Question 3: 'Wearable medical technology has developed rapidly over recent years. Discuss the benefits that this brings to patients who live with chronic disease e.g. diabetes'

Over recent decades, wearable medical technology has been emerging as one of the most promising additions to modern healthcare; it is well known that wearables can empower individuals suffering with chronic disease, by providing them with the ability to self monitor, as well as assisting with diagnosis.[1] An area in which this rapid development is evident is in the management of type 1 diabetes: due to the complex and demanding nature of the condition, I have chosen to centre my essay around the benefits brought to these patients in particular, and the future direction of such wearable technologies.

Type 1 diabetes, also known as juvenile diabetes or insulin-dependent diabetes, remains one of the most prolific chronic conditions and major public health epidemics to date, having surfaced more rapidly in recent decades[2]. In the past century since the discovery of insulin, diabetes treatment and management has seen remarkable technological acceleration; minimally invasive technology to maintain a normal lifestyle, such as miniaturised monitoring systems, are now not merely scientifically possible, but accessible. However, in order to explore the evolving landscape of wearable medical technology, and the benefits it brings to type 1 patients, it is necessary to define what we mean by 'wearable'. In this essay, I have opted for the most comprehensive definition, encompassing subcutaneous insulin pumps (which an individual "wears" under the skin), as well as flash glucose monitors, continuous monitors, and more recent watch technology (such as Apple Watches).

Type 1 Diabetes Mellitus (T1DM) is thought to be caused by an autoimmune response: the cells in the pancreas that make insulin, beta cells, are depleted, to an extent that causes dangerously low insulin production. Insulin is a peptide hormone, secreted to move glucose from the bloodstream into our body cells, and therefore decreasing blood sugar levels. We can measure blood sugar levels through HbA1c detection: this is a form of haemoglobin chemically linked to sugars, as most monosaccharides spontaneously bond with it in the

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[1] Kang, H.S. and Exworthy, M. (2022). Wearing the Future—Wearables to Empower Users to Take Greater Responsibility for Their Health and Care: Scoping Review. *JMIR mHealth and uHealth*, [online] 10(7). doi:https://doi.org/10.2196/35684.

[2]Ogrotis, I., Koufakis, T. and Kotsa, K. (2023). Changes in the Global Epidemiology of Type 1 Diabetes in an Evolving Landscape of Environmental Factors: Causes, Challenges, and Opportunities. *Medicina*, 59(4), p.668. doi:https://doi.org/10.3390/medicina59040668. [Accessed: 20/07/24, 17:33]

bloodstream. Without enough insulin, glucose builds up in the blood, causing hyperglycemia, which can lead to organ, tissue and nerve damage or even ketoacidosis (DKA), requiring immediate medical treatment. Even more urgently, type 1 is on the rise worldwide: this may be a result of the accumulation of faulty genes in populations, and some studies argue that it is due to evolution. Overall, the effects of both genetic and environmental factors are thought to be the underlying aetiology of T1DM.[3]

It is clear, therefore, that type 1 diabetes is an issue that needs to be thoroughly addressed and funded. The aforementioned rapid development of technology and research in this medical field is opening doors to many new wearable technologies, including closed insulin loops. However, these methods are not without their flaws; although there are huge benefits, which I intend to delve deeper into, there are barriers to making such technologies accessible.

Typical treatments and closed-loop systems

It can certainly be said that the cornerstone of type 1 diabetes treatment is basal shots (long-lasting insulin that provides a small but constant stream, or a continuous pumping of small, fast-acting insulin), combined with bolus shots (short-acting insulin given at mealtimes); basal/bolus insulin-replacement therapy is typically administered through a series of multiple daily injections (MDIs) to mimic pancreatic action. Being the most clinically feasible and affordable option for most, patients usually combine one of these with a continuous glucose monitor (CGM) allowing levels of insulin to be constantly checked: this is the wearable element of the treatment, which attaches generally to the back of the arm. With a CGM, or a flash glucose monitor, the amount of sugar in the fluid surrounding the cells, interstitial fluid, is measured. For those with severe hypoglycemia (low blood sugar due to too much insulin) or the ‘dawn phenomenon’, in which patients experience early morning episodes of hyperglycemia, continuous subcutaneous insulin infusion (CSII) may offer more benefits as an alternative[4]. This utilises a portable, battery-operated pump to continuously deliver insulin via injection or infusion, improving patient quality of life due to its convenience. The ‘artificial

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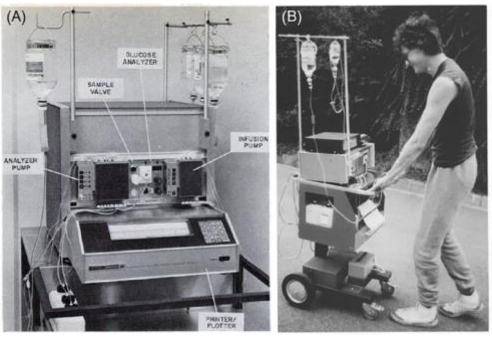
[3]Huang, M., Chen, W., Wei, M., Huang, Y.-S., Liu, H., Yue, M., Chen, Y., Tang, Z. and Jia, B. (2023). Advanced Delivery Strategies for Immunotherapy in Type I Diabetes Mellitus. *BioDrugs*, 37(3), pp.331–352. doi:https://doi.org/10.1007/s40259-023-00594-6. [Accessed: 21/06/24, 16:02]

[4]Janež, A., Guja, C., Mitrakou, A., Lalic, N., Tankova, T., Czupryniak, L., Tabák, A.G., Prazny, M., Martinka, E. and Smircic-Duvnjak, L. (2020). Insulin Therapy in Adults with Type 1 Diabetes Mellitus: a Narrative Review. *Diabetes Therapy*, [online] 11(2), pp.387–409. doi:https://doi.org/10.1007/s13300-019-00743-7. [Accessed: 27/02/24, 08:05]

pancreas', however, is a fairly new technology, to which only 835 people gained access on a recent rollout from NHS England[5].

Closed-loop systems through history

The first closed-loop system was created by Arnold Kadish in the early 1960s, involving an analyser with 2 syringe pumps that were shut and opened according to glucose levels. In the 1970s, Pfeiffer et al. developed the apparatus shown in **Figure 1**.



This was commercialised in 1977, and named the Biostator; the impractical yet intricate system consisted of a pump, glucose analyser, computer to calculate amounts needing to be infused, and a printer for recording. This was a system that used venous glucose sensing and intravenous insulin delivery, and remained the staple in this area of technology until the first wearable system was developed by Motaoki Shichiri in the early 1980s[6]. This involved a CGM, paired with intravenous pumps, and is most similar to the hybrid system used commonly today.

Benefits of closed loops

Figure 2, taken from What a Difference a Day Makes by Mo Wootten, details the transformative effect on patient quality of life of closed-loop therapy. This is just one example of the staggering benefits of this form of wearable medical technology.

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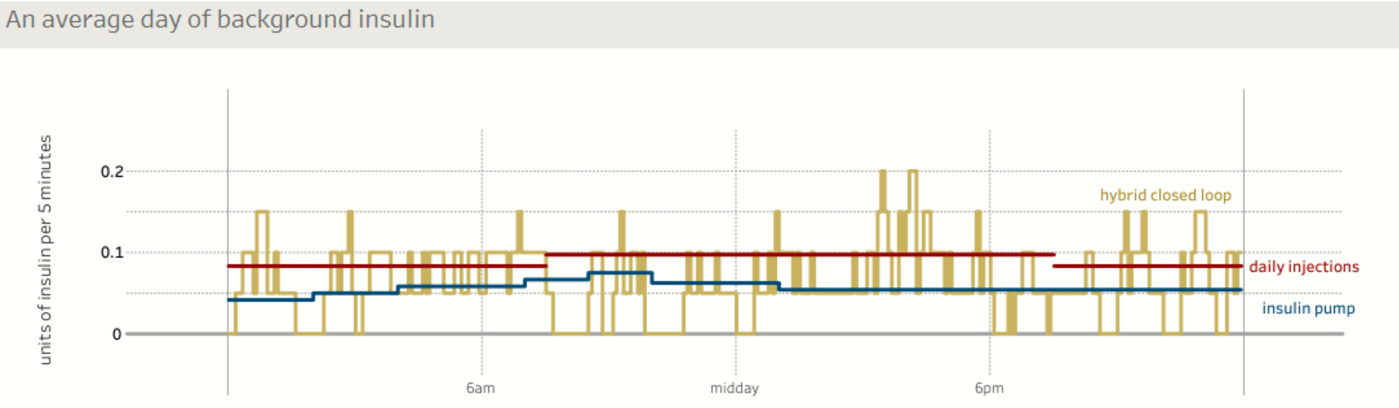
[5] www.england.nhs.uk. (n.d.). *NHS England» NHS rolls out artificial pancreas in world first move*. [online] Available at: https://www.england.nhs.uk/2024/04/nhs-rolls-out-artificial-pancreas-in-world-first-move/#:~:text=The%20mass%20rollout%20of%20the. [Accessed: 13/03/24, 14:15].

[6] Templer, S. (2022). Closed-Loop Insulin Delivery Systems: Past, Present, and Future Directions. *Frontiers in Endocrinology*, 13. doi:https://doi.org/10.3389/fendo.2022.919942. [Accessed 11/03/24, 09:42]



This is how much background insulin I used on an average day from a recent weekend.

Background insulin is what I need to keep my blood glucose in range outside of mealtimes or when I am asleep.

Over the 20+ years I have been diabetic, new technologies have increased my ability to customise my background insulin to match my lifestyle. This improves the quality of my life as well as the control of my blood sugar.

Whilst more conventional treatment options not including such advanced features of wearable technology show varying flatlines, the hybrid closed-loop system is able to fluctuate much more frequently in adjustment to blood glucose levels, allowing a more precise range of insulin dosage.

The lifestyle improvements suggested by this are more numerous than they first appear. In the long term, the patient's newfound autonomy significantly reduces the mental burden of care for the chronic condition: without it, patients and families must "review complex data and make multiple calculations to optimise insulin dosing"[7]. In turn, this catalyses economic benefits, as people feel comfortable to return to work; this includes parents of young patients who may have unpleasant experiences with constant injections and irregular metabolism. There are also both short and long term physical health benefits to the individual, as more strict control over type 1 prevents acute complications and the development of other autoimmune or chronic conditions (for example, microvascular and macrovascular complications, thyroid disease, and coeliac disease)[8].

After interviewing Dr Babeeta Staples, a general practitioner with a specialist interest in diabetes, I was able to gain local professional expertise to support my research. "The idea is

[7]England, N. (2024). *NHS England» Hybrid closed loop technologies: 5-year implementation strategy*. [online] www.england.nhs.uk. Available at: https://www.england.nhs.uk/long-read/hybrid-closed-loop-technologies-5-year-implementation-strategy/.

[8]https://www.facebook.com/NationalInstituteforHealthandCareExcellence (2024). *CKS is only available in the UK | NICE*. [online] NICE. Available at: https://cks.nice.org.uk/topics/diabetes-type-1/https://cks.nice.org.uk/topics/diabetes-type-1/ [Accessed 20 Aug. 2024].

that everyone with type 1 will eventually be converted to closed loops," Dr Staples states, "The idea of one system communicating rather than the patient having to do calculations creates so much more freedom". Dr Staples also commented on the specific benefits for people engaging in a highly active lifestyle: "it solves the pitfall of exercise. We find it such a difficult area to standardise, as no one person reacts the same so you cannot give the same suggestions". The closed loops can adapt accurately to blood glucose fluctuations in this situation. The Dexcom technology currently used is increasingly on the horizon, particularly in newly diagnosed children, and Dr Staples believes they will see a lot more of it in coming years. When asked about the potential disadvantages of wearable technology, particularly closed loops, Dr Staples interestingly mentioned that "people may become reliant on the system, which could potentially be a problem if they do not necessarily learn how to adjust their glucose without it. It's always ideal to have patients who know how to adjust doses in case something fails". A potential way to combat this challenge may be through educating patients with compulsory classes or appointments, to ensure the high level of knowledge used to maintain type 1 today can be continued.

It is also necessary to consider the specific populations who would benefit particularly from these treatments. Unique physiological and behavioural characteristics which may influence glycemic health can be seen in pregnant patients, very young children and critical care patients, for example. A study of hybrid closed-loop usage during pregnancy (Stewart et al.) found reduced hypoglycemia compared to typical pump therapy, and more time spent in the tighter glycemic range standard for pregnant women without a significant difference in overall insulin dosage. Therefore, this treatment is better for maintaining the strict margins necessary for pregnant women, reducing the likelihood of disease transferring to their newborn[9]: it is important to take these examples into consideration when discussing methods to reduce the burden of diabetes care. These psychosocial implications will hopefully be better assessed in a more consistent and diverse manner in the future.

Therefore, the consensus suggested by the National Institute of Care Excellence is that CSII should be offered where multiple daily injections prove ineffective. For these reasons, and its success in practice, it is fair to conclude that closed-loop treatment is perhaps the most effective and widespread wearable technology for T1DM to date.

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[9] England, N. (2024). *NHS England» Hybrid closed loop technologies: 5-year implementation strategy*. [online] www.england.nhs.uk. Available at: https://www.england.nhs.uk/long-read/hybrid-closed-loop-technologies-5-year-implementation-strategy/.

Other accessible technology

There are some forms of wearable technology which offer benefits more accessible to more people with type 1 diabetes. The Do-It-Yourself System, or the Open Artificial Pancreas System, began to gain traction in 2013, when collaborators online expressed their frustration at the slow development of these systems, and devised software to connect insulin pumps and CGMs to an algorithm that analyses glucose data and remotely adjusts insulin delivery[10]. The '#WeAreNotWaiting' movement has certainly proved useful for a number of patients: one user, who uses the free, open-source internet service AndroidAPS, as well as a CGM and a compatible Bluetooth-enabled pump, stated that the system has been 'a technological transformation in both measurable outcomes and quality of life. [He's] not cured, but this is the next best thing for now'[11]. There is huge value to the cost-effective and customisable nature of these systems: although a compatible pump is needed, and there may be technologically complex elements, the abundant community of online users and supporters means it is definitely possible to succeed using this system. The mere idea of the Do-It-Yourself system encapsulates the cutting edge of patient-led healthcare, in a world where there are many barriers in the medical device industry, both in development and distribution. However, with only approximately 2000 users worldwide and few clinical trials, comparison of reliable and relevant data is limited, and it is important to mention that this method is not medically regulated or approved, potentially limiting its effectiveness.

Similarly, Apple Watches are now able to be equipped with a diabetes app connected to a body sensor worn on the abdomen. The sensor checks blood glucose levels every five minutes, and sends the data to the watch, or any remote device[12]. Although this can be 'worn', perhaps increasing convenience, it should be acknowledged that this is technologically the same as a phone app, remaining a lower-cost yet convenient device.

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[10] Templer, S. (2022). Closed-Loop Insulin Delivery Systems: Past, Present, and Future Directions. *Frontiers in Endocrinology*, 13. doi:https://doi.org/10.3389/fendo.2022.919942. [Accessed 11/03/24, 10:00]

[11] Marshall, D.C., Holloway, M., Korer, M., Woodman, J., Brackenridge, A. and Hussain, S. (2019). Do-It-Yourself Artificial Pancreas Systems in Type 1 Diabetes: Perspectives of Two Adult Users, a Caregiver and Three Physicians. *Diabetes Therapy*, 10(5), pp.1553–1564. doi:https://doi.org/10.1007/s13300-019-00679-y. [Accessed 11/03/24, 14:14]

[12] Diabeteswellness.net. (2024). *Apple Watch Has Diabetes App | drwf*. [online] Available at: https://www.diabeteswellness.net/news/apple-watch-has-diabetes-app#:~:text=The%20body%20sensor%20measures%20your [Accessed 20 Aug. 2024].

Future avenues

Naturally, progress has turned to the development of a wearable, fully closed-loop system with automatically administered injections and no need to input bolus injections. Although this has not yet become a reality, its development is thought to be promising, considering the huge success of the existing hybrid systems; in fact, a commercially available model, the STG-55 (Nikkiso, Tokyo, Japan) has recently been developed as a bedside device, usable for a maximum setting of three days around the time of surgery. According to a study conducted by Diabetes Technology & Therapeutics, the use of the insulin delivery system can be summarised as having 'significant quality-of-life benefits and provided a welcome break from the day-to-day demands of living with diabetes.'[13] However, there are certainly future challenges to evaluate with regard to closed-loop technology and their capability to adapt to complex scenarios. The main challenge surrounding this prospect lies in tackling postprandial (post-mealtime) hyperglycemia, as manual input is needed to calculate the timing and carbohydrate content of meals; due to the delayed action of current insulins, these can often also be followed by hypoglycemia due to overdosing on insulin. Current research investigates using algorithms to identify unannounced meals and estimate carbohydrate intake based on required insulin boluses or rate of change of glucose. Another limitation regarding these seemingly optimal closed-loop systems is that they, along with many other treatment types, do not consider additional pancreatic defects, rendering them unsuitable as a sole treatment in the long term for many patients. Autoimmune β-cell death also affects amylin and can cause dysfunction of glucagon secretion.[14] Amylin, in normal physiology, is secreted with insulin to assist with satisfaction and slow gastric emptying after meals; although injections can prevent the hyperglycaemia which may occur due to a deficiency of this, the potential of hypoglycemia due to a lack of glucagon to counteract the insulin remains an issue to be solved, as dual glucagon-insulin secretion is not yet widely used, after falling out of practice in the mid-2000s[15]. Fortunately, this is negligible in a

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[13] Rama Lakshman, Hartnell, S., Ware, J., Allen, J.M., Wilinska, M.E., Munachiso Nwokolo, Evans, M.L., Hovorka, R. and Boughton, C.K. (2024). Lived Experience of Fully Closed-Loop Insulin Delivery in Adults with Type 1 Diabetes. *Diabetes technology & therapeutics*. doi:https://doi.org/10.1089/dia.2023.0394. [Accessed: 11/03/24, 10:51]

[14] McCrimmon, R.J. and Sherwin, R.S. (2010). Hypoglycemia in Type 1 Diabetes. *Diabetes*, [online] 59(10), pp.2333–2339. doi:https://doi.org/10.2337/db10-0103. [Accessed: 14/02/24, 19:20]

[15] Bakhtiani, P.A., Zhao, L.M., Youssef, J.E., Castle, J.R. and Ward, W.K. (2013). A Review of Artificial Pancreas Technologies with an Emphasis on Bi-hormonal Therapy. *Diabetes, obesity & metabolism*, [online] 15(12), p.10.1111/dom.12107. doi:https://doi.org/10.1111/dom.12107. [Accessed 02/04/23, 09:22]

broader scheme, due to the advantage of frequent insulin adjustment which comes with closed-loop systems.

Conclusion

Wearable technologies for type 1 diabetes have undoubtedly revolutionised treatment, allowing a multitude of lifestyle benefits on many levels, arguably even more so than most other chronic conditions. The autonomy given to patients through wearable devices allows a chain of improvements: from families being able to return to work, benefitting society and the economy, to healthcare systems improving from the reduction of chronic disease, as a result of stricter control over type 1 and thus less complications. The field, not only for type 1 diabetes, but wearable technology as a whole, is vast, complex and opportune, and the minor disadvantages of this technology in the current scheme of healthcare, such as some patients becoming reliant on it, can certainly be combated. It is crucial that we continue to facilitate pioneering research in this area to improve the lives of patients, families and children, and sustain the rapid developments seen in recent years.

Images and diagrams citations:

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FIGURE 2: Wootten, Mo. Tableau.com. (2024). Available at: https://public.tableau.com/app/profile/mo.wootten/viz/WhataDifferenceaDayMakes/WhataDifferenceaDayMakes. [Accessed 20/02/24, 13:17]

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