;14:523-526.
28. Wong JC, Foster NC, Maahs DM, et al. Real-time continuous glucose monitoring among participants in the T1D Exchange Clinic Registry. *Diabetes Care*. 2014;37:2702-2709.
29. Borges U Jr, Kubiak T. Continuous glucose monitoring in type 1 diabetes. *J Diabetes Sci Technol*. 2016;10:633-639.
30. DiaTribe survey. Available at: https://diatribe.org/issues/67/learning-curve.
31. Lawton J, Kirkham J, Rankin D, et al. Who gains clinical benefit from using insulin pump therapy? A qualitative study of the perceptions and views of health professionals involved in the Relative Effectiveness of Pumps over MDI and Structured Education (REPOSE) trial. *Diabetic Med*. 2016;33:243-251.