# Pediatric Type 1 Diabetes Management Technologies

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Abstract

Continuous subcutaneous insulin infusion (CSII) and continuous glucose monitors (CGM) simplify management of type 1 diabetes among pediatric patients. This disease shortens lifespans by an average of 23 years and has long-term implications for health and quality of life. This paper evaluates the effectiveness of combined technology use in children, and addresses barriers, stakeholders, financial considerations, and future innovations resulting from CGM and CSII. Combined, CGM and CSII provide superior glycemic control while simultaneously providing long-term cost-effectiveness. Recommendations for multidisciplinary care are made, which improve adherence and better patient outcomes. Medical training with these devices is necessary for all provider types. Ongoing patient education is necessary to promote use, prevent complications, improve device performance, and minimize complications. Policymakers and insurers are encouraged to promote adoption of this technology via research utilizing the newest available devices. Future innovations of a bionic pancreas are hinged upon these technologies and their continued utilization and improvement.

*Keywords*: pediatrics, type 1 diabetes, glucose monitoring, continuous insulin, technology

# Pediatric Type 1 Diabetes Management Technologies

Pediatric continuous subcutaneous insulin infusion (CSII) and continuous glucose monitors (CGM) simplify type 1 diabetes management for pediatric populations. This combined technology is described as closed-loop and improves healthcare by simplifying a chronic illness that is difficult to manage even for health literate families (Heinemann et al., 2015). Over 50% of pediatric patients fail to meet glycated hemoglobin (HbA1c) goals with recommended therapies alone (Scaramuzza & Zuccotti, 2015). Target HbA1c for pediatric and adolescent age groups is 7.5%, yet the average value is 9.2% (Forlenza, Buckingham, & Maahs, 2016). Diabetes is a leading cause of limb amputation, blindness, and cardiovascular disease (DiMeglio, Evans-Molina, & Oram, 2018; Ng, 2018). This disease also shortens the lifepsan by an average of 23 years (Ng, 2018). Type 1 diabetes is frequently diagnosed in childhood, although some individuals are diagnosed into their 30's and 40's.

A combined CGM and CSII system can be used by people with type 1 diabetes who require full support to replace deficient pancreatic insulin due to the autoimmune destruction of the pancreatic head that occurs in type 1 diabetes. There is a great burden for monitoring, nutrition management, exercise planning, insulin administration, and endocrine specialist appointments after initial diagnosis (DiMeglio et al., 2018). Initial diagnosis often occurs during a ketoacidosis event that results in the child being hospitalized. When elevations in blood glucose are noted that lead to diagnosis, providers must differentiate between type 1 and type 2 diabetes. Diabetes type 1 is an autoimmune disorder wherein the body destroys the head of the pancreas, eliminating the ability to produce meaningful amounts of insulin, which requires a different management approach compared with type 2 (DiMeglio et al., 2018). Individuals with type 1 diabetes are considered insulin dependent for life (DiMeglio et al., 2018). Glycemic

control and safety are intertwined in the management of type 1 diabetes to improve long-term survival and maximize health outcomes (Ng, 2018; Scaramuzza & Zuccotti, 2015). Technologies like CSIIs and CGMs improve glucose tracking, recording, and precise medication delivery (Scaramuzza & Zuccotti, 2015).

## Description

Pediatric continuous subcutaneous insulin infusion (CSII) and continuous glucose monitors (CGM) are available as a combined wearable technology. Continuous glucose monitors have been in use since 1989 (Scaramuzza & Zuccotti, 2015), while insulin pumps have been available since the 1970's (Forlenza et al., 2016; Heinemann et al., 2015; Martin, Criego, Carlson, & Bergenstal, 2019). These technologies exist independently, but in combined and integrated forms provide the best glycemic control. These devices are worn externally and involve a needle or catheter threaded through the dermis into the subcutaneous tissue via the infusion set (Carchidi, Holland, Minnock, & Boyle, 2011). The sensors on the catheter or needle measure the glucose of the blood at regular intervals which allows for rapid delivery of both steady-state insulin and bolus insulin for spikes and mealtimes, based on individual needs (Carchidi et al., 2011). Fully automatic, these devices adjust insulin upwards in boluses in response to elevated glucose levels and reduce or stop insulin administration to prevent hypoglycemia. There are at least six popular brands which have increased in efficiency with revisions for the prevention of acute episodes of hyper-and-hypoglycemia (Funtanilla, Caliendo, Hilas, & Candidate, 2019). The devices come in two parts: a sensor for glucose measurement, storage, and data transfer, and an electronic pump with an infusion set and insulin cartridges (Scaramuzza & Zuccotti, 2015). These devices are becoming more popular among pediatric populations in need of insulin, although they have been available for pediatric populations for

nearly two decades. The purpose of this paper is to explore the aspects related to this technology that enhance or detract from provider recommendation for and patient use of these devices.

Connectivity, monitoring, and recording of glucose and insulin delivery requires internet, WiFi, Bluetooth capability, or a physical connection. Some devices are self-contained and their digital contents can be uploaded to a provider at a physician visit. This gives the provider a day-by-day overview of trends, highs, and lows in glucose, allowing for adjustments to physiologic needs (Ng, 2018).

## Literature Review

A literature search was conducted via the databases Medline, Cochrane Database of Systematic Reviews, CINAHL, and ERIC for the terms continuous glucose monitor, insulin pump, and pediatrics. Results were limited to those published between 2015 and 2020. The search returned 65 results which were manually reviewed by title and abstract for relevancy to adoption of these technologies. Seven articles were selected for inclusion which are outlined in the table in Appendix A. Themes of recommendations and efficacy were identified.

### Recommendations

Continuous glucose monitoring and CSII are recommended for adolescent or pediatric patients who are already performing frequent testing, have severe hypoglycemia episodes, have failed to reach HbA1c targets, or who have hypoglycemia unawareness, nocturnal hypoglycemia, or large fluctuations in blood glucose (Scaramuzza & Zuccotti, 2015). Heinemann et al. (2015) recommended careful patient selection based on readiness, educational training, and availability of support. Martin, Criego, Carlson, and Bergenstal (2019) recommended against combined use for children with newly diagnosed type 1 diabetes, opting instead to support initial use of CGMs, which are rated class II (high risk) for safety. These findings are supported by Patton, Noser,

Youngkin, Majidi, and Clements (2019) who found greater efficacy with the CGM than with an insulin pump when started within 12 months of type 1 diabetes diagnosis. Patton et al. (2019) did not study the efficacy of a combined system however, recommending that future studies be performed to evaluate this against individual metrics. This contrasts with findings by Scaramuzza and Zuccotti (2015) who found safety and superior benefit with combined use.

Multidisciplinary care may include the use of nutritionists, psychologists, endocrinology, primary care pediatricians, and diabetes educators for support and guidance (Heinemann et al., 2015; Ng, 2018). A team approach continues to be a mainstay of overall care management for these patients (Heinemann et al., 2015; Ng, 2018). Pediatric endocrinologists and diabetes specialists play a central role in recommending these technologies (Marks, Wolfsdorf, Waldman, Stafford, & Garvey, 2019; Ng, 2018). Ng (2018) reported that the inclusion of telemedicine visits had a positive impact on patient wellbeing, in addition to improved HbA1c and reduced hospitalizations. By using multiple layers of support and technology to assist clients, insulin pump use increased from 7% to 34% over five years through a massive improvement project (Ng, 2018). When integrated with smart devices, additional cost-savings are found for the patient who must purchase one less component to complete the system (Martin et al., 2019). According to Forlenza, Buckingham, and Maahs (2016), prior recommendations were that pediatric patients had to earn the right to use technology by achieving a low HbA1c; this is no longer supported by evidence, which states patients who are not meeting HbA1c goals benefit the most from CGM and CSII.

**Efficacy**

According to Scaramuzza and Zuccotti (2015), these devices demonstrate superior efficacy when combined, leading to the lowest HbA1c values. In combination with social media

and a team-based approach to diabetes management, CGM and CSII significantly reduce rates of ketoacidosis, hospitalizations, hospital length of stays, and HbA1c in children (Ng, 2018). In the improvement project by Ng (2018), median HbA1c was reduced from 9.2 to 7.9 through combined CGM and CSII use, and 35% of children achieved a HbA1c of less than 7.5%. Length of hospital stays were reduced from 2.7 days to 1.8 days, and family satisfaction rates were reported to be from 81% to 87% for various aspects of usage (Ng, 2018). In combined form, CGM and CSII were found to be both safe and effective for children with type 1 diabetes (Scaramuzza & Zuccotti, 2015).

When used independently, for children recently diagnosed with type 1 diabetes, CGM use alone slightly decreased HbA1c (Patton, Noser, Youngkin, Majidi, & Clements, 2019). Insulin pump use alone caused a slight increase in HbA1c, but this was significantly lower in comparison with children who did not use an insulin pump but rather performed the usual care of multiple daily injections (MDI) (Patton et al., 2019). When used alone, CSII performed better for adolescents; the only benefit found for the very young was decreased hospitalization rates for those with recurrent admissions related to complications (Forlenza et al., 2016). The use of CSII was found to decrease overall insulin requirements, lower HbA1c, improve health-related quality of life, and decrease the risk for hypoglycemia (Forlenza et al., 2016). The use of CGM also lowered HbA1c and reduced hypoglycemia episodes (Forlenza et al., 2016). Other benefits to CGM use included reduced anxiety and improved overnight glucose control (Forlenza et al., 2016). Scaramuzza and Zuccotti (2015) also reported that despite the alarms and discomfort of wearing a combined device, users reported improved quality of life, fewer hypoglycemic episodes, and less anxiety.

## Stakeholders

Leadership teams that understand the long-term value of diabetes control in children are essential to promoting CGM and CSII utilization (Smith & Satyshur, 2016). Coordination of services and a multidisciplinary team is required for implementation of CGM and CSII to be effective; these teams have improved patient outcomes and satisfaction in their clinics and practices (Ng, 2018). Challenges are found in the initial upfront costs of putting together cohesive programs that accomplish better HbA1c control in children, which includes the adoption of monitoring and injection devices. Biases against upfront cost are mitigated with federal grants and scholarships that support diabetes care (Ng, 2018). Telehealth applications can further bolster support for and improve adherence by patients (Ng, 2018; Smith & Satyshur, 2016).

School nurses, advanced practice registered nurses (APRNs), and pediatricians were identified as stakeholders by Smith and Satyshur (2016). These stakeholders are the most likely to overcome public educational barriers through provision of hands-on care and supervision of diabetes management. While more of their direct patient-care time would be used to educate and support, the future savings is found with reduced hospitalizations (Ng, 2018). Specialists like endocrinologists are uniquely placed to provide education and advocacy for the use of devices, when properly trained and frequently updated on new technologies (Marks et al., 2019). Benefit to their practice is found when joint use of devices leads to improved health outcomes for pediatric patients, reducing future workload and improving adherence and long-term costs (Marks et al., 2019).

Ancillary providers such as nutritionists, psychologists, and diabetes educators were identified as vital people in the adoption of CGM and CSII (Heinemann et al., 2015). Support team members like these would see increased business from a centralized model that

incorporates multidisciplinary care and advances the use of these technologies. However, bias that involves fear of technology or change can impede their willingness to support use of these devices. Utilization of old evidence based on findings from decade-old technology can further impede cooperation (Forlenza et al., 2016). Staff members of pediatric clinics are also stakeholders because these parties also provide patient services and troubleshooting of devices (Marks et al., 2019).

Companies that manufacture these devices stand to gain increased revenue from sales (Heinemann et al., 2015). Bias was found in the incomplete event reporting and risk sharing that hid known defects. Insurance companies stand to lose a significant amount spent on devices, depending on the type and coverage offered (Martin et al., 2019). Insurance companies realize savings in the long run, because the cost of a single hospitalization far exceeds that of even the most expensive device on the market and several months of insulin and cartridge refills (Martin et al., 2019).

## Financial Considerations

The cost of type 1 diabetes was previously driven by preventable hospitalizations; however, increased insulin prices and technology utilization have changed this (Crossen, Xing, & Hoch, 2020). Between 2012 and 2016, the annual cost of type 1 diabetes for children increased from $11,178 to $17,060, and this increase was primarily attributed to insulin which doubled in price during those years (Crossen et al., 2020). However, the price of CGM and CSII also increased from $1,747 to $4,581 per year. Future savings and long-term costs offset this expense (Crossen et al., 2020). Similarly, initial prices for a closed-loop system exceeded $8,200, and monthly costs approached $900 in the evaluation by Martin et al. (2019).

Berg et al. (2020) evaluated the cost of treating skin complications arising from CGM and CSII. They reported that among 145 pediatric patients the cost of preventive skin treatments and products totaled approximately $11.5 thousand, and these were related more to the monitor than to the pump (Berg et al., 2020). Pediatric patients with severe skin problems such as eczema realized a slightly higher cost, with a clear relationship established between sensitive dermatologic issues and diagnoses and the use of expensive products to mitigate CGM-related sensitivities.

The use of CGM alone was found to be more cost-effective by Martin et al. (2019), having a greater overall effect on HbA1c and of which partial cost is assumed by the patient's use of smartphones for collection of information. The cost-effectiveness of CGM has been calculated differently for various patient groups and has been performed according to HbA1c, sensor use, and age (Scaramuzza & Zuccotti, 2015). However, CGM and SCII combined produce the greatest cost-effectiveness for people who are not yet at their target HbA1c level, and who are willing to wear the device greater than 70% of the time (Scaramuzza & Zuccotti, 2015).

Herman et al. (2018) simulated a comparison of costs of conventional treatments with intensive and technology-oriented therapies among type 1 diabetics over 30 years to determine long-term cost-effectiveness. The cost of intensive therapies ranged from $127,500 to $181,600 more over 30 years, depending on available discounts. Costs of CGM with CSII over 30 years ranged from $442,420 to $622,121, taking into account the decreasing cost of technology as it becomes commonplace (Herman et al., 2018). They reported that overall, an additional 1.62 quality adjusted life years (QALYs) could be gained over 30 years, per patient, with a cost-savings of $100,000 per QALY. Overall, they predicted the cost per QALY to be cost-

ineffective, as modern therapies cost greater than $250,000 per QALY, and recommended the least expensive option to gain HbA1c control. However, they based the entire study on a hypothesized population that was achieving "excellent glycemic control" with standard treatments and conceded that modern intensive therapy would indeed be more cost-effective due to fewer incidences of hypoglycemia, better glycemic control, less complications, and better health-related quality of life (Herman et al., 2018, p. 935). One pitfall to the study was that a thirty-year period is not long enough to realize the benefits of full glycemic control, given the cumulative organ damage and risk that occurs during aging. Other cost benefit analyses have shown that decreased visits to emergency departments and hospital admissions from both hypoglycemia and long-term complications were found with combined CGM and CSII use (Forlenza et al., 2016).

## Dissemination and Adoption

The Chronic Care Model (CCM) takes into account three important components towards adoption of better disease management (Smith & Satyshur, 2016). This model recognizes an approach must be made from an individual, provider, and community resource perspective. This model has been used to improve diabetes management in the past and involves a multidisciplinary approach with ongoing education for all parties (Smith & Satyshur, 2016). In addition to utilizing many specialists, family-centered support is emphasized, which is integrated through coordinated services and telemedicine application.

Adoption delays have been attributed to the lateness of recent evidence and controversy over who qualifies for or should receive these devices (Scaramuzza & Zuccotti, 2015). Formerly, patients had to earn their device by having good glycemic control; this is no longer the guideline, but some providers are unaware of the new recommendations (Forlenza et al., 2016).

This technology has also rapidly developed over the past two decades. Therefore, results and feedback from devices even five to ten years past influences usage of today's updated devices. Controversy about device efficacy based on old tools has impeded clinicians' recommendations for their use (Scaramuzza & Zuccotti, 2015). Therefore, educational updates are required to improve adoption. Marks et al. (2019) recommended thorough and frequent clinician education about these devices. Information to be included in educational updates involves teaching about advanced features on new pumps, which were found to be most useful for adolescent populations (Forlenza et al., 2016). Other areas of ongoing education should include troubleshooting, use of infusion sets, skin complications, glucose data availability and utilization by the patient and the practice, and updates in technology advances (Marks et al., 2019). Clinicians should be taught that there is no one single best device for every patient or family, because fear of making a best recommendation has impeded adoption altogether (Forlenza et al., 2016). Device choice can be made on insurance coverage and the individual needs of the patient (Martin et al., 2019).

The importance of providing clinical leadership, financial investments, and a team approach was emphasized by Martin et al. (2018) and Ng (2018). This requires buy-in from stakeholders who set aside budgets to support these endeavors. To accomplish this, a system-based improvement of streamlined process is needed, along with the provision of outcomes based on the newest devices available (Heinemann et al., 2015). Patients, staff, and clinicians must be taught that previous pitfalls and failures in devices were a necessary step in innovation that should be embraced and viewed as an integral step in achieving optimal technology-related outcomes (Weberg & Davidson, 2021).

To address psychological factors impeding adoption, Forlenza et al. (2016) recommends motivating the patient and parents. This is accomplished through addressing the psychological

factors by use of mental health specialists and support laypeople who work with children with type 1 diabetes.

## Barriers to Adoption

Consistency in use has been identified as a barrier, as many patients use it less than the recommended 70% or greater of the time (Scaramuzza & Zuccotti, 2015). Motivation by the patient and the parents is a key factor in overcoming this barrier (Forlenza et al., 2016). Poor self-image, potential activity restrictions, and concerns about malfunctions are patient-related barriers (Forlenza et al., 2016). Forlenza et al. (2016) found that patient motivation for improved glycemic control and desire for flexible insulin dosing improved use of and adherence with the CSII. Greater technology use was found when psychosocial factors were addressed, realistic expectations were set, and an active and team-based approach to management was fostered (Forlenza et al., 2016). Passive approaches to management and viewing the technology as a cure-all detracted from its use (Forlenza et al., 2016). Newer technologies allow for remote monitoring which improves adherence (Forlenza et al., 2016).

Technology availability alone is not sufficient; clinical leadership, investments, and a team-oriented approach is necessary for adoption of these devices (Martin et al., 2019; Ng, 2018). Even among providers such as pediatric endocrinologists, curriculum about these devices and training for their implementation was found to be significantly lacking (Marks et al., 2019). Many different systems and combinations of monitors and pumps are available, with varying degrees of control over insulin delivery. Known risks such as insulin pump failure, infusion blockages, infusion site infections, glucose stability, and human errors have been evaluated against the benefits of CSII and CGM (Heinemann et al., 2015). Notable pitfalls were found in safety monitoring and reporting; monitoring of recalled devices for problems has fallen short and

there are no standards to test device safety against after recall (Heinemann et al., 2015). Glucose monitoring can require multiple calibrations, sensors have a shelf life up to one week requiring frequent replacement, and some medications can interfere with readings (Forlenza et al., 2016).

The most accurate CGM devices are those that are newer, i.e., developed in 2018 or later, indicating that this technology is still improving (Martin et al., 2019). Providers cited keeping up with evolving and emerging technology changes as a barrier (Forlenza et al., 2016). Cost barriers include those that are initial and ongoing according to Martin et al. (2019), and Forlenza et al. (2016) cited limited insurance coverage as a hindrance. To begin CSII utilization, between two and four hours of patient education is required, whereas CGM education is simplified (Martin et al., 2019). Older combined systems did less to prevent hypoglycemia, endangering patients (Martin et al., 2019). These previous shortcomings have worked against adoption of the combined technology. Therefore, advocacy for insurance coverage is needed, and can be accomplished through research trials on newer, safer models that have proven outcomes of longevity and HbA1c control (Forlenza et al., 2016; Martin et al., 2019).

A minor drawback to closed-loop systems is the customization necessary for each individual, which requires training on the management and use of the product (Martin et al., 2019). Although this device takes over two key aspects of diabetes management, full reliance without ongoing daily maintenance is not recommended. Human and electronic error contributes to incorrect programming, power problems, and clogged lines; remediation involves cleaning, calibration, refills, battery replacement, and protection from elements (Heinemann et al., 2015). Data must also be able to be transferred seamlessly without delay for parents and providers to make timely and safe adjustments (Scaramuzza & Zucotti, 2015). Likewise, if programmed numbers are incorrectly programmed via faulty means and connections, two great risks to the

child are ketoacidosis (under-therapy) or hypoglycemia (over-therapy) (Carchidi et al., 2011). Conflicting evidence for and against CSII incorporation into CGM technologies has been noted by Martin et al. (2019).

## Societal Implications

Implications of CGM and CSII utilization among pediatric populations are that society will be positively affected in the long-term with a reduced burden for disability, greater QALYs among type 1 diabetics, and reduced cost to the health system (Crossen et al., 2020; Herman et al., 2018). Ethically, arguments have arisen regarding the use of HbA1c to measure glycemic control, as these values are more convenient than daily sampling, yet their cutoff values identify fewer people with diabetes (Hussain, 2016). These values are a benchmark of control in all studies evaluating effectiveness of CGM and CSII.

Due to conflicting evidence for safety when comparing combined CGM and CSII and CGM alone with MDI, considerations for technology use must be weighed against family dynamics and patient readiness for the devices (Martin et al., 2019; Patton et al., 2019; Scaramuzza & Zuccotti, 2015). In the United States, during premarket evaluation, device safety is often pushed through Food and Drug Administration approval by method of predicate device equivalency. Therefore, clinical safety for each new device is not well established when the devices are released for use (Heinemann et al., 2015). As a closed-loop system, this technology is defined as a class III, or higher risk, device (Heinemann et al., 2015). Bolus amounts are not standardized, and educational requirements for various manufacturers varies widely (Heinemann et al., 2015). Alarm fatigue can occur if devices emit too many warnings, causing the user to ignore critical sounds and endangering a child (Heinemann et al., 2015). Solutions to these problems require standardization, safety parameters, inclusion in medical training, and long-term

cost-effectiveness analyses to inform and gain the support of policy-makers and insurers (Crossen et al., 2020; Heinemann et al., 2015). The newest devices have safety parameters built in to prevent hypoglycemic episodes (Funtanilla et al., 2019). Combined, these devices are now considered safer than the alternative of MDI, producing fewer hypoglycemias in pediatric patients (Forlenza et al., 2016).

## Future Applications

Combined CGM and SCII in pediatric populations has the propensity to lead researchers into new arenas. The field of immunotherapy and stem cell therapy holds much promise as a tool for regenerative treatment against the autoimmune destruction of the pancreas (Scaramuzza & Zuccotti, 2015). Recent investigation has indicated hematopoietic stem cell transplantation with immunosuppression holds promise for these patients, which works best in conjunction of controlled HbA1c for optimal immune protection. This combined technology as a closed-loop system is also a vital step towards the development of a bionic pancreas, as the algorithms that are created and refined to improve safety and control will be utilized in artificial organs (Forlenza et al., 2016; Scaramuzza & Zuccotti, 2015). Future development that improve safety include modifications in pumps for the delivery of stable forms of glucagon, which are not yet available in aqueous long-term solution for CSII (Forlenza et al., 2016). These applications are underway, and combined CGM with CSII in pediatric populations are paving the way for their innovation.

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Appendix A

Literature Review Summary Table

| Year | Author(s) | Title | Purpose | Methods, Samples, and Measurements/Variables | Significant Findings |
|---|---|---|---|---|---|
| 2015 | Scaramuzza & Zuccotti | Modern clinical management helps reducing the impact of type 1 diabetes in children | To review efficiency of combined CGMs and CSIIs | Literature review<br><br>- Glycemic control<br><br>-Hypoglycemia episodes<br><br>-QOL | • Combined use of CGM and CSII technologies leads to lowest HbA1c<br>• Combined, are safe, effective, and beneficial for pediatric patients with DM1<br>• Encouraged use paves the way for bionic pancreas<br>• Despite alarms and device discomfort, QOL by wearers is increased with decreased hypoglycemic episodes, anxiety<br>• Adoption delays due to late evidence, controversy<br>• Cost-effectiveness for people with HbA1c above target levels who are willing to wear >70% of the time; mostly for long-term benefits, not hypoglycemia prevention<br>• Adoption limited by motivation and parental involvement |
| 2018 | Ng | Technology, telemedicine and social media are tools to improve health outcomes, education and patient engagement in a paediatric diabetes service | Demonstrate how health outcomes, education, and patient engagement can be improved through technology utilization | NHS improvement project<br><br>2011-2012 comparison to 2017 of:<br>-HbA1c<br>-Hospital admissions<br>-Hospitalization length of stay<br>-Technology utilization rates | • CGM and CSII, along with regular engagement, social media, child psychologists, telemedicine and web-based EHR accessible to devices, improved outcomes<br>• Clinical outcomes improved: median HbA1c reduced from 9.2 to 7.9 and 35% of children <7.5. |

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| | | | | -Patient satisfaction<br><br>- 150 patients at onset; no figure provided regarding number of patients at the end of the project period | • Insulin pump use increased from 7% to 34% over 5 years<br>• Reduced rates of ketoacidosis, hospitalizations, and length of hospital stays (2.7 to 1.8 days)<br>• Patient/family satisfaction between 81%-87%<br>• Technology availability alone is not sufficient; clinical leadership, investments, and team-oriented approach necessary for adoption |
| 2015 | Heinemann et al. | Insulin pump risks and benefits: A clinical appraisal of pump safety standards, adverse event reporting, and research needs: A joint statement of the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group | Address shortcomings in technology assessment | Guideline recommendation and clinical review/literature review | • Adverse event reporting related to CSII and CGM was incomplete and difficult to access<br>• Companies owning patents to technologies were not transparent with known risks<br>• Primary data, safety, and efficacy of devices is not available from manufacturers for devices that have been recalled or returned, and regulatory processes are not standardized<br>• Most recalls are related to infusion sets and cartridges |
| 2019 | Martin, Criego, Carlson, & Bergenstal | Advanced technology in the management of diabetes: Which comes first-continuous glucose monitor or insulin pump? | To determine if CGM or CSII should be utilized first in therapy management | Literature review of clinical trials<br><br>- Glucose metrics<br><br>- Cost comparisons | • Some clinical trials found that CGM with MDI (without CSII) can achieve lower target HbA1c than combined with CSII<br>• Other trials found that CSII use correlated with longer duration in therapeutic blood glucose ranges, with more hypoglycemia (<70) as well |

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| | | | | | • Reported initial and on-going out of pocket costs for six popular devices<br>• CSII device selection and education requires 2-4 hours of time<br>• CGM integration with smart devices saves additional cost |
| 2019 | Marks, Wolfsdorf, Waldman, Stafford, & Garvey | Pediatric endocrinology trainees' education and knowledge about insulin pumps and continuous glucose monitors | To assess provider knowledge, attitudes, and practices regarding CGM and CSII in pediatric DM1 management | Mixed methods survey<br><br>- 42 pediatric endocrinology fellows and 69 attending physicians<br><br>- 5-point likert scale surveys | • Among pediatric endocrinologists, 14.7% of fellows had formal training on these devices<br>• Knowledge gaps existed about device use and troubleshooting, features on advanced pumps, infusion sets, skin complications, glucose data availability and utilization, and advances in technology |
| 2019 | Patton, Noser, Youngkin, Majidi, & Clements | Early initiation of diabetes devices relates to improved glycemic control in children with recent-onset type 1 diabetes mellitus | To determine if CGM, CSII, or a combination of both influences HbA1c in a large cohort of children with DM1 within the first 12 months of diagnosis | 30-month longitudinal study<br><br>- 111 families of children ages 5-9 years of age<br><br>- Initial and 6-month utilization of CGM, CSII, and combination rates of use | • Insulin pump use increased from 17% to 35.1% and HbA1c increased slightly but not as significantly as the control group without pump use.<br>• CGM use increased from 17.1% to 25.2% and HbA1c decreased slightly, greatly improved over the control group. |
| 2016 | Forlenza, Buckingham, & Maahs | Progress in diabetes technology: Developments in insulin pumps, continuous glucose monitors, and progress towards the artificial pancreas | To provide an overview of the progress CSIIs and CGMs have made over the past 40 years, disseminate information | Review of technology progress | • Earn-a-pump strategy by having a good HbA1c is no longer a recommended strategy<br>• CSII alone is not as effective as CGM<br>• CSII alone has shown no increased benefit for the very young, although it decreases hospitalization rates in those with recurrent admissions |

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| | | | | | • Adolescents benefit from advanced features of CSIIs<br>• Barriers to CSII include psychosocial factors and rapidly evolving technologies, fear of making the best recommendation<br>• Factors associated with greater CGM use are age, frequency of pre-CGM monitoring<br>• CGM use associated with better HbA1c and fewer episodes of hypoglycemia<br>• Calibration needs and sensor replacement detract from CGM use<br>• Limited insurance coverage is a barrier |

*Note*: CGM = continuous glucose monitor; CSII = continuous subcutaneous insulin infusion; DM1 = diabetes type 1; EHR = electronic health record; HbA1c = glycated hemoglobin; MDI = multiple daily injections; NHS = National Health Service; QOL = quality of life