Criteria for Personalised Choice of a Continuous Glucose Monitoring System: An Expert Opinion

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ABSTRACT

Despite the growing evidence supporting the outpatient use of continuous glucose monitoring (CGM) for improving glycaemic control and reducing hypoglycaemia, there is a need for a detailed understanding of the specific features of CGM devices that best meet individual patient needs. This expert opinion, based on a comprehensive literature review and the personal perspectives of clinicians, aims to provide the healthcare professionals (HCPs) with a comprehensive framework for selecting CGM devices. It evaluates the current state of CGM technology, categorizing features into essential features, major drivers of choice, and additional/useful features. Moreover, the practical model presented outlines a patient's journey with CGM, emphasising the importance of aligning device features with patient needs. This includes understanding the patient's lifestyle, clinical conditions, and personal preferences to optimize CGM use and improve diabetes management outcomes.

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Key Summary Points

The use of continuous glucose monitoring (CGM) improves glycaemic control and reduces hypoglycaemia in people with diabetes (PwD). Device features impact PwD experience and may subsequently influence the achievement of metabolic benefits.

The high number of available CGM systems poses a challenge in deciding the best device for the individual patient, based on clinical needs, lifestyle habits and personal preferences.

The proposed approach, which categorizes CGM features into essential features, major drivers of choice, and additional features, may support clinical practice by achieving a balance between PwD and healthcare providers' aims.

INTRODUCTION

Diabetes mellitus is a growing global health concern, with about 537 million adults living with the condition around the world [1]. This trend is projected to increase to 643 million by 2030 and 783 million by 2045, predominantly driven by type 2 diabetes, which accounts for 90–95% of all diabetes cases [1]. Regular self-monitoring of glucose levels is critical for effective diabetes management and for the prevention of long-term complications [2].

In the last two decades, the field of glucose monitoring has evolved significantly, with continuous glucose monitoring (CGM) systems, comprising a disposable sensing device that measures interstitial glucose levels, a transmitter that wirelessly sends the data, and a receiver or a smartphone application that displays the glucose readings, now being recognised as superior to self-monitoring of capillary blood glucose (SMBG) for managing diabetes in a majority of people with diabetes (PwD) [2, 3]. Indeed, CGM systems provide the PwD with more comprehensive information than traditional BG meters, in this way facilitating timely adjustments in insulin therapy, diet, and physical activity [4].

Use of CGM systems has been associated with decreased HbA1c levels, optimized time in target glucose range, minimized hypoglycaemic episodes, and improved quality of life [5–11]. Moreover, when included as part of diabetes self-management education and support (DSMES) interventions, "CGM coaching" may result in improved adherence to dietary plans, healthy eating, and increased physical activity [12]. Accordingly, international guidelines recommend that insulin-treated adults and youths with type 1 and type 2 diabetes are offered CGM as far as they are capable of using the devices safely, and the choice of device is based on individual preferences, requirements, and device functionality [13].

As different CGM systems with specific distinctive features are available on the market (see Table S1 in the supplementary information for details), practical knowledge of essential device properties is required for choosing a CGM system that addresses both the clinical needs and the personal preferences of the individual PwD, in this way enabling tailored treatment plans [14].

This is as an expert opinion aimed at elucidating the features of CGM systems that meet specific patient needs and thus equipping the healthcare professionals (HCPs) with practical criteria for patient-tailored selection of devices. In our vision, CGM features can be classified into three categories (Fig. 1): (i) essential features (i.e. features that are absolutely necessary for all PwD); (ii) major drivers of choice (i.e. features that address more relevant clinical issues and/or meet the needs of specific subgroup of PwD); (iii) additional features (i.e. features that improve patient's experience with the device but are less important for decision-making in the majority of PwD).

The article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.
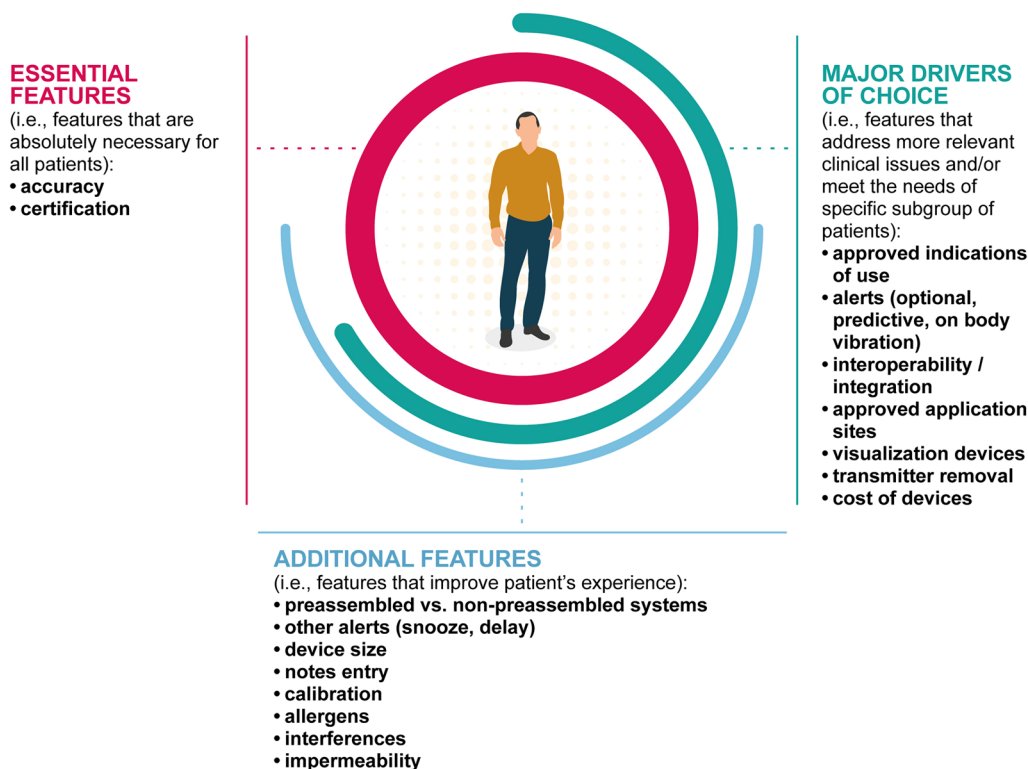
ESSENTIAL FEATURES
(i.e., features that are absolutely necessary for all patients):
• accuracy
• certification

MAJOR DRIVERS OF CHOICE
(i.e., features that address more relevant clinical issues and/or meet the needs of specific subgroup of patients):
• approved indications of use
• alerts (optional, predictive, on body vibration)
• interoperability / integration
• approved application sites
• visualization devices
• transmitter removal
• cost of devices

ADDITIONAL FEATURES
(i.e., features that improve patient's experience):
• preassembled vs. non-preassembled systems
• other alerts (snooze, delay)
• device size
• notes entry
• calibration
• allergens
• interferences
• impermeability

Fig. 1 Classification of CGM features

ESSENTIAL FEATURES

Accuracy

Accuracy refers to the closeness of CGM readings to actual BG levels and is typically assessed via the mean absolute relative difference (MARD). In the absence of universal standards for CGM accuracy, a MARD value of less than 10% is widely acknowledged as a safe threshold for therapeutic decision-making without additional finger stick verification [14]. Provision of reliable glucose data for diabetes self-management is crucial for building trust in technology, and fostering long-term adherence to CGM, with the ultimate aim of replicating trial results in everyday clinical practice [15]. Accordingly, international guidelines consider accuracy as a primary factor when choosing a particular CGM device [16, 17].

While MARD remains a popular and easily interpretable measure of accuracy, it does not capture the full scope of performance of CGM devices. Indeed, various factors, including sensor lifetime, number of paired data points, and the evaluation protocol, may influence MARD assessment. Notably, overall MARD does not account for interindividual variability nor provides information in specific (hyperglycaemic, euglycaemic, and hypoglycaemic) glucose ranges. Accordingly, in the absence of standardized evaluation criteria, any comparison between different devices that is solely based on overall MARD should be interpreted with caution [17].

Moreover, additional metrics should be used for better evaluation of CGM performance, including mean absolute difference (MAD), precision absolute relative difference (PARD), and concordance of measurements within prespecified thresholds in different glucose ranges [17]. Moving form analytical to clinical accuracy, Clarke and Parkes error grid analysis classifies clinical implications of discrepancies between sensor readings and reference BG values into five risk categories from A (no effect on clinical

action) to E (altered clinical action, which could have dangerous consequences) [17]. For clinical accuracy, at least 95% of the measured values should fall within zone A or B of the grid, with none falling in zone E: this indicates that the readings are clinically acceptable for making therapeutic decisions.

Very recently, the US Food and Drug Administration (FDA) introduced very strict requirements to ensure reliable and secure transmission of glucose measurement data to digitally connected devices, including automated insulin delivery (AID) systems. Specifically, FDA standards involve availability of high-quality accuracy studies published in peer-reviewed journals, representation of different populations (e.g. adults and youths, compensated and decompensated subjects, insulin and non-insulin users), in-depth description of study population characteristics, and performance analysis across the full glucose range and the whole duration of the sensor's life cycle [18]. To date, there are only few CGM systems on the market that meet such requirements, and they are referred to as integrated CGM (iCGM) systems. Of note, achieving clearance from FDA as iCGM puts a device into a level 2 (moderate to high) risk category, whereas clearance as non-iCGM puts it into a level 3 (high risk) category [18].

In the real world, the accuracy of CGM systems can be impacted by several factors, either specific to the sensor or related to daily living. Indeed, day of sensor wear, sensor-to-sensor variation, sensor insertion site, loss of skin integrity, scar tissue, or compression artefacts can all affect sensor performance [19]. Of note, several studies have shown an important lack of accuracy on the occasion of rapid changes in glucose levels, commonly seen during exercise, ultimately increasing the risk of hypoglycaemia [20].

Certification

Certification of CGM devices entails rigorous assessment and validation by regulatory bodies. The FDA and Australia's Therapeutic Goods Administration (TGA) use tighter controls than European regulatory bodies, requiring comprehensive product-specific clinical data evaluation. As a result, several CGM devices have Conformité Européenne (CE) marking for wide-ranging indications beyond available data, unlike FDA and TGA approval [21].

MAJOR DRIVERS OF CHOICE

Approved Indications of Use

CGM systems are approved for use in people with type 1 and type 2 diabetes aged 2 years old and above, with brand-specific age approval.

CGM use has been evaluated also in pregnant women with diabetes and has been found to be both safe and efficacious in improving the health of offspring through better management of maternal glucose levels [22–25]. However, only few CGM systems are officially licensed by the regulatory bodies for use in pregnant women.

Adjunctive CGM requires the user verify their glucose levels or trends with a BG meter prior to any treatment decision-making. For a few years, some devices are claimed for non-adjunctive use owing to their improved accuracy. Nevertheless, confirmatory finger-pricking is always required when sensor readings do not match the patient's symptoms or expectations, and in case of assumption of medications that interfere with the sensor readings (e.g. paracetamol, high dose of ascorbic acid) [26].

Complying with the indications contained in the technical data sheet is crucial for safe and successful use of devices in clinical practice. For people with physical, psychological, or occupational barriers to regular use of SMBG, CGM with non-adjunctive use (i.e. not requiring SMBG for confirmation) should be considered as first choice.

Alerts

CGM systems are equipped with a variety of alerts notifying the users of critical changes in glucose levels, with the aim to foster timely intervention and limit severe hypo- and

hyperglycaemia. CGM alerts include high/low alerts, which notify the users when glucose levels cross specified thresholds, predictive alerts, which anticipate changes in glucose levels before they occur, and rate of change alerts, which indicate rapid rise or fall in glucose levels [14].

Optional Alerts

Most of CGM systems have visual, audible and/or vibratory alerts for glucose that cannot be disabled; however few systems allow the users the choice to turn off all the alerts according to their individual needs and preference.

Although glucose alerts are important for mitigating the occurrence and severity of acute events by warning the users of actual and impending hypoglycaemia and hyperglycaemia, they can sometimes become a source of nuisance [27]. Indeed, CGM users may feel overwhelmed and fatigued with too many alerts (in particular, false or useless ones) interrupting their usual activities, and, over time, become less prone to react appropriately to true alerts [28]. Moreover, nocturnal alarm fatigue has been identified as a major cause of disrupted sleep and CGM discontinuation [29]. Also, "alarm embarrassment" has been described when alerts occur in situations of social exposure, e.g. in the middle of an important meeting. Adolescents are particularly concerned about this issue and may refuse a system with alerts that cannot be silenced as a result of worry about the alerts going off in school and causing them to be the focus of attention [30].

CGM systems with optional alerts provide the flexibility to disable alerts temporarily to address alarm fatigue and/or embarrassment and accommodate professional or privacy considerations [30]. Therefore, they can be considered for PwD who find CGM alerts troublesome, and particularly for CGM-naïve PwD who are reluctant to even try CGM because of concerns about how the alerts will affect the quality of their lives. Of note, in the latter scenario expert opinion papers suggest keeping any alerts disabled for an initial period of 1–2 weeks of sensor use, unless the user experiences frequent hypoglycaemia or has hypoglycaemia unawareness; in such cases, setting a low glucose alert may be appropriate from the outset [31]. Such a stepwise approach

may allow the user to become comfortable with other aspects of CGM and avoid a potentially overwhelming multitude of high and low alerts.

Predictive Alerts

While all CGM systems allow high/low alerts to be sent to the reader or connected device, only few have also predictive alerts. Specifically, few have a non-modifiable predictive alert (the so-called urgent low soon [ULS] alert) that warns the users when their glucose readings are predicted to reach 3 mmol/L (55 mg/dL) within 20 min, while other systems have alerts for either hypo- and hyperglycaemia prediction that can be customized both in their threshold and their time of prediction, in this way aligning the device functionality with individual treatment plans and lifestyle preferences. Scientific evidence supports the benefits of predictive alerts. Real-world analyses demonstrate that enabling predictive alerts in CGM systems significantly reduces the occurrence of both high and low glucose excursions in individuals with diabetes either on multiple daily injections (MDI) or continuous subcutaneous insulin infusion (CSII) therapy [32]. Furthermore, research in adolescents with type 1 diabetes underscores the superiority of predictive alerts in reducing time spent in hypoglycaemia and risks associated with glycaemic variability as compared with threshold alerts [33]. More recently, activation of the ULS alert has been linked to significant reductions in exposure to hypoglycaemia below 2.8 mmol/L (50 mg/dL) in the 24 h after exercise compared with a threshold alert [34, 35].

For individuals experiencing problematic hypoglycaemia, i.e. characterised by frequent or severe episodes, nocturnal occurrences, or a lack of awareness of hypoglycaemic states, CGM systems with predictive alerts are crucial, as they can pre-emptively notify the users, allowing them to take appropriate action to prevent a hypoglycaemic event and any subsequent hyperglycaemic rebound. Moreover, predictive alerts may be considered for PwD regularly engaged in physical activity who need an enhanced layer of protection against hypoglycaemia. By contrast, for those with a lower risk of hypoglycaemia, such as individuals with newly diagnosed type 2

diabetes or those on less intensive therapies, CGM with threshold alerts may be adequate.

On-Body Vibrations

A unique feature offered by a specific CGM system with fully implantable sensor is the provision of vibration alerts directly on the body through a "smart" transmitter. These tactile notifications are activated when specific glucose thresholds are reached or anticipated, providing a subtle yet effective alerting mechanism that is beneficial in situations where audible alerts may go unnoticed or are undesirable, or when the users do not have visual access to their device's display [14].

Therefore, these alerts may be fitting for PwD who are not able to check their device frequently, such as during sleep, while driving, or in loud environments.

Interoperability and Integration with Other Devices

Some CGM systems are designed to work in connection with specific insulin pumps and connected insulin pens to provide additional functionalities and data analysis [36]. Of note, the FDA has coined the definition of iCGM to indicate CGM systems that "are designed to reliably and securely transmit glucose measurement data to digitally connected devices" for the purpose of glycaemic management [18]. On the other hand, device interoperability has been defined as "the ability of medical devices to communicate with each other, and/or work together as intended" and includes the concept of interchangeability of components in a system [37].

Connected pens can record and wirelessly transmit information on dose and time of insulin injections, with the most advanced systems also providing reminders, bolus calculation, and active insulin estimation [36]. It has been demonstrated that use of connected pens is associated with fewer missed bolus injections, increased time in range (TIR), decreased hypoglycaemia, increased satisfaction, and economic benefits [38–41]. Moreover, availability of integrated CGM and insulin data may help identify abnormal glucose events and/or recurrent glucose patterns and guide appropriate therapy changes, in this way overcoming therapeutic inertia [36]. A recent consensus of experts has identified the patient profiles that are supposed to benefit the most from using connected pens, including PwD who omit or delay mealtime insulin doses, those with inadequate glucose control, and individuals relying on caregivers for insulin administration [36].

Integration of CSII and CGM technology has allowed for development of sophisticated systems providing AID, including automated suspension of basal insulin delivery in response to a detected low glucose level (low glucose suspend, LGS) or a predicted low glucose level (predictive low glucose suspend, PLGS) and closed-loop regulation of insulin delivery to manage both high and low glucose levels [42].

Several randomised clinical trials and meta-analyses have shown the benefits of AID over non-integrated systems on HbA1c levels, TIR, and glycaemic variability, with similar or even improved psychosocial outcomes [43].

From a clinical practice standpoint, careful consideration of interoperability of CGM devices should be integral to the routine decision-making process, as it allows a stepwise approach to technology implementation in diabetes care (i.e. switching from a connected pen to an insulin pump communicating with the same CGM system).

PwD who are candidates for use of connected pens should be preferably oriented towards CGM devices that can interface with these pens [36]. On the other hand, for PwD who are already using an insulin pump and are happy with it, but also for individuals on MDI who are considering closed-loop therapy in the near future, choosing CGM devices that communicate with pumps is important for enabling AID [44].

However, possible barriers to the implementation of connected pens in a real-life context have been identified, including patient preference and motivation, insurance coverage, insulin compatibility, need for an advanced diabetes education, poor digital competence, owning a non-compatible smartphone, lack of training on digital tools for HCPs, obtaining and using data report [36, 45]. Also, PwD may not be interested

in the integration of the CGM system with an insulin pump because of cost, alarm annoyance, perceptions of accuracy, body image issues, and perceived hassle [44].

In this scenario, the HCPs have the responsibility to keep themselves updated on the latest advancements, explain the expected benefits of integrated technologies, address any concern that PwD may have, and offer support for enhancing their technological skills. Ultimately, if a person is still not interested in integrated systems, a CGM device that is intended only for standalone use could be offered.

Approved Application Sites

Approved application sites for CGM systems may vary for adult and paediatric PwD to accommodate anatomical considerations. Indeed, in adult subjects the approved sites typically include the abdomen or the back of the upper arm, while for the paediatric population between 2 and 17 years of age the upper buttocks are also an approved site, acknowledging the differences in body composition and activity levels in younger individuals [14]. Importantly, the number of approved sites may vary with the different brands, ranging between one and more than one.

Having two or three alternative sites that are approved for sensor placement is essential for individuals who experience sensor accuracy issues, have localised lipodystrophy, or prefer a more concealed sensor placement for personal comfort or aesthetic reasons.

Available Visualization Devices

All the latest-generation systems allow real-time data visualization through a smartphone application; however, few also offer a dedicated hand-held receiver (for certain systems referred to as the reader).

While the availability of a dedicated receiver meets the needs of those who do not have a compatible smartphone or choose not to rely on the smartphone as part of their diabetes management strategy, use of apps enables real-time remote monitoring from caregivers or HCPs [43].

Real-time sharing and following of CGM data in children and elderly or frail adults have allowed for better sleep and fewer episodes of severe hypoglycaemia, providing peace of mind and a sense of security for both PwD and their caregivers [43, 46, 47]. The advantages of real-time remote monitoring have been demonstrated also in other settings like hospitals, where PwD are often bedridden, and healthcare staff need to monitor multiple individuals simultaneously [48, 49]. Of note, a clinical trial evaluating the use of CGM combined with a glucose telemetry system, which wirelessly transmits CGM data to a centralised monitor, has recently demonstrated the potential to reduce hypoglycaemic events significantly in a non-critical care hospital setting [48]. This approach facilitates the management of glucose levels without placing additional burdens on bedside nurses, and PwD have well tolerated the use of these devices without significant complaints of discomfort or sleep interruption [50].

Moreover, use of apps can enable auditory access to key information including current glucose, trend arrows, and glucose alerts through text-to-speech solutions, in this way supporting diabetes management in visually impaired patients with diabetes. Of note, in a small cohort of legally blind patients with diabetes from the U.S., voice-activation resulted in improved TIR and HbA1c without increased hypoglycaemia [51].

For individuals who are not inclined toward the latest technology or who do not possess a latest-generation smartphone, a CGM system with a dedicated receiver is often preferred. Moreover, the option of a dedicated receiver can simplify the user experience for those who prefer to keep use of their medical and personal device separate. On the other hand, availability of the Share feature in CGM systems is especially valuable for parents of children with diabetes and caregivers of frail/older adults.

Removable Transmitter

The transmitter is a component that wirelessly communicates glucose data from the sensor to

a separate reader or smartphone. There are various designs of transmitters across different CGM systems; however, one single system allows the transmitter to be removed as needed without sacrificing the sensor [52].

This removability is pivotal for individuals who need to temporarily remove external medical devices for professional or privacy reasons, are engaged in contact sports, or require frequent skin care to minimize the risk of allergic or hypersensitivity reactions to the adhesives used in CGM devices [52].

The removability of the transmitter also allows for safe completion of MRI imaging procedures, assuming specific conditions are met to ensure the patient's safety and the integrity of the sensor.

Cost of Devices

While there is growing evidence that CGM may be cost-effective both in people with type 1 and type 2 diabetes, including those on basal insulin therapy, cost of devices is still a major barrier to widespread use of this technology [44, 53–57]. The cost of a CGM system can vary significantly depending on brand, features, and insurance coverage. Moreover, while health insurance plans generally cover the costs of CGM devices, each plan may have different benefits and requirements, so that pricing ultimately acts as a relevant driver of choice for many PwD. In the Italian scenario, the National Health System permits the reimbursement of devices in people with either type 1 and type 2 diabetes; however, eligibility criteria and budget vary from one region to the other, and competitive bidding processes may restrict access to specific products [58].

Anyway, amongst people with low socio-economic means, lower access to CGM has been reported irrespective of reimbursement issues [59]. Therefore, prescription and education pathways should be aimed at avoiding potential discriminations.

ADDITIONAL FEATURES

Preassembled Versus Non-preassembled Systems

Preassembled systems combine the sensor and the transmitter into a single device and are designed for quick, easy application even by relatively unskilled users.

Accordingly, preassembled systems can improve patient experience and overall treatment satisfaction, especially in those individuals who feel uncomfortable with complicated insertion/removal procedures, or have manual dexterity limitations.

On the other hand, CGM with reusable/rechargeable transmitters can reduce plastic and electronic waste generation as compared with single-use devices, with clear implications for environmental sustainability [60].

Other Alerts

Certain CGM systems offer the option to delay the first high alert until the sensor reading is high for a predefined period of time ("delay 1st alert" feature), and to be re-notified of a high or low that is not changing within a predefined period of time ("snooze" feature).

The "delay 1st alert" feature allows one to minimize the number of alerts and focusing on events that require therapeutic intervention and therefore they can be useful in those PwD feeling overwhelmed or fatigued by too many unnecessary interruptions, while the "snooze" feature is crucial for avoiding prolonged exposure to either hypoglycaemia or hyperglycaemia.

Device Size

Size and weight vary substantially between brands, ranging from 19 to 46 mm and from 1 to 12 g, respectively.

Sometimes the size of the devices needs to be taken into account to increase the likelihood of acceptance and their regular use. Particularly

for PwD who risk thicker devices getting stuck in clothes or machinery, or those who expose parts of their bodies as part of their job or in social context, a smaller sensor could be a significant deciding factor.

A small sensor size may help overcome barriers especially in individuals who are resistant to accepting their chronic condition or embracing technological devices for diabetes management for privacy reasons.

Notes Entry

Some CGM systems allow written and/or dictated notes about meals, carbohydrate intake, physical activity, capillary BG, and insulin doses to be entered into the proprietary app or receiver.

From the patient's perspective, the ability to insert notes in real time into their CGM system may reduce the burden of disease management as it simplifies the writing of the diabetes diary and enables easier review for both the patient and the clinician, particularly in a remote setting. Indeed, this detailed input aids healthcare providers in interpreting sensor data more accurately, and facilitates more effective therapeutic modifications [43].

Calibration

Calibration involves entering BG measurements obtained through traditional finger stick tests into a CGM system to align sensor readings with actual glucose levels, and ultimately improve the overall accuracy of the device. However, requiring too many capillary glucose measurements for calibration may lead to reduced adherence in some PwD, especially those who are averse to finger-pricking with lancets. Moreover, poor quality of BG tests can cause inaccuracies with the sensor readings and therefore performing "clean" calibrations (i.e. washing hands before testing or taking the second drop of blood when handwashing is unfeasible, and calibrating when glucose values are likely stable, such as before a meal, insulin administration, or exercise, ideally within the target range) is critical albeit burdensome [61].

Manufacturers have responded to these challenges by introducing calibration-free or reduced-calibration CGM systems, which have been well received by PwD owing to their convenience and integration into daily life, thus increasing device satisfaction [62]. Accordingly, for people with physical, psychological, or occupational barriers to regular use of SMBG, the choice should be oriented towards a factory-calibrated CGM.

While most CGM systems that are now available do not require mandatory calibration with capillary BG, some of them still allow calibration at will (optional calibration) to enhance sensor accuracy. Optional calibration is particularly relevant for PwD on injectable insulin therapy encountering inaccuracies in sensor readings that can be rectified with additional calibration entries, thereby increasing trust in the device and allowing for a more accurate interpretation of data by the physician [52, 63].

Allergens

Cutaneous reactions caused by allergens present in CGM adhesives occur at a rate of approximately one event every 8 weeks in clinical trials, and are reported in up to 70% of subjects evaluated in observational studies. Importantly, cutaneous complications cause discontinuation of CGM in 40% of children and in 42% of adults, respectively [64]. Irritant contact dermatitis (ICD) is a nonallergic skin reaction caused by repeated exposure to chemical or mechanical agents with subsequent release of inflammatory mediators, and develops rapidly at the sensor application site with symptoms such as a burning or stinging sensation [65]. Allergic contact dermatitis (ACD), on the other hand, is a widespread reaction involving a delayed hypersensitivity reaction (type IV) to allergens in the adhesive, and presenting with profound itch [52, 64, 66]. The most common allergens responsible for ICD and ACD are isobornyl acrylate (IBOA), ethyl cyanoacrylate, colophonium, and *N*,*N*-dimethylacrylamide (DMAA). To prevent and treat these reactions, appropriate skin preparation and the use of liquid or physical barriers may be utilized. For PwD with known allergies

to specific components, choosing a sensor without that particular allergen is crucial. However, the complete adhesive composition may not be disclosed in the product information leaflet and therefore reactions are sometimes revealed only through actual use [64, 67].

Interfering Substances

One potential drawback of CGM systems is that specific drugs and supplements may falsely elevate sensor glucose readings [68]. For instance, some CGM systems have been reported to show interference with hydroxyurea, a medication used primarily in chemotherapy and sickle cell treatment [63]. Acetaminophen can affect the accuracy of multiple systems; however, for few of them, interference only occurs above the maximum dose of 1000 mg every 6 h (4000 mg/day). Ascorbic acid at high doses (i.e. >500 or >1000 mg/day) is also known to interfere with the different models of a specific brand [63]. Moreover, users of the implantable CGM need to be aware of potential interferences with mannitol and sorbitol delivered intravenously or as peritoneal dialysis solution, and with tetracycline antibiotics [63, 68].

Awareness and education about these interferents are part of good clinical practice, and can influence device choice on the basis of patient medication history. It is recommended that HCPs review the drugs and supplements their patients are using to identify possible interfering substances. When potential interferences are identified, PwD should be advised on the necessity of using additional BG meter measurements to confirm sensor values, particularly when they are suspected to be unreliable because of these substances, or switching to a different CGM [68].

Impermeability

CGM devices differ in the ability to withstand use in the water, as expressed by different ingress protection (IP) ratings. The IP rating consists of two digits that indicate how much a device is protected against solid particles (such as dust) and liquids, respectively. When there are no protection values for one of these criteria, the digit is replaced by the letter X. For glucose sensors, IPX7, which means immersion for 30 min at a depth of up to 1 m, is the most common rating, albeit some devices are protected against prolonged immersion at a greater depth (IPX8). Different degrees of water resistance can meet the needs of different groups of users; however, the IPX7 rating is supposed to be enough for outdoor sporting requirements [14].

CLINICAL SCENARIOS

In a real-life setting, PwD bring with them instances that are not solely related to glycaemic control. CGM is nowadays a cornerstone of diabetes management, and device choice may significantly impact usability, trust in technology, and the burden of self-management. To better clarify our vision, Figure 2 provides some practical examples showing how to match device features and patient needs (lifestyle habits, comorbidities, and/or personal preferences) in clinical practice.

However, successful implementation of CGM in the real world also requires that the HCPs put in place education and support measures for PwD to enhance their management skills and set their expectations in line with long-term use of technology [69]. Of note, CGM-specific education has the potential to increase utilization of and response to low-glucose and rate of change alerts, which may help enable more preventive elements in daily glucose management [70]. Strategies for successful implementation of CGM typically involve the maintenance of a high level of contact with the users during the first few months of wear, including setting realistic expectations, start-up training, and follow-up visits after CGM initiation to download data, review alarm settings, encourage ongoing CGM use, and address potential drawbacks [71].
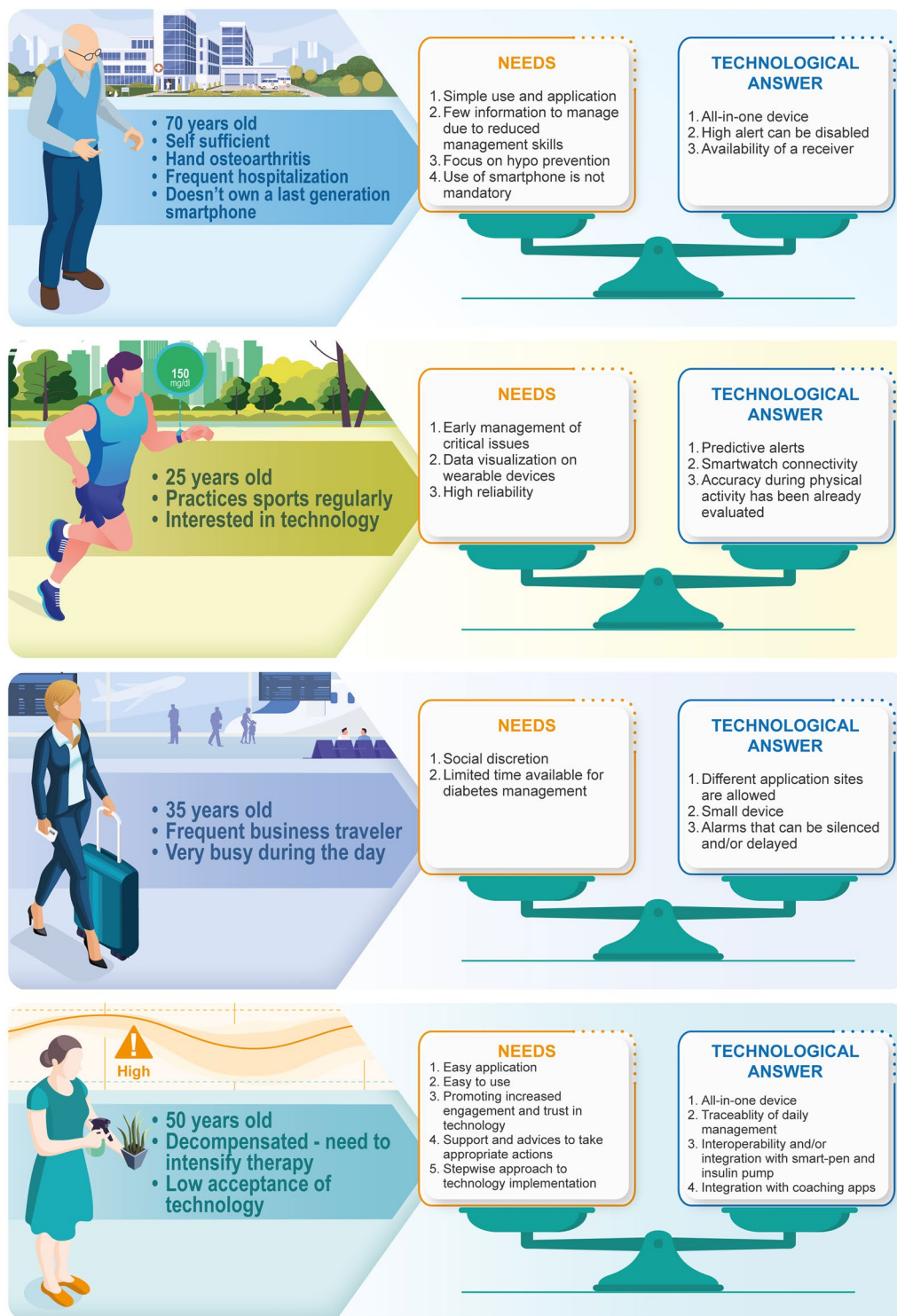
Fig. 2 Practical examples of matching device features with patient needs across various clinical scenarios

CONCLUSION

While there is growing evidence supporting the use of CGM for improving glycaemic control and reducing hypoglycaemia in people with diabetes, device choice is often challenging, and may impact PwD experience. Moving from analysis of several technical features, and showing how they can align with the needs of different subjects, in this expert paper we provide practical guidance for choosing the best CGM device in the individual patient. In the era of patient-centred care, we believe that such an approach may contribute to enabling more tailored treatment plans in people with diabetes.

Declarations

Conflict of Interest. Sergio di Molfetta has received consulting fees from Roche Diabetes Care, Ascensia Diabetes Care, and Eli Lilly and received payment or honoraria for lectures, presentations, spekers bureaus, manuscript writing or education events from Movi S.p.A and Ascensia Diabetes Care. Antonio Rossi, in the last two years, has received speaking and/or consulting fees from AstraZeneza, Roche Diabetes Care, Menarini Diagnostics, Alpha Pharma, Abbott, Sanofi, and Theras. Federico Boscari has received consulting fees from Roche, and Glooko and received honoraria for lectures and presentations from Roche, Novo Nordisk, Sanofi Aventis, and Movi. Concetta Irace has provided advisory board services for Novo Nordisk, Lilly, Roche Diabetes Care Italy, Abbott, Menarini, Ascensia, and Senseonics and has received speaker fees from Novo Nordisk, Roche Diabetes Care Italy, Abbott, Ascensia, Lilly, and Boehringer Ingelheim Pharmaceuticals. Luigi Laviola has received consulting fees from Abbott, Boehringer Ingelheim, AstraZeneca, Eli Lilly Italia, GSK, Medtronic, Menarini, MOVI, Novo Nordisk, Roche Diabetes Care, Sanofi and honoraria for lectures and presentations from Abbott, Boehringer Ingelheim, AstraZeneca, Eli Lilly Italia, Medtronic, Menarini, MOVI, Mundipharma, Novo Nordisk, Roche Diabetes Care, Sanofi. Daniela Bruttomesso has received consulting fees from Menarini, Novo Nordisk, Roche, and Terumo and received honoraria for lectures and presentations from Abbott, Eli Lilly, Novo Nordisk, Roche, Sanofi Aventis, and Theras.

Ethical Approval. This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

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