LISBOA
UNIVERSIDADE DE LISBOA

FACULDADE DE MEDICINA LISBOA

TRABALHO FINAL
MESTRADO INTEGRADO EM MEDICINA

Unidade de Epidemiologia

Innovation in diabetic care: from patient-centered care to public policies to reduce the impact of diabetes

Hugo Cereceda Ferreira

Orientado por: Dr. Paulo Jorge Nicola

JULHO'2022

Resumo

Introdução

A diabetes, nomeadamente a diabetes tipo 2, é uma doença crónica, que necessita de cuidados de saúde em continuidade, de longa duração e muitas vezes multidisciplinares. A diabetes consome vastos recursos de saúde, financeiros e de assistência social, exigindo, em todos os níveis de cuidados de saúde, e às famílias um grande esforço. Sendo uma doença que exige capacitação do paciente, literacia, adesão ao tratamento e promoção de comportamentos saudáveis, é também o paradigma de uma doença onde a relação com os profissionais de saúde e o cuidado centrado no paciente são fatores fundamentais para seu controle.

A saúde tem sido palco de muitas inovações, tanto tecnológicas, como também de gestão, prática clínica, farmacológicas, dispositivos vários e uso da informação. Os cuidados na diabetes e outras doenças crónicas estão na linha de frente do desenvolvimento, testagem e implementação destas inovações, o que iremos ilustrar ao longo deste trabalho.

Objetivo

Identificar e analisar como a inovação nos cuidados prestados aos doentes com diabetes tem vindo a alterar a capacidade de prestar cuidados centrados no doente, e demonstrar abertura a novas iniciativas e ao desenvolvimento de políticas públicas de gestão em saúde, financiamento, tecnologia/informação e sociais com vista providenciar melhores cuidados e reduzir os impactos desta doença. Neste contexto, é nosso objetivo descrever, conceptualizar e sistematizar como a inovação tem evoluído e influenciado os cuidados ao paciente diabético e identificar os respetivos impactos.

Métodos

Procedeu-se à revisão da literatura usando as bases de dados PubMed, Scopus e Word of Science, pesquisando a associação entre diabetes tipo 2 e inovação. Foram encontrados 254 artigos. A partir da seleção desses trabalhos foi efetuada uma busca manual de artigos a descrever, ilustrar e avaliar as inovações identificadas, num total de 69 artigos.

Resultados

No âmbito dos cuidados aos doentes com diabetes, foram identificados dezasseis processos de inovação com inegável relevância em quatro áreas – três casos de inovação em gestão, quatro financeiras, seis tecnológicas e três de ação social.

Conclusão

Constata-se que as diversas categorias de inovação estão interligadas e são complementares, possibilitando oferecer melhores cuidados centrados no paciente, ao mesmo tempo que vislumbram a necessidade de proceder ao "redesenho" dos sistemas e serviços de saúde. Admite-se que, no futuro, a sua adequada integração acarretaria melhores cuidados e permitiria reduzir o impacto da diabetes, podendo vir a ser o modelo a utilizar no manejo de outras doenças crónicas.

Palavras-chave: diabetes tipo 2, cuidados centrados no doente, inovação, sistema / serviços de saúde, cuidados integrados

Abstract

Background

Diabetes, namely type-2 diabetes, is a chronic disease that requires continuous, long-term, and often multidisciplinary medical care. Diabetes consumes a vast amount of health, financial and social care resources, demanding great efforts at all levels of health care and families. As a disease that requires patient training, literacy, adherence to treatment, and the promotion of healthy behaviors, it is also the paradigm of a disease where health professionals' relationship and patient-centered care are key factors for its control.

Health has been the scene of many innovations, both technological, as well as management, clinical practice, medication, a wide variety of devices, and information uses. Diabetic, and of other chronic diseases, is at the forefront of the development, testing, and implementation of these innovations, which we will illustrate throughout this work.

Aim

Identify and analyze how innovation in care provided to patients with diabetes has been changing the ability to provide patient-centered care, and open-up new initiatives and development of public policies in health, financing, technological/information and social management with the view to provide better care and reduce the impacts of this disease. In this context, we will describe, conceptualize and systematize how innovation has evolved and influenced diabetic patient care and identify the respective impacts.

Methods

A literature review was carried out using PubMed, Scopus, and Word of Science databases, investigating the association between type 2 diabetes and innovation. Two hundred and fifty-four articles were found. From the research, a manual search of articles aiming to describe, exemplify, and evaluate the innovations in diabetes care, was carried out, resulting in a total of 69 articles.

Results

Four main areas were identified within the scope of diabetes patients' care, in which innovation processes are present with undeniable relevance – management, financial, technological, and social action, which will be analyzed on the course of this work.

Conclusion

It was possible to observe that the different categories of innovation are interconnected and complementary, making it possible to offer better patient-centered care, while at the same time envisioning the need to "redesign" of health systems and services. It is accepted that, in the future, their appropriate integration would lead to better care and reduce the impact of diabetes, as well as potentially become the model that could be used in the management of other chronic diseases.

Keywords: diabetes type 2, patient-centered care, innovation, healthcare system/services, integrated care

Index

Index of tables

Index of figures

List of abbreviations

CCM – Chronic Care Model

CDCES – Certified Diabetes Care and Education Specialist

NPCD – Non-Physician Clinician-Driven

EHR – Electronic Health Record

FFS – Fee For Service

P4P – Payment for Performance

PMPM – Per Member Per Month

QOF – Quality and Outcomes Framework

NICE – National Institute for Health and Care Excellence

GP – General Practitioner

NHS – National Health Service

ACO – Accountable Care Organization

MSSP – Medicare Shared Savings Program

SDH – Social Determinants of Health

PCMH – Patient Centered Medical Home

AHC – Accountable Health Communities

SIM – State Innovation Model

PIPH – Plan to Improve Population Health

HbA1c – Glycated Hemoglobin

ENDO ECHO – Endocrinology Extension Community Healthcare Outcomes

DPP – Diabetes Prevention Program

CDC – Center for Disease Control and Prevention

AI – Artificial Intelligence

FDA – Food and Drug Administration

CGM – Continuous Glucose Monitor

ADA – American Diabetes Association

CSII – Continuous Subcutaneous Insulin Infusion

EASD – European Association for the Study of Diabetes

TPE – Therapeutic Patient Education

Background

Diabetes, namely type-2 diabetes, is a chronic disease, which needs ongoing, long duration, multidisciplinary healthcare. Diabetes consumes a large proportion of health, financial and social care resources, straining primary and secondary healthcare systems and family resources. Being a disease that requires patient empowerment, appropriate levels of health literacy, treatment adherence, and the promotion of healthy behaviors, it is also the paradigm of a condition where patients / professionals' relationships and patient-centered care are key factors for its control (1).

According to the 10th edition of the Diabetes Atlas (2) of the International Diabetes Federation, in 2021, globally, an estimated 537 million adults aged 20–79 years had diabetes mellitus (1 in 10), and type 2 diabetes accounted for over 90% of cases. This number is predicted to rise to 783 million by 2045. In addition, over 3 in 4 adults with diabetes live in developing countries. Diabetes reduces the life expectancy by 15 years, which is worse than the risk of premature death caused by smoking and that diabetes is often associated with obesity and smoking. Diabetes-related complications were responsible for 6.7 million deaths in 2021 (1 every 5 seconds). Also in 2021, diabetes care resulted in nearly 1 trillion dollars in health expenditure – 300% increase during the last 15 years. In addition, it is estimated that three-quarters of that figure is related to the treatment of preventable complications. Moreover, approximately 50% of patients with type 2 diabetes do not achieve adequate glycemic control, an outcome that is often related to poor adherence to medication (3).

Considering the increasing prevalence of diabetes, poor outcomes, and highly costly and life-debilitating complications, it is time to reimagine how care is delivered. Healthcare has been the stage for much innovation, both technological, but also on management, clinical practice, medication, and information use. Diabetic care and care of other chronic diseases have been on the frontline of the testing, implementation, and dissemination of such innovations.

For the purpose of our analysis, we incorporated the definition of patient-centered

care produced on the NEJM Catalyst overview (2017) (4).

> *"Patient-centered care focus particularly on individual's health needs and preferences to guide all healthcare decisions and quality measurements. Patients and providers become true partners in the treatment that goes beyond clinical practice, creating individualized, comprehensive care plans that consider equally the emotional, mental, spiritual, social and financial dimensions. Patient- and family-centered care promotes the active collaboration and shared decision-making between patients, providers, and families and revises the approach to healthcare delivery."*

Patient-centered care is based on the following elements:

1. Alignment of mission and values with patients goals,
2. Collaborative, coordinated, accessible care,
3. Focus on physical comfort and emotional well-being,
4. Respect of patients' and families' viewpoints,
5. Decisions always including patients and families,
6. Families present in the care setting, and
7. Full transparency and fast delivery of information.

This approach requires a shift from all stakeholders directly and indirectly present in the care delivery to engaging in this process. The values and principles must be incorporated at the top and bottom of the organization. Patients and families transition from passive roles to active team members. And patients' recommendations are taken into account on how to improve healthcare services from both a physical and operational perspective. With the scale-up of this value-based health care, patient engagement and satisfaction, provider productivity and morale, and clinical efficacy are expected to improve. The continuum of care should increase resource allocation, reduce expenses and increase financial margins. Finally, patient-centered care can take a variety of forms (personalized medicine), in different health care settings (doctor's office, hospital…)

For this review, we based our definition of innovation on the concepts presented by Ellen Nolte (2018) (5).

> *"Innovation in health care is a novel solution that represents a change from traditional delivery care. Innovation can be a product, a process, or a technology that improves health outcomes, effectiveness, efficiency, or patients' experience. The innovation process involves different maturation phases. These rarely follow a linear and predictable sequence. Instead, they tend to be 'messy', dynamic and interact in ways that are often not knowable."*

The process of innovation in health care can be divided in the following maturation phases:

1. Adoption – the decision to implement an innovation;
2. Implementation – the process of integrating an innovation;
3. Sustainability – the process by which an innovation becomes a routine element;
4. Spread – the process of the diffusion of an innovation, as an unplanned, informal and decentralized process (passive spread);
5. Dissemination – the active and planned work to adopt an innovation;
6. Scale-up – a systematic approach to expanding the coverage of a successful innovation.

Several innovations need public policies to be implemented and disseminated, local, regional, or nationwide, as for example the Quality and Outcomes Framework in the UK (24), the social-orientated alternative payment models in the US (18), the therapeutic patient education in Austria (63), or the integration of social and health care in Finland (69).

In this review, we explore how innovation in diabetes care has been changing the ability to provide patient-centered care to diabetic patients, and open-up new initiatives and public policies concerning health management, finances, technology, and social support. Some of the innovations bring better care, therefore the importance of impact evaluation. The vision described in this review highlights

innovations that may provide access to the state-of-the-art diabetes care.

Methods

A review of the literature was conducted and updated in March 2022, using PubMed, Scopus, and Word of Science databases. Only open access English reviews, published between the 1st of January 2012 and the 31st of March 2022, were considered. The search terms “diabetes” and “innovation” were combined and explored in the Title and/or Abstract, yielding 254 articles. After excluding duplicates, screening abstracts and full texts for eligibility focusing on type 2 diabetes and innovation of care, 15 studies were included in the qualitative analysis.

These processes of innovations were analyzed systematically, looking for case-studies, their purposes, claimed advantages, requirements, and evidence of impact, and the lessons learnt from their implementation. Four main areas were identified – management, financial, technological, and social action.

From those, a manual search of articles describing, exemplifying, and evaluating the effectiveness of these innovations was performed. 69 articles were reunited in this review.

According to Nolte (5), was conducted a systematization of innovations in diabetes care classified by their maturation, presented in Table – 1 (see page 40).

Results

Management Innovation

Diabetes is frequently associated with comorbidities that increase the complexity of treatment. Such comorbidities include hypertension, hyperlipidemia, chronic kidney disease, retinopathy, and/or cardiovascular diseases. And even if there were enough specialists to treat each condition, the absence of coordination leads to fragmented care, and therefore to low effectiveness and efficiency of care (loss of information and need for repetition), and bad experiences for patients overwhelmed by the complexity of their health situation (6).

Healthcare systems or hospitals more precisely were designed to treat acute and episodic care, with siloed departments promoting the dichotomy between health and social care or in- and outpatient care. So, it is not surprising that the traditional model of care often does not meet the needs of complex patients with chronic conditions that need ongoing and multidisciplinary care (7).

1. Integrated care

Integrated or team-based care brings together a variety of experts to provide the appropriate diabetes care. Integration of hospital and primary care information, communication, and decisions are extremely important, even if this model is often dominated by general practitioners, it can be led by other doctors, nurse practitioners, and pharmacists. What the different examples of implementation around the world have in common is the purpose to deliver quality care through more efficient organization and allocation of resources, and to adopt a team collaboration and decision approach based on patient empowerment, abandoning the common practice of the doctor being the center of care and knowledge that may, eventually, delegate on the other team members. This model has the potential to enhance success of diabetes care systems, thanks to communication, responsibilities sharing, and

satisfaction of hospitals and primary care providers (8).

Integrated care tackles fragmentation transitioning towards a continuum of care. Its purpose is also to promote the gathering of health and social systems, integrating e-health infrastructures, critical to information sharing. Data privacy requirements become more important as this model is implemented.

This model has been around since 1996, when Ed Wagner described the Chronic Care Model (CCM). Since then, it had different denominations to adapt to its limitations and regional necessities. The original CCM included six essential elements that must be integrated (7):

- community resources,
- health system,
- self-management support,
- delivery system design,
- decision support, and
- clinical information systems.

Several systematic reviews and randomized studies conducted in the US and China reported positive outcomes for this model (9,10). However, a meta-analysis conducted in 2017 by Bongaerts *et al.* revealed limited evidence of the effectiveness of European multifaceted diabetes care that addresses a wide range of outcomes indicators. After one year of integrated care, newly diagnosed diabetic patients showed a decrease in the value of glycated hemoglobin (HbA1c), but such outcomes were not observed in the group with prevalent diabetes, when compared with the usual care group (11). In a 2016 systematic review on the economic impact of diabetes integrated care models, Desmedt *et al.* identified positive economic results (12).

Multimorbidity seems to be a factor that was not sufficiently explored in the implementation of the CCM and may explain the apparent failure of demonstrating its initial potential. It is clear today that integrated models must be dynamic and adaptable to the everyday life of patients. Boehmer *et al.* (2018) suggested that the

assessment should take into consideration patient-centered outcomes, care experiences, and resources needed for implementation (13).

To recapitulate, the purpose of integrated care is to cluster the whole range of professionals involved in diabetic care into teams, to provide a more complete, continuous, and quality care to patients that have become active decision-makers at the center of the care team. This demands new capacities and a specific mindset from health providers, as well as patient empowerment through awareness and education. This approach also requires that the myopic focus on clinical outcomes is abandoned, while adopting a holistic approach where the different needs of people with diabetes are addressed, if we want to improve the effectiveness and efficiency of care. This approach also requires that an essential factor must be present: “flexibility”. Clinicians must be able to differentiate the type of care required and tailor it to specific patients' needs. Simultaneously, they must adapt to new disruptive practices and technologies independent from rigid protocols that promote defensive medicine and fail to consider the heterogeneity of patients, caregivers, and their communities. Meanwhile, existing guidelines should consider and implement integrated care models that accommodate the dynamism and adaptability required to promote successful diabetic care to patients. Therefore, comorbidities and functional status of patients must be addressed by an integrated and holistic approach, instead of treating each disorder separately. According to the 2019 EFPIA report on diabetes (14), guidance on how to prioritize care is fundamental as well as the development of validated outcomes measures.

2. Risk-stratification

Risk-stratification is the process of screening patients to identify those at risk of developing complications from diabetes and to act preventively.

The idea of prioritizing those at high risk makes sense. However, how to stratify patients to address the different care needs is questionable.

Risk-stratification should guide service allocation and individualized care in primary

health care, where the holistic patient-centered services should be the reference. For those at high risk, the integrated approach with specialist care should be the rule. Meanwhile, this focus on complications that we want to prevent represents a way to approach multimorbidity and allocate scarce resources to deal with complications in a more just way (15).

This is especially important since most resources are devoted to treating advanced complications, and a smaller portion is allocated to the vast majority of diabetic patients, particularly when accepting that those at this immediate risk level may progress to advanced complications in a foreseeable way. New models will certainly have to incorporate improved risk stratification and identify when to act earlier in diabetes progression. This model will enable timely targeted clinical support, based on the knowledge of the natural progression of the disease, aiming at reducing diabetes impact.

Currently, some IT-integrated risk assessment tools are being developed. In addition, academic papers on machine learning models seem promising, supporting decisions on how to prevent mortality, glycemic control deterioration, diabetic ketoacidosis, eye disease, foot ulcers, kidney failure, and cardiovascular complications. However, most of these models are experimental (16).

3. Connected Diabetes Care

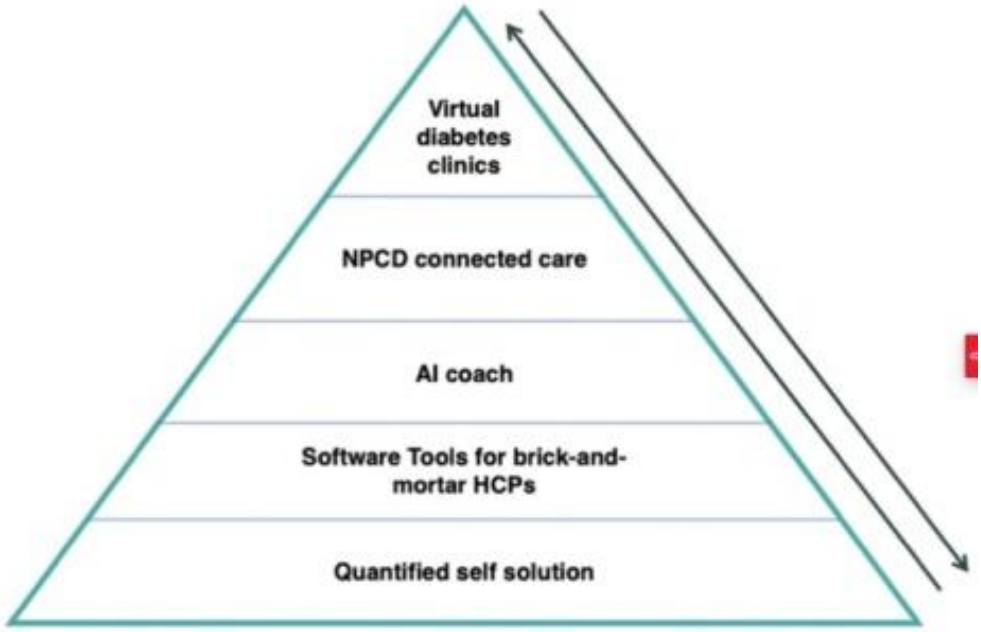
Over the last 10 years, there has been a substantial expansion of connected diabetes care products and programs, thanks to the improvement of glucose monitors and trackers for physical activity, sleep, weight, and other biometrics measures.

With the use of virtual diabetes management programs such as smartphones, connected devices, and remote coaching, connected diabetes care can support the shift from fragmented care to continuous care, being scalable and potentially improving quality management. With the irreversible shift to virtual care brought by

the COVID-19 pandemic, all stakeholders must participate in this transitional model.

Levine *et al.* (2020) (17) suggested merging the different solutions available to create an integrated connected diabetes care model, according to personnel needs and care alternatives. The authors present five categories to deliver the best level of care according to the patients' decisions and needs. Patient care escalates or deescalates according to preference and health requirements, in a continuum pyramid of care, ensuring the best care quality, patient satisfaction, and cost. Next we will present and discuss the categories of connected care (see Figure – 1).

Fig. 1 – Theoretical risk stratification pyramid showing how the different categories of connected diabetes care could be deployed to improve population health



From: Levine, B. J., Close, K. L., & Gabbay, R. A. (2020). A care team-based classification and population management schema for connected diabetes care. NPJ digital medicine, 3, 104. https://doi.org/10.1038/s41746-020-00313-3

The first category comprehends the virtual diabetes clinics with medical doctors, physician assistants, nurse practitioners, pharmacists, and possibly certified diabetes care and education specialists (CDCES) and psychosocial experts. Through connected

devices, smartphone-based logging/data capture, and interaction, virtual clinics aim to replicate a traditional clinic. They provide medical services and can optimize medication and reduce therapy inertia. Cost-effectiveness may result from reduced emergencies and in- and outpatient care. However, due to the high financial and operational requirements, a virtual clinic may be appropriate for high-risk and –cost patients that need more support between in-person visits.

However, for all remote solutions, patients will always need to see a physician, for example for other therapeutic needs, feet, and eye examinations. In addition, the physician must be familiar with patients' interactions using remote solutions and data.

The second category is operated by non-physician clinician-driven (NPCD) connected care with CDCES, registered dietician nutritionists, and trained health coaches. It focuses on self-management support, lifestyle interventions like exercise and nutrition, and adherence to treatment, with the help of smartphone apps, live coaching, and connected devices. This option should be best suited for high-risk and -cost patients that are on a successful therapeutic regimen and/or have frequent in-person visits.

The third category is comprised of artificial intelligence health coach apps. These are algorithms, some also including machine learning, that interacts with the patient in real-time according to the data expressed by manual entry or connected devices. They remind patients to do self-management tasks such as taking medication, exercising, or checking glucose, provide education, motivation, and personalized feedback. Then the more advanced automated coach apps can learn how to best interact and produce better outcomes and engagement, thanks to the knowledge acquired about patients' behaviors. These apps, the best-cost effectively remote solutions, may be suited to patients who enjoy daily support, and do not mind interacting with a chatbot.

The fourth category includes software tools for brick-and-mortar healthcare providers. They provide clinicians the capacity for remote management, risk-stratification modules, two-way secure communication, and congregate all patient data for inspection during and between visits. Clinicians may then reach out to high-risk

patients by virtual means or invite them for a visit.

The fifth category contains quantified self-solutions that are connected devices such as activity trackers, wireless blood cuffs, and scales, without coaching but that may incorporate some sort of engagement like gamification or another kind of motivation. They could be appropriate for those more engaged in their self-care and to be independent in achieving their health goals. By monitoring data, health systems could recommend that at-risk patients move to a more intense program.

Following the connected diabetes care pyramid proposed by Levine *et al.* (2020) (17) (see Figure – 1), patients may be initially better suited for a specific category and later move up or down depending on their evolution and control of diabetes. First, those at-risk or diagnosed may fit to be helped by software tools of their office clinicians. Then, patients who could benefit from coaching can be directed to an AI coach. But if human care and education is needed, it should be provided by the NPCD connected care. Subsequentially, those at high risk that would require special attention from a team of healthcare practitioners may benefit from a virtual diabetes clinic. Remembering that virtual care cannot dismiss in-person visits, this strategy works as means to augment access and provide continuum care as an adjuvant of traditional care. This remote model can be organized vertically by an integrated organization or platform, or by several different ones. Escalation protocols applied to a care management virtual setting could provide more scalable and successful care at population level.

To achieve this purpose, there is the need for an integrated care team that combines clinical information included in the workflows in EHR. This goes against the status quo of cultural, social, and political biases and EHR fragmentation. Hopefully, new financial models should promote a shift to technology-enabled population-based care models. The unique characteristics of connected diabetes care make possible to engage integrated care teams, automation, connected devices, and software to support patients outside the doctor's office (17).

Table 2 – Classification of connected diabetes care programs

	Care team composition	Estimated relative cost	Likely target user	Examples
Virtual diabetes clinic	All clinicians, including physicians, nurse practitioners, and physician assistants	Highest	Highest-risk, highest-cost patients who are furthest from target and need frequent therapeutic adjustments	Virta, Onduo
NPCD	All clinicians, excluding physicians, nurse practitioners, and physician assistants	High	High-risk patients who (a) have access to high-quality, frequent in-person care and/or (b) are on a fairly stable and successful therapeutic regimen	Livongo Health, mySugr, Omada Health, One Drop, Cecelia Health (soon aims to be Virtual Diabetes Clinic), Vida Health, Noom, Dariohealth, Canary Health
AI coach	Automated coaching	Low	Members of large employer/health plans who prefer daily engagement/coaching and do not need frequent therapeutic adjustments	Welldoc, Lark Health
Software tools	Brick-and-mortar clinicians	Low	Everyone with a diabetes or prediabetes diagnosis and a brick-and-mortar clinician	Glooko, Tidepool, Fitbit (Twine Health), device manufacturer software, specific EHR modules
QSS	None	Middle	Motivated people who may be at risk of developing disease	UHC Motion Program, Devoted Health Medicare Advantage, Aetna Attain

From: Levine, B. J., Close, K. L., & Gabbay, R. A. (2020). A care team-based classification and population management schema for connected diabetes care. NPJ digital medicine, 3, 104. https://doi.org/10.1038/s41746-020-00313-3

Financial Innovation

Diabetes represents 10% of the total health care expenditure worldwide, which represents almost 1 trillion US$, and it is expected to keep growing. So, the need for innovative financial models that encourage better efficiency, better quality of care, more access to services, and promote the development of new technologies, is particularly decisive in diabetes care for the future. In the US, the model of fee for service (FFS) is shifting towards being complemented by alternative models of payments (bundle payments, payments for performance (P4P), shared savings…). Since these new payment options change health care organization, we may consider them social innovations too.

1. Bundle payments

According to the definition presented by Loren Saulsberry, "bundle payments" are those that, through a single payment, cover the cost of services delivered over a defined period of time, potentially involving multiple providers, to treat a given episode of care (for example a year's worth of diabetes care) (18). This innovative financing model should reduce inefficiencies by, for example, encouraging healthcare providers to produce more efficient treatments and therefore benefit from a bigger share of the profit.

Bundle payments are designed to encourage health care integration, reduce expenditure, and enhance the quality of care. Several countries are trying other solutions with the same objectives - to integrate the delivery of services and provide more effective and efficient care. An example is the US health care system that started to pay a single fee for all medical services involving an episode of care (18). We can also mention the subtype of capitation, one payment for a period, usually, one month, referred to per member per month (PMPM).

The Netherlands has a long experience with bundle payments for diabetes care. In

2010, this approach was implemented not only for diabetes but also for other conditions in the whole country. In this bundle payment model, insurers paid to a care group a single fee that includes all treatments needed by patients followed in primary care (19). Initially, the program showed improvements in the organization and coordination of care, resulting in better collaboration among providers and better adherence to protocols. Nevertheless, general practitioners monopolized care groups, and considerable differences in price between care groups were identified, partially explained by variations in the amount of care provided and the administrative load associated with obsolete technology systems.

In a long-term evaluation study, Karimi *et al.* (2021) found that bundled payments for diabetes in the Netherland increased healthcare expenditure per patient, by 13% of the 2008 half-year cost. The increase was higher for those with multimorbidity (20). In a two-year follow-up study of bundled payments for diabetes in the US, Mohnen *et al.* (2015) also showed result revealing increases in costs particularly in multimorbid patients (21).

In conclusion, bundled payments in diabetes care showed improvements in quality of care, and health care organization, despite cost increases for reasons yet to be explained. So, the question remains - is improved care cost-effective or not? It is obvious the need to review and better comprehend the financial models according to the specific needs of patients with more than one disease is mandatory.

2. Payments for performance

Pay-for-performance (P4P) is a reimbursement payment that directly relates a proportion of the remuneration of providers to the achieved result on performance indicators (22).

It is comprehensible that physician behavior is influenced by financial incentives, so if they provide better care, they expect to be better compensated. Therefore, as a consequence of physician behavior change, we should expect an improvement in the

management of diabetes and the effectiveness of therapies. That is why P4P has been extensively embraced, particularly in the management of chronic diseases. In the literature, we have seen an increase in studies on P4P effects on diabetes management. Nevertheless, the heterogeneity of P4P plans and demographic differences do not provide clear results and leave inconsistency and controversy. The evidence on the effectiveness of P4P is slowly growing, providing little information that new programs are learning from previous mistakes regarding the design and evaluation (23).

The oldest, largest established, and most studied P4P program, is the UK's Quality and Outcomes Framework (QOF) initiated in 2004. It is important to consider P4P schemes as one element of a nicely planned reimbursement system, blending different payment options and non-financial incentives. Over the years, technical issues became obvious. Payments built on responses to a national patient survey were put through a random variation, so practices would improve care from one year to the next, but receive less money. The initial payment formula indivertibly beneficiated larger practices which consistently got higher payments than smaller ones, despite the same level of quality provided. Also, the registry codes were modified to contain only records that reveal the type of diabetes, which intentionally resulted in the loss of patients with less specific diabetes codes from the practices' QOF registers. In addition, some indicators brought up problems after the implementation. Some of these could have been prevented if indicators were better studied before implementation. This happened when the National Institute for Health and Care Excellence (NICE) was brought over to decide about the indicators in 2009. Despite the initial indicators generally related to aspects of care that general practitioners (GPs) considered important, the alignment of indicators with professionals' values decreased gradually. Part of the cause was that the easy goals have been accomplished and the new evidence-based indicators that were put in place had little gains and were associated with a high workload. Then there was a growing awareness of multimorbid patients that were provided with worse care, since the indicators were not adapted to their needs, focusing, instead, on single diseases.

So, it is no surprise that the QOF program has become persistently more unpopular among providers, because of its administrative load which comes at a time when GP workloads have been at their highest. General practice has been getting a decreasing share of the health budget, while the work stress is increasing more than ever. One may conclude that P4P schemes appear to influence process indicators more pronouncedly than outcome indicators, in other words, the behaviors of physicians are more probably to be influenced (24).

Furthermore, QOF has been associated with enhanced quality and access to stimulating activities, especially in socioeconomically deprived regions. This is due to the successes in accelerating the process of systematic management of chronic disease with integrated teams, and the dissemination of electronic medical records. However, effects on outcomes like mortality have been little or absent. And primary care P4P schemes in other countries have shown similar results. Even if there is unanimity that QOF needs to be considerably changed, removing P4P incentives could negatively affect the quality of care. There is little knowledge on what would work better, nevertheless, the constant improvement of quality during the QOF proposes that the implementation of protocols and standards incentivized by local clinical audit are effective (24).

In a systematic review, Huang *et al.* (2013) concluded that the evidence on the effectiveness of P4P programs in the quality of diabetes is variable. The results stretched from nonsignificant to very positive. So, although the inconsistency among the effects described in the studies, it is suggested that well-designed P4P programs can increase the quality of medical care for diabetes and increase patients' outcomes to some level also. Especially patients with diabetes satisfactorily managed, significantly improve was observed with the implementation of a P4P program. Thus, this review showed that P4P can increase better outcomes in patients with diabetes (22).

Several studies conducted with diabetes patients in Taiwan, suggested that the P4P program was cost-effective, especially for patients with multimorbidities (25); these

studies indicated that the P4P program considerably increased survival among diabetic patients without raising cost, and notably decreased the risk of cancer and chronic kidney disease (26); demonstrated potential benefits of diabetes P4P programs in reducing the risk of deaths due to diabetes or cardiovascular conditions in cancer survivors (27); and indicated that the P4P program reduced all-cause mortality in patients with newly diagnosed diabetes, particularly in the patients with better adherence to the program (28).

Improved quality and safety of care demand well-thought strategies, prolonged over time, and adaptability to changes. It is understood that technical elements of a quality improvement initiative are as important as winning hearts and minds with persuasion, collaboration, and close alignment of health professionals and managerial objectives. UK's QOF was not the best solution to improve care, it needs change, but neither its replacements will be the magic bullet (24). Blended payment models need to be tested, evaluated, and meliorated. In the meanwhile, we will see which approaches will flourish in the different regions of the NHS. In the elaboration of studies, heterogeneity of P4P programs is certain due to several structural differences, but, it does not permit comparisons and obtain solid results. Rigorous prospective design should be the rule for further studies, as well as appropriate randomization. By standardizing P4P programs among studies, we could get a more precise insight into how P4P programs work in diabetes care, and so reach better quality of care by motivating physicians more effectively (22).

3. Shared savings

According to the definition presented by Loren Saulsberry, "shared savings" occur when a provider or health care organization shares in the savings that accrue to a payer when actual spending for a defined population is less than a previously expected target amount (18). This model requires defining financial and healthcare quality targets, so the clinician can share a portion of the savings they generate with the payer. The idea behind the global payment model of ACOs is to move from volume to

value healthcare services.

In 2010, in the US, the Accountable Care Organizations (ACO) were created with the intention to deliver better care to complex patients and chronic diseases associated with high healthcare services utilization, resulting in high costs. This association was designed to motivate coordination and cooperation among physicians through financial incentives for high quality and reduce spending for a group of patients, especially those with diabetes. So, they incentivize the integrated care to coordinate complex health plans. In 2012, the Medicare Shared Savings Program (MSSP) was initiated, and rapidly this model became the dominant method of payment other than traditional FFS. So, in 2016, about 60 percent of ACO had integrated shared savings arrangements. Evidence shows that some shared savings programs produce reductions in costs, thanks to providers spending below financial targets (29).

Despite most studies producing evidence that shared savings programs increase quality and lead to cost savings, the real cost of the model can exceed the benefits. This happens because if organizations overspend, payers like Medicare do not penalize them, in other words when ACOs spend above the target, payers could lose money. Many ACOs produced savings, but Medicare has lost money in the MSSP since it could not get compensated from ACOs that overspent. This means that providers' organizations experienced no financial risk. Other considerations to be taken on possible consequences are that payers still reimburse providers on a FFS basis, which is counterproductive to the shift from volume to value and outcomes; that providers often are awarded a year after the performance period, so they are not instantly involved in the procurement of results; and more importantly, the principle of financial targets being based in historical spending punish the efficient organizations, leaving less space to accomplish additional cost reductions (30).

McWilliams *et al.* (2017), studying the impact of the "Saving Shared Program" on diabetes and cardiovascular disease, showed in year three that there were no considerable improvements in the adherence and use of medications that would translate into better outcomes for these patients (29).

Ouayogodé and collaborators (2017) showed there was no characteristic organizational structure that was connected to the outcomes of savings per patient or the probability of reaching shared savings. But ACOs with risk-adjusted contracts produced savings and increased chances of obtaining shared savings payments. So, it seems that ACOs have savings opportunities under risk-adjusted contracts (31).

Therefore, considering the results and the limitations of the shared savings model, it is unclear whether it will increase the value equation, even if some programs present more promise with time. Nevertheless, several shared savings contracts with ACOs, both public and private, are set to shift to shared risk in year three or five. The effectiveness of this transition will have to be studied and if payers making ACOs retain some of their overspendings produces continuous improvements in quality, efficiency, and affordability (29).

4. Social-orientated US Alternative Payment Models

In the US, programs aiming at providing improved health and social care proliferated, while at the same time reducing costs associated with diabetes care. Social needs may decrease the patient's capacity to manage their conditions, raise costs, and increase preventable care utilization. Meanwhile how healthcare systems can promote wider population changes in social determinants of health (SDH) which heavily affect overall health needs yet to be established.

Below we present some of those initiatives:

a) "Patient-centered medical homes" (PCMHs) can be funded by blended financial options (bundle payments, FFS, and P4Ps). They are designed to empower primary care to increase access and coordination of medical and social services. For that purpose, they collect the social needs of the patients with diabetes and incorporate them into the definition of personalized care plans.

b) “Accountable Health Communities” (AHCs) are developed to better link medical and community services. AHCs cover:
    - screening of patients’ unmet health-related needs (housing, food security, transportation, etc.);
    - referral to community services;
    - navigation services to access community resources; and
    - responsive of community services to the patient’s needs through medical and community collaboration.
c) “State Innovation Models” (SIMs) – innovative multi-payer healthcare delivery and payment models, that focus on integrating primary and social care services, in particular addressing SDH (employment, housing, and food security). They must present a Plan to Improve Population Health (PIPH) at state level, one of the areas being diabetes. SIMs are financed by federal grants to states, and beat the dependence on a FFS system, planning new approaches to the integration of medical and social care.

Section 1115 Medicaid waivers supply states with the liberty to test innovative models in Medicaid that are not included or differ from federal law. This gives the flexibility to operate. Oregon initiated a program of housing-related services, investing in local housing. Colorado implemented payments on a per member per month basis to orientate patients to community services.

Diabetes, like other chronic conditions, represents an unreasonable charge to minority, underserved, and isolated populations, that have socioeconomic vulnerabilities and will go through difficulties in accessing care. So, population health initiatives of integrated care and strong collaboration between medical and social services are probably the best solution to improve health equity, while improving health outcomes and bending the cost curve. Jointly, these new financing models are knotting payment to outcomes and produce references for “total cost of care”.

The awareness to address SDH in health innovation shows an engagement to study whether better integration of care produces gains in population health. These

transitions to integrate SDH, public health, and health delivery need to be assessed and comprehended. However, it is expected they will bring significant results in quality, costs, and outcomes for patients with diabetes.

Nevertheless, the level to which these programs promote the integration of SDH into clinical care may not be enough, because higher provider payments have suggested mixed patients results. Other adversities are the need for standardized approaches and the discrepancies in the preparation and ability of health organizations and community services to engage in integrated models of care.

In this context, the future cost-effectiveness analysis on integrating SDH becomes crucial to establish the results and outcomes of these interventions. Evidence on health outcomes, payment alternatives, and return on investment are critical to sustaining these SDH interventions. This study is required for policymakers to decide on the most favorable health payment models consider the different variables with which health systems operate (18).

Technological Innovation

With the advance in information and communications technologies, digital health is revolutionizing health care systems. The full potential of digital health is yet to be unleashed. In alignment with traditional in-person care, it should bring better outcomes, reduce costs and fragmentation of care, and help accomplish the holistic centered-patient approach, while increasing satisfaction of health care professionals.

1. Telemedicine

Telemedicine is the use of information and communication technologies to deliver health care services remotely (32). Telemedicine is a promising tool to improve clinical outcomes by increasing access to diabetes care.

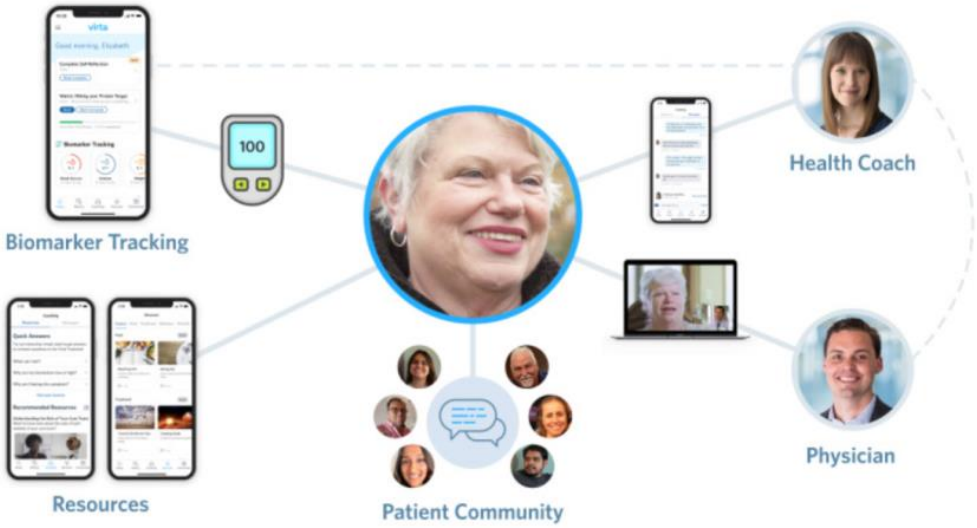
In a two-year non-randomized clinical trial exploring a novel digitally-monitored continuous care intervention, an example of a virtual clinic, Athinarayanan *et al.* (2019) presented results in HbA1c reduction (0,9%) comparable to those shown by pharmacotherapy, while reducing two-thirds of diabetes medications, insulins and sulfonylureas that represent risks for weight gain and hypoglycemia. In addition, the program displayed 74% retention, what must be considered a high percentage when contemplating most digital health solutions. Finally, reversion of diabetes was also observed (33).

Telemedicine brings convenience to anyone or any institution owning a smartphone, computer, or tablet with an internet connection. This was critical during the COVID-19 pandemic. Telemedicine can take a range of different strategies in diabetes care and education (34), while providing access to physician and non-physician professionals. By doing so, some may argue that continuous remote care can bring a more patient-centered experience (35).

During the COVID-19 pandemic, some centers had to rapidly transition to

telemedicine. Taking for example the Prisma Health DSMES program in the US, the technological infrastructure was already in place thanks to the electronic health record (EHR) portal that allows providers video visits via smartphone, computer, or another device. Then staff training was needed. Toolkits were created for both staff and patients. As most participants were not accustomed to the technology, a helpline was put in place to give technical assistance to access virtual visits. Tip sheets were also assembled to assist the staff conduct the visit and help participants with technical issues and problem-solving. Furthermore, there was a clinical care and education specialist with specialized skills to routinely and closely help the staff (36). The Figure – 2 presents the multifaced holistic care offered by continuous remote care model.

Fig. 2 – Multifaced holistic care offered by the continuous remote care model



From: Hallberg, S., & Harrison, D. (2021). Telemedicine via Continuous Remote Care: A Proactive, Patient-Centered Approach to Improve Clinical Outcomes. JMIR diabetes, 6(4), e23646. https://doi.org/10.2196/23646

Patients adhere to and embrace this solution, for example, people living in rural areas far from care centers, people working that cannot take a leave day to go to a consultation, or the elderly in an equipped institution that will need to travel less frequently. The attendance was higher with virtual visits than with in-person visits (36).

In a meta-analysis on the effectiveness of telemedicine, Faruque *et al.* (2017) demonstrated a reduction of glycated hemoglobin (HbA1c), however no effect in other clinical outcomes was observed (32). In another network meta-analysis, Lee *et al.* (2017) demonstrated that most telemedicine strategies were effective in producing a clinically meaningful improvement of HbA1c. The decreasing of the effectiveness of all strategies goes as (i) teleconsultation, (ii) telecase-management plus telemonitoring, and (iii) tele-education plus telecase-management (34).

2. Electronic Consultations

Electronic Consultations (eConsults) uses telehealth to establish communication and collaboration between clinicians. eConsults can be defined as nonsimultaneous communication between a specialist and the referring primary care provider to discuss a patient case. They are designed to improve access to quality specialty care without the need for the traditional face-to-face visit. They also promise to provide cost-effective and convenient care for patients (37). The results across specialties are well reported including increased access to specialists, provider satisfaction, and naturally education for primary care providers. During the COVID-19 pandemic, Agarwal and collaborators report on endocrinologist-led education for providers who profit from real-time feedback on cases, while increasing the reach of the specialist and bringing joy to their work (8).

In Australia, an eConsult service was implemented under the structure of endocrinologists from a tertiary hospital delivering help to GPs in Brisbane South. They suspect that with the right financial model, the dissemination of eConsults could address specialist waiting lists and promote integrated care (38). In a prospective randomized controlled study, Basudev (2016) showed that eConsults were as effective as traditional care for glycemic control, achieving clinically significant improvements in HbA1c (39).

By allowing more detailed patients care plans to be designed, thanks to the integration

of primary care with specialists in hospitals, they enable the patients with diabetes and their primary care team to interact more effectively. These innovative approaches represent a shift that follows the growing demand for primary care, the use of technology, and encouragement for more efficient care (40).

3. Project ECHO

Project ECHO (Extension for Community Healthcare Outcomes) is a scalable, global, evidence-based telementoring program whose goal is to advance the internal competency of primary care providers to maximize diabetes care through ongoing case-based learning. The project works with for example an endocrinologist that collaborates with geographically dispersed groups of primary care clinicians. These physicians report their cases, receive feedback on how to better manage diabetic plans, and continuously build local expertise. Initial centralization of knowledge acquisition proceeded by spread to multiple providers augments the reach of diabetology far beyond the specialist ability, which represents a good promise for the constant extent of new therapeutics to everyone. ENDO ECHO programs existed today in four countries and are of immense interest when providing primary care professionals with limited access to specialty services (8).

In New Mexico, USA, a multidisciplinary team Project ECHO promoted communication among primary care and community health workers (CHWs) in ten health centers. Among these professionals in rural and medically underserved areas, the participation in ENDO ECHO for 2 years had a substantial increase in confidence in dealing with complex diabetes case management. The authors concluded that the implementation of the ECHO program for complex diabetes care is helpful in resource-poor communities with no access to endocrinology (41).

Even though Project ECHO has been extensively spread, there has been, in general, an absence of a consistent evaluation of the model. This much be in part explained by the fact that most of the evidence on the project is linked to the hepatitis C program, the

condition for which it was first developed. Moreover, in the previously mentioned intervention conducted in New Mexico, the Project ECHO demonstrated a considerable short-term improvement in HbA1c, contrasting with the appropriate comparison group. So, one may expect that Project ECHO could provide benefits to glycemic control in the long-term (42).

4. Remote self-management

Remote self-management in diabetes care has already been explored in this review in the "Connected Diabetes Care" program which puts together the whole range of technological solutions to use, as a way to reproduce the traditional care, and ambitioning to produce better quality and outcomes together with in-person care. So, to summarize, the landscape of digital health, anchored in health information technologies, has at its disposals smartphone or web applications categorized as mobileHealth, plus device sensors and wearables that produce digital biomarkers, telehealth, and while incorporating those should be able to produce personalized care. Currently, digital health, digital medicine, and digital therapeutics are transforming the health care system.

It is important to understand the context of diabetes support technologies. In 2002, a study by Knowlerand and collaborators (43) demonstrated that intensive behavioral intervention aiming at diet and exercise considerably reduces people's risk of developing type 2 diabetes, being potentially more effective than medication. This finding led the US CDC to create the landmark Diabetes Prevention Program (DPP) in 2010. In addition, some companies pursued delivering the program digitally, as a more scalable and efficient option. They began to address weight loss in patients with obesity. In 2015, the CDC defined benchmarks to recognize in-person and online DPP interventions. Since then, virtual DPP interventions have grown in number. Most solutions focus on self-management, digital monitoring, social support, and interactions with live or automated coaches.

So, we have illustrated the potential and effectiveness of telemedicine to deliver remotely traditional integrated clinic care involving a variety of professionals. Next, we must identify the apps that incorporate one-on-one coaching (or the NPCD connected care) that precisely focus on lifestyle interventions, plus education, self-management support, and adherence to treatment. For example, in 2016, a weight-loss mobile DPP, which consisted of an app that incorporated food intake, physical activity, specific evidence-based weight-loss interventions, and motivational strategies, produced in less than 6 months an average 6-7% weight loss. Moreover, participants did highly adhere to the program with 84% of retention, showing a high engagement level and significant outcomes (44).

Despite smartphone and web-based interventions directly connecting patients with professionals, a higher degree of automation may represent a more scalable and efficient way to deliver DPP while being effective and adequate to the patients' preferences and needs. In this context, we must return to the AI or automated coaches. Through data acquisition, these algorithms and machine learning models identify how to best adapt to the patient's individuality. So, they provided all the services needed and available (self-management support on medication, lifestyle, glucose monitoring, education, and motivation) while learning the patient's behaviors. They deliver care in a more personalized approach, with the potential to reach high quality, continuum care, engagement, and expected health outcomes, and reducing drastically the resources needed to achieve these goals. We suggest they should be preferably adopted by patients that would benefit and want to self-manage their condition by interacting with an intelligent app rather than professionals, having in mind that in-person visits continue to be necessary and fundamental to complete care. For example, the first type 2 diabetes app available on prescription was approved by the FDA in 2017, which opened the door for evidence-based interventions delivered by software designed to manage and treat conditions in all specialties, they are mentioned as digital therapeutics. This is an example of a self-management patient coach that produces provider decision support to patients using automated and real-time behavioral messaging based on the individual data, sending quarterly summaries to the provider. In 2011, this automated coach demonstrated in one year an

extraordinary improvement of Hb1Ac (-1.9% in the maximal treatment group and -0.7% in the usual care group) (45). The authors then suggested that the association of behavioral mobile coaching with blood glucose, lifestyle behavior, and patient self-management data in a personalized approach and presented with evidence-based guidelines to providers, produced a considerable glycemic control.

In addition, we must consider that patients with diabetes have highly prevalent psychological distress, affecting health outcomes (46). Diabetes-specific distress, also known as diabetes burnout, can present symptoms as guilt, self-denial, and burden of self-management that causes an overwhelming emotional state. Meanwhile, mHealth represents a promise to assess patients' psychological well-being, it shows that through tailored messaging and structured emails it is possible to figure out psychosocial outcomes in patients with diabetes. Furthermore, wearables can produce digital biomarkers (heart rate and its variability, blood pressure, galvanic skin response, and physical activity) that can quantify stress being more reliable than questionnaires impacted which have social and self-reported biases (47). In 2017, Holland-Carter et al., in a randomized control trial loss-weight program, produced evidence of improved psychosocial outcomes among patients with diabetes (48).

Finally, there is potential in exergames - videogames that provide physical exercise increasing motivation for regular activity, and gamification of physical activity through technology, to provide an enjoyable new initiative, increasing exercise adherence in diabetic patients (49).

5. Remote monitoring

An estimation for the 2018 to 2030 period indicated that over 15% of type 2 diabetes patients in the world will need insulin therapy (50). Meanwhile, the evolution of connected technologies related the glucose monitoring such as continuous glucose monitors (CGMs), smart insulin pens, and insulin pumps, accommodated virtual registers of blood glucose levels and insulin administration regimens, which can be

shared with the care team. And as seen before, there are many more useful biomarker indicators that may be monitored.

CGMs give regular, reliable, real-time information and alerts. Very important to insulin-treated diabetic patients are hypoglycemia alerts. Also, the detection of asymptomatic and nocturnal hypoglycemia enables dose adjustments, which enhance clinicians' confidence to safely intensify insulin therapy. From another perspective, healthy lifestyle practices and motivation to exercise are boosted by the ability to review continuous glucose data, decreasing insulin resistance, and increasing cardiovascular health. In 2016, the first implantable CGM was made available, producing glucose data for up to 180 days. The American Diabetes Association (ADA) advocates that CGMs can be employed for lowering HbA1c and decrease hypoglycemia in adults with type 2 diabetes that are not reaching glycemic targets (51).

Smart insulin pens record doses and upload the data to an online platform. It becomes advantageous to combine smart insulin pens with CGM data and to share it with the care team (or a prescription app) that can remotely review and adjust the therapy. The data captured by the pens may identify those with lower adherence thus poor glycemic control and inform who would benefit from education and support with behavior modification (51).

Insulin pump therapy or continuous subcutaneous insulin infusion (CSII) have been used since the 1970s, seeking to reproduce the physiological insulin delivery. It administers rapid-acting insulin from a refillable reservoir into subcutaneous tissue via a cannula that is substituted every 2 to 3 days. Currently, UK's NICE encourages against the use of insulin pump therapy for patients with type 2 diabetes (52), and the ADA and European Association for the Study of Diabetes (EASD) consensus of 2018 shortly mention a limited role for CSII in a minority of type 2 diabetic patients (53). In a meta-analysis, Pickup *et al.* (2017) validated previous evidence of higher glycemic control in patients with poorly controlled type 2 diabetes and pointed to a one-quarter reduction in insulin needs and no weight change (54). As importantly, there was no increase in hypoglycemia episodes (55). Optimization of insulin therapy with CSII also proved to

decrease the need for concomitant oral anti-hyperglycemic medications, representing a cut in costs and polypharmacy (56). Reduced health care utilization argues in favor of the cost-effectiveness of this therapeutic delivery option. Nonetheless, it seems that health providers have limited expertise in the use of insulin pumps which represents an obstacle to the widespread adoption of this solution.

Other biological fluids have been studied for glucose determination, for example, the interstitial fluid, sweat, tears, saliva, and urine, since there is an interest in finding continuous and non-invasive glucose detection. Unfortunately, these new solutions are still not enough sensitive or reliable (57).

For activity and physiological indicators, we already have several devices and wearables, and in the future, these will improve in reliance and accuracy, as well as new biomarkers will be collected. Plus, with the internet of things, it will become possible to share home activity, blood pressure, weight, and other indicators with the care team, through automatic and manual data entry. These can help manage ongoing lifestyle changes and optimize treatment.

Then, processes have been made to try to provide remote foot and eye care, which still needs in-person visits. There are already some commercialized technologies to monitor foot ulcers (58). A smart mat measures the foot temperature daily detecting local inflammation produced by trauma, and it produced encouraging results (59). Smart socks as wearable devices, capture continuously digital biomarkers like plantar pressure, temperature, and big toe range of motion, but results are still unclear. A smart insole provides continuous screening of plantar pressure and alerts the patient when a continued pressure is identified, but it needs stronger evidence.

Finally, for retinopathy assessment, smartphones have been tried as retinal cameras, but the technology limitations do not make it an option for patients yet. So, researchers are using AI to try to develop reliable retinal disease detection from smartphone camera images (60).

6. Data use

Registries and data sources have information that allows a continuous increase in quality of care and health outcomes for diabetic patients. Evaluating and comparing diabetes outcomes, and recognizing the reasons for variation, permits to identify domains where better outcomes and efficiency gains may be obtained. Standardized outcome definitions and common data gathering procedures are fundamental to outcome comparison and following improvements. Being aware of existing silos in funding and prioritizing health data in healthcare management are crucial to using the power of registries and data. Creating the infrastructure to gather and interpret health data dispersed across the health system, as assuring the political will to enforce knowledge from outcomes data, is essential. Registries have the potential to gather abundant datasets that can instruct governing – including public health, public health policy, governance. They can identify and reward merit, signal services that need improvement, and determine therapies and treatment models that provide benefits for patients and payers (14). In Europe, the variety of existing diabetes registries and data sources makes it difficult to compare the quality of care and health outcomes. Some examples can represent good practices, but it is necessary to share experiences effectively to expedite the development and provide equitable effects for patients with diabetes (61).

New technologies are producing a transition from traditional diabetes care enlightened by a limited number of clinical indicators to a new era where patients, professionals, and researchers should have access to and share quality real-time and real-world data. This can allow better informed decisions and instant remote diabetes management by healthcare providers and motivate diabetic patients to greater self-management. This suggests substantial improvements in prevention of adverse outcomes. So, patients, payers, and professionals transitioning to a new model of healthcare can completely redesign healthcare delivery services. With the evolution of big data and artificial intelligence, the field of research can envision deep understandings thanks to real-world data. The data from EHRs, registries, health apps, connected devices, and other sources will revolutionize clinical trial data, being of

great interest for diabetes. Researchers will figure out what works based on abundant real-time, real-world datasets. So, the digital revolution must increase the awareness for health systems to be ready to implement this emerging evidence. With this knowledge in diabetes, effectiveness and access to treatments could increase (14).

Social Innovation

Socially disadvantaged populations have an unequal load of diabetes-related morbidity and mortality. As presented previously, although many programs to improve the quality of diabetes care are put in place and tested, nevertheless, the evidence of the use of these initiatives on disadvantaged groups is still unclear (62).

1. Therapeutic patient education

Therapeutic patient education (TPE) is, as the name indicates, a patient-centered approach because it places the patient at the heart of the process instead of the physician. It focuses on patients' needs, resources, and values, and does not limit to diabetes self-management education. The idea is that patients become empowered partners in the care team and experts on their management and on how to improve their lifestyle. Physicians have the role of coaches. TPE in diabetes involves a profound societal change, reinventing the social and medical dynamic between patients and providers. In the traditional compliance model, patients are passive members that receive the standardized information the physician provides to all patients. The physician is the expert who decides prescriptions and encourages lifestyle, diet, and exercise recommendations. TPE increases patients' knowledge and skills about their condition, but also their treatment. Thus, TPE gives a better quality of life, a greater therapeutic adherence, and a decrease in complications (63).

The most determinant part of the process is when patients need to change their behavior. Motivational and cognitive-behavior interventions are of great help, guiding patients by progressive step-by-step change. The investment in the resistance to change is elementary, and doubt when confronted with the choice of a new way of life must be evaluated, debated, and negotiated. The negotiation of goals must allow patients to decide their own strategies, which usually should cost them the least possible, psychologically, and provide maximal gains (63).

The effectiveness of patient-centered education leads to improved health and psychological outcomes in diabetes patients as a recent meta-analysis by Correia *et al.* documents (65). Other studies showed an 80% reduction of amputations in diabetes patients (66), and that 50% of obese patients keep their body weight loss after five years (67).

When we look at the implementation TPE program in Austria, we find barriers to the institutional disruption and change, created by diabetologists. On one side, there are those encouraging social innovation centered on the patient, and on the other side, those who want to maintain the "*status quo*" of practitioner-driven health. At the core of the TPE divergence was a claim that traditional care is ineffective for chronic conditions, and that evidence proves that patients are more effective in managing their condition, being TPE more effective then. So those defending the change and adoption of TPE argued that given the principle of "*primum non nocere*", it was ethically and morally indefensible wanting to preserve an established model when a more effective and proven one exits. Finally, the professional associations were able to lead the institutional work needed to implement TPE in Austria (64).

To implement TPE for diabetes, there is the need for (re)training health care professionals in this new approach providing patient-centered health. It demands from practitioners more time, understanding how to deal with lifestyle and socioeconomic needs of patients. This training is not currently provided in medical schools, requiring that health care professionals will acquire appropriate skills on how to instruct, educate, train, negotiate, motivate, and guide patients in the long-term follow-up of their condition (63).

2. Peer support

Peer support in diabetes occurs when diabetic patients help others through sharing their own experience, proposed as a way of improving the physical and mental health of patients. Peer support can be provided face-to-face by other patients, but also by

health professionals in education programs for self-management, by mentors or coaches sharing the experience of the condition, or by CHWs that link often-marginalized communities to health professionals (68).

Physicians seek to deliver their clinical knowledge but recognize that they lack experimental knowledge possessed by patients with diabetes which can be of considerable benefit. That is why they promote support by others with the condition. Peer support is suggested to increase the quality of life and self-care, but the evidence relating to health outcomes is unclear (68).

Finally, the first and foremost benefit may be when patients feeling lost and overwhelmed by the diagnosis and complex management of type 2 diabetes can talk to people who had experienced similar situations. This may provide another perspective of the disease, and by doing so, bring hope and openness to the education provided by the trained health professionals.

3. Integration of the Social and Health care

Across Europe, a shift to implement models of integrated care is clear, which should imply bringing together health and social care services. Nevertheless, it is not unusual for these care services to work in silos. Emphasis on primary and specialist care occasionally forgets other important elements of care. Cooperation between health and social care is essential to improve health outcomes, as well as to deliver a more holistic approach. Frequently these initiatives care for the elderly or chronic patients, but many want to reach a broader whole population approach at a regional level.

In the district of South Karelia, Finland, in 2010, primary, secondary, dental, and social care were integrated as one, delivered by an authority called Eksote, aiming to deliver patient-centered and locally tailored care. All citizens in the district are covered corresponding to 133,000 people, and services comprehend family and social welfare.

Eksote was able to reach one of its goals – efficiency – through savings in management, financial systems, and personnel costs. This was obtained by implementing the functional integration of having one administrative framework covering all services, with a developed set of common cultural values. Every citizen possesses one EHR that can be viewed by any health provider, and one Electronic Social Care Record.

They also created new welfare centers, substituting traditional health centers, with health and social care workers, digital health, prevention, and rehabilitation services. They have mobile clinics that provide care to rural areas. Finally, they implemented telecare reaching the important rural population.

Effects from the initial years showed considerable savings, increased health outcomes, and gains in productivity. Two of the outcomes observed were increase savings providing home care, and better responses to the integrated mental health and substance abuse service (69).

Table 2 – Innovations in diabetes care classified by their maturation phase

		Maturation phase					
Areas	Innovation type	Adoption	Implementation	Sustainability	Spread	Dissemination	Scale-up
Management	1. Integrated care					X	
	2. Risk-stratification		X				
	3. Connected diabetes care	X					
Financial	1. Bundle payments					X	
	2. Payment for performance					X	
	3. Shared savings					X	
	4. Other APMs*				X		
Technological	1. Telemedicine						X
	2. eConsult			X			
	3. Project ECHO**			X			
	4. Remote Self-Management				X		
	5. Remote Monitoring				X		
	6. Data use					X	
Social	1. Therapeutic Education					X	
	2. Peer support					X	
	3. Integrated Social care					X	

*APM: Alternative Payment Mode

** ECHO: Extension Community Healthcare Outcomes

Conclusions

As presented, the current model of care for diabetic patients is inadequate and fragmented. We conclude that it is necessary to introduce the innovations presented and documented in this work, within the scope of public policies of clinical practice / health care delivery. For example, the therapeutic patient education focuses on bringing behavioral changes through a motivational approach. For this to be implemented, the different health professionals need to work as a team around the patient that should be empowered to become actor and manager of his condition. This means bringing together patient-centered care and reframing health care delivery.

Diabetes is a disease that needs ongoing, long duration, and often multidisciplinary medical care. It also requires patient empowerment, literacy, adherence to treatment, and promotion of healthy behaviors. Nowadays, care is shifting to a holistic and patient-centered approach where the development of a new relationship model is central. Therefore, one must consider the need for significant professionals' reeducation programs.

Diabetes is a slow-motion pandemic evolving for over 40 years, leading to the St. Vincent Declaration of 1989. Diabetes has a high incidence worldwide, represents a substantial financial burden for healthcare systems, and is characterized by highly debilitating and preventable complications. Despite innovative therapies and increased adoption of digital health tools, it is expected that diabetes will keep growing in prevalence and costs. Neither pharmacological nor technological innovations alone will be sufficient to resolve this issue. Public health initiatives should be developed, for example the project ECHO to provide care to deprived populations. The whole system from the doctors to patients using these innovations and accepting a major shift in the medical practice needs to be taken into account. Changing the status quo becomes mandatory to bring better quality of life to chronic patients, and by doing so reduce the overall impact of chronic conditions. If not, this will continue to impact the healthcare systems' sustainability, as well as patients' quality of life and health professionals' workload. It becomes obvious that it is urgent to improve diabetes care

through innovative initiatives, such as technologies that increase access to care in developing countries, and that it needs to be addressed as a concerted major international public health challenge.

With this work we reviewed innovations that have been around for decades, which implementation and dissemination have not been linear, and improving care evidence is unclear or not substantial. We are not able to affirm that some of today's less efficient innovations cannot become highly beneficent in the near future, it means that there is the need to evolve, adapt and firmly evaluate. These innovations represent a huge potential to reach the goal of reducing the impact of diabetes.

Diabetes patients need an integrated care team that bridges hospitals, primary care, and social services. This team must include a variety of professionals who work together to mentor the patient that becomes an active member at the center of the team and an expert in the management of his condition. Risk stratification will be part of the service delivery, orientating resources to engage with high-risk patients. Advances in technology are helping to make these innovations a reality. The "connected diabetes care" model has the potential to increase access, as well as be effective and efficient, by reducing fragmentation of care, bringing flexibility and choice, and reducing waiting lists.

Financial innovations are essential to bringing new incentives to improve integrated health and social care and develop and deploy digital innovation. Blended payment models with bundle and performance payments, must be tested to find the better solutions to diabetes, embracing outcomes-driven healthcare and transitioning to the holistic approach of care.

Technologies seem to be able to break barriers and bring new ways of collaboration, but the limitations to their full implementation are precisely technical and they need embracement from the healthcare community. Through complementation of in-person care, they showed to be effective, providing a range of alternatives that best suit patients. Synergies between the remote and in-person world still have to be perfected, with a warning to not abuse virtual care. The world of exploring data will change considerably healthcare, complementing integrated care, helping to improve

systems, and bringing more useful information directly to patients, professionals, and researchers. But cybersecurity, patients' rights, and the misuse of data knowledge must be addressed by the legislators before the implementation of such innovations.

Social considerations are central in all this process. Social innovations bring change to the societal organization, and in the end, we can consider all previous innovations as actually social innovations too. They provide changes in relationships and empowerment through education, valuing community support, and leading the integration of social services as means to improve health outcomes.

In conclusion, diabetes care has been the stage of much innovation. The lessons learned are definitely useful for other chronic conditions. Innovations like integrated and connected care, patient centered education, peer support or bundle payments seem to be easily applicable with potential outcomes to other chronic diseases, like OCPD, cancer, dementia, or psychiatric conditions.

All over the world, resources and efforts have been deployed to bring innovation to diabetes care, as to reduce the burden costs, and transform quality care. With a financial and technological backbone, integrated health and social care may improve equitable health outcomes. The purpose is to advance approaches to chronic disease management supporting patient-centered care. The COVID-19 pandemic disrupted the healthcare environment and showed that it is possible to implement innovations in times of need. The momentum has to be grabbed, as the desire and duty to redesign healthcare will continue. There will be the need to improve managerial capacity, develop health information infrastructure, new training for healthcare professionals, as well as a shift of mindset from the doctor that delegates to other team members and prescribes to passive patients to the holistic patient-centered approach of care. Advocacy initiatives, community actions, and all stakeholders are being called to participate in the innovation process, improving the quality of life for people with diabetes and other chronic conditions.

References:

(1) Davies, M. J., D'Alessio, D. A., Fradkin, J., Kernan, W. N., Mathieu, C., Mingrone, G., Rossing, P., Tsapas, A., Wexler, D. J., & Buse, J. B. (2018). Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes care, 41(12), 2669–2701. https://doi.org/10.2337/dci18-0033

(2) International Diabetes Federation. IDF Diabetes Atlas. 10th ed.; 2021. https://diabetesatlas.org/atlas/tenth-edition/ (Accessed March 12th 2022)

(3) Cheung, B. M., Ong, K. L., Cherny, S. S., Sham, P. C., Tso, A. W., & Lam, K. S. (2009). Diabetes prevalence and therapeutic target achievement in the United States, 1999 to 2006. The American journal of medicine, 122(5), 443–453. https://doi.org/10.1016/j.amjmed.2008.09.047

(4) Catalyst, N. (2017). What Is Patient-Centered Care? NEJM Catalyst. https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0559

(5) Ellen Nolte (2018). Policy Brief. How do we ensure that innovation in health service delivery and organization is implemented, sustained and spread? © World Health Organization. https://www.euro.who.int/__data/assets/pdf_file/0004/380731/pb-tallinn-03-eng.pdf (Accessed March 12th 2022)

(6) Samal, L., Dykes, P.C., Greenberg, J.O. et al. Care coordination gaps due to lack of interoperability in the United States: a qualitative study and literature review. BMC Health Serv Res 16, 143 (2016). https://doi.org/10.1186/s12913-016-1373-y

(7) Timpel, P., Lang, C., Wens, J., Contel, J. C., Schwarz, P., & MANAGE CARE Study Group (2020). The Manage Care Model - Developing an Evidence-Based and Expert-Driven Chronic Care Management Model for Patients with Diabetes. *International journal of integrated care*, *20*(2), 2. https://doi.org/10.5334/ijic.4646

(8) Agarwal, S., Griffith, M. L., Murphy, E. J., Greenlee, C., Boord, J., & Gabbay, R. A. (2021). Innovations in Diabetes Care for a Better "New Normal" Beyond COVID-19. The Journal of clinical endocrinology and metabolism, 106(1), e377–e381. https://doi.org/10.1210/clinem/dgaa704

(9) Stellefson, M., Dipnarine, K., & Stopka, C. (2013). The chronic care model and diabetes management in US primary care settings: a systematic review. Preventing chronic disease, 10, E26. https://doi.org/10.5888/pcd10.120180

(10) Kong, J. X., Zhu, L., Wang, H. M., Li, Y., Guo, A. Y., Gao, C., Miao, Y. Y., Wang, T., Lu, X. Y., Zhu, H. H., & Patrick, D. L. (2019). Effectiveness of the Chronic Care Model in Type 2 Diabetes Management in a Community Health Service Center in China: A Group Randomized Experimental Study. Journal of diabetes research, 2019, 6516581. https://doi.org/10.1155/2019/6516581

(11) Bongaerts, B. W., Müssig, K., Wens, J., Lang, C., Schwarz, P., Roden, M., & Rathmann, W. (2017). Effectiveness of chronic care models for the management of type 2 diabetes mellitus in Europe: a systematic review and meta-analysis. BMJ open, 7(3), e013076. https://doi.org/10.1136/bmjopen-2016-013076

(12) Desmedt, M., Vertriest, S., Hellings, J., Bergs, J., Dessers, E., Vankrunkelsven, P., Vrijhoef, H., Annemans, L., Verhaeghe, N., Petrovic, M., & Vandijck, D. (2016). Economic Impact of Integrated Care Models for Patients with Chronic Diseases: A Systematic Review. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research, 19(6), 892–902. https://doi.org/10.1016/j.jval.2016.05.001

(13) Boehmer, K. R., Abu Dabrh, A. M., Gionfriddo, M. R., Erwin, P., & Montori, V. M. (2018). Does the chronic care model meet the emerging needs of people living with multimorbidity? A systematic review and thematic synthesis. PloS one, 13(2), e0190852. https://doi.org/10.1371/journal.pone.0190852

(14) EFPIA White paper (2019) Improving Outcomes For People With Diabetes: The role of health data, access to innovation and rethinking care. https://www.efpia.eu/media/413307/improving-outcomes-for-people-with-diabetes.pdf (Accessed March 12th 2022)

(15) Basudev, N. (2021), Shaping the future of diabetes care: innovation, people and partnerships. Pract Diab, 38: 10-15. https://doi.org/10.1002/pdi.2365

(16) Wake, D. J., Gibb, F. W., Kar, P., Kennon, B., Klonoff, D. C., Rayman, G., Rutter, M. K., Sainsbury, C., & Semple, R. K. (2020). Endocrinology in the time of COVID-19: Remodelling diabetes services and emerging innovation. European journal of endocrinology, 183(2), G67–G77. https://doi.org/10.1530/EJE-20-0377

(17) Levine, B. J., Close, K. L., & Gabbay, R. A. (2020). A care team-based classification and population management schema for connected diabetes care. *NPJ digital medicine*, *3*, 104. https://doi.org/10.1038/s41746-020-00313-3

(18) Saulsberry, L., & Peek, M. (2019). Financing Diabetes Care in the U.S. Health System: Payment Innovations for Addressing the Medical and Social Determinants of Health. Current diabetes reports, 19(11), 136. https://doi.org/10.1007/s11892-019-1275-6

(19) de Bakker, D. H., Struijs, J. N., Baan, C. B., Raams, J., de Wildt, J. E., Vrijhoef, H. J., & Schut, F. T. (2012). Early results from adoption of bundled payment for diabetes care in the Netherlands show improvement in care coordination. Health affairs (Project Hope), 31(2), 426–433. https://doi.org/10.1377/hlthaff.2011.0912

(20) Karimi, M., Tsiachristas, A., Looman, W., Stokes, J., Galen, M. V., & Rutten-van Mölken, M. (2021). Bundled payments for chronic diseases increased health care expenditure in the Netherlands, especially for multimorbid patients. Health policy (Amsterdam, Netherlands), 125(6), 751–759. https://doi.org/10.1016/j.healthpol.2021.04.004

(21) Mohnen, S., Baan, C., & Struijs, J. (2015). Bundled Payments for Diabetes Care and Healthcare Costs Growth: A 2-Year Follow-up Study. The American Journal of Accountable Care, 12(15), 63–70.

(22) Huang, J., Yin, S., Lin, Y., Jiang, Q., He, Y., & Du, L. (2013). Impact of pay-for-performance on management of diabetes: a systematic review. Journal of evidence-based medicine, 6(3), 173–184. https://doi.org/10.1111/jebm.12052

(23) Zaresani, A., Scott, A. Is the evidence on the effectiveness of pay for performance schemes in healthcare changing? Evidence from a meta-regression analysis. BMC Health Serv Res 21, 175 (2021). https://doi.org/10.1186/s12913-021-06118-8

(24) Roland, M., & Guthrie, B. (2016). Quality and Outcomes Framework: what have we learnt?. BMJ (Clinical research ed.), 354, i4060. https://doi.org/10.1136/bmj.i4060

(25) Hsieh, H. M., Gu, S. M., Shin, S. J., Kao, H. Y., Lin, Y. C., & Chiu, H. C. (2015). Cost-Effectiveness of a Diabetes Pay-For-Performance Program in Diabetes Patients with Multiple Chronic Conditions. PloS one, 10(7), e0133163. https://doi.org/10.1371/journal.pone.0133163

(26) Chen Y-C, Lee CT-C, Lin BJ, Chang Y-Y, Shi H-Y. Impact of pay-for-performance on mortality in diabetes patients in Taiwan. Medicine. 2016;95:e4197. https://doi.org/10.1097/MD.0000000000004197.

(27) Hui-Min Hsieh, Herng-Chia Chiu, Yi-Ting Lin, Shyi-Jang Shin, A diabetes pay-for-performance program and the competing causes of death among cancer survivors with type 2 diabetes in Taiwan, International Journal for Quality in Health Care, Volume 29, Issue 4, August 2017, Pages 512–520, https://doi.org/10.1093/intqhc/mzx057

(28) Kung, F. P., Tsai, C. F., Lu, C. L., Huang, L. C., & Lu, C. H. (2020). Diabetes pay-for-performance program can reduce all-cause mortality in patients with newly diagnosed type 2 diabetes mellitus. *Medicine*, *99*(7), e19139. https://doi.org/10.1097/MD.0000000000019139

(29) McWilliams, J. M., Najafzadeh, M., Shrank, W. H., & Polinski, J. M. (2017). Association of Changes in Medication Use and Adherence With Accountable Care Organization Exposure in Patients With Cardiovascular Disease or Diabetes. *JAMA cardiology*, *2*(9), 1019–1023. https://doi.org/10.1001/jamacardio.2017.2172

(30) Murray, R., Delbanco, S. F. (2018). The Evidence On Shared Savings: Do We Know Enough?, Health Affairs Blog, July 17, 2018. DOI: 10.1377/hblog20180705.615709 –

(31) Ouayogodé, M. H., Colla, C. H., & Lewis, V. A. (2017). Determinants of success in Shared Savings Programs: An analysis of ACO and market characteristics. *Healthcare (Amsterdam, Netherlands)*, *5*(1-2), 53–61. https://doi.org/10.1016/j.hjdsi.2016.08.002

(32) Faruque, L. I., Wiebe, N., Ehteshami-Afshar, A., Liu, Y., Dianati-Maleki, N., Hemmelgarn, B. R., Manns, B. J., Tonelli, M., & Alberta Kidney Disease Network (2017). Effect of telemedicine on glycated hemoglobin in diabetes: a systematic review and meta-analysis of randomized trials. CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne, 189(9), E341–E364. https://doi.org/10.1503/cmaj.150885

(33) Athinarayanan, S. J., Adams, R. N., Hallberg, S. J., McKenzie, A. L., Bhanpuri, N. H., Campbell, W. W., Volek, J. S., Phinney, S. D., & McCarter, J. P. (2019). Long-Term Effects of a Novel Continuous Remote Care Intervention Including Nutritional Ketosis for the Management of Type 2 Diabetes: A 2-Year Non-randomized Clinical Trial. Frontiers in endocrinology, 10, 348. https://doi.org/10.3389/fendo.2019.00348

(34) Lee, S.W.H., Chan, C.K.Y., Chua, S.S. et al. Comparative effectiveness of telemedicine strategies on type 2 diabetes management: A systematic review and network meta-analysis. Sci Rep 7, 12680 (2017). https://doi.org/10.1038/s41598-017-12987-z

(35) Hallberg, S., & Harrison, D. (2021). Telemedicine via Continuous Remote Care: A Proactive, Patient-Centered Approach to Improve Clinical Outcomes. JMIR diabetes, 6(4), e23646. https://doi.org/10.2196/23646

(36) Odom, J., Beauchamp, C., Fiocchi, C., Eicken, M., Stancil, M., Turner, J., & Bruch, J. (2020). Rapid Innovation in Diabetes Care During Covid-19. ADCES in Practice, 8(6), 28–32. https://doi.org/10.1177/2633559X20951168

(37) Vimalananda, V. G., Gupte, G., Seraj, S. M., Orlander, J., Berlowitz, D., Fincke, B. G., & Simon, S. R. (2015). Electronic consultations (e-consults) to improve access to specialty care: a systematic review and narrative synthesis. *Journal of telemedicine and telecare*, *21*(6), 323–330. https://doi.org/10.1177/1357633X15582108

(38) Russell, A. W., Adkins, P., Hayes, L., Prior, E., McCormack, C., & DiGregorio, J. (2021). Electronic consultations (eConsults): a proof of concept trial in Australia. Internal medicine journal, 10.1111/imj.15495. Advance online publication. https://doi.org/10.1111/imj.15495

(39) Basudev, N., Crosby-Nwaobi, R., Thomas, S., Chamley, M., Murrells, T., & Forbes, A. (2016). A prospective randomized controlled study of a virtual clinic integrating primary and specialist care for patients with Type 2 diabetes mellitus. Diabetic medicine : a journal of the British Diabetic Association, 33(6), 768–776. https://doi.org/10.1111/dme.12985

(40) Mold, F., Hendy, J., Lai, Y. L., & de Lusignan, S. (2019). Electronic Consultation in Primary Care Between Providers and Patients: Systematic Review. *JMIR medical informatics*, *7*(4), e13042. https://doi.org/10.2196/13042

(41) Bouchonville, M. F., Hager, B. W., Kirk, J. B., Qualls, C. R., & Arora, S. (2018). Endo ECHO improves primary care provider and community health worker self-efficacy in complex diabetes management in medically underserved communities. Endocrine practice : official journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists, 24(1), 40–46. https://doi.org/10.4158/EP-2017-0079

(42) Blecker, S., Paul, M. M., Jones, S., Billings, J., Bouchonville, M. F., Hager, B., Arora, S., & Berry, C. A. (2021). A Project ECHO and Community Health Worker Intervention for Patients with Diabetes. *The American journal of medicine*, S0002-9343(21)00811-1. Advance online publication. https://doi.org/10.1016/j.amjmed.2021.12.002

(43) Knowler, W. C., Barrett-Connor, E., Fowler, S. E., Hamman, R. F., Lachin, J. M., Walker, E. A., Nathan, D. M., & Diabetes Prevention Program Research Group (2002). Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. The New England journal of medicine, 346(6), 393–403. https://doi.org/10.1056/NEJMoa012512

(44) Michaelides, A., Raby, C., Wood, M., Farr, K., & Toro-Ramos, T. (2016). Weight loss efficacy of a novel mobile Diabetes Prevention Program delivery platform with human coaching. BMJ open diabetes research & care, 4(1), e000264. https://doi.org/10.1136/bmjdrc-2016-000264

(45) Quinn, C. C., Shardell, M. D., Terrin, M. L., Barr, E. A., Ballew, S. H., & Gruber-Baldini, A. L. (2011). Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. Diabetes care, 34(9), 1934–1942. https://doi.org/10.2337/dc11-0366

(46) Holt, R. I., de Groot, M., & Golden, S. H. (2014). Diabetes and depression. Current diabetes reports, 14(6), 491. https://doi.org/10.1007/s11892-014-0491-3

(47) Bassi, G., Gabrielli, S., Donisi, V., Carbone, S., Forti, S., & Salcuni, S. (2021). Assessment of Psychological Distress in Adults With Type 2 Diabetes Mellitus Through Technologies: Literature Review. Journal of medical Internet research, 23(1), e17740. https://doi.org/10.2196/17740

(48) Holland-Carter, L., Tuerk, P. W., Wadden, T. A., Fujioka, K. N., Becker, L. E., Miller-Kovach, K., Hollander, P. L., Garvey, W. T., Weiss, D., Rubino, D. M., Kushner, R. F., Malcolm, R. J., Raum, W. J., Hermayer, K. L., Veliko, J. L., Rost, S. L., Sora, N. D., Salyer, J. L., & O'Neil, P. M. (2017). Impact on psychosocial outcomes of a nationally available weight management program tailored for individuals with type 2 diabetes: Results of a randomized controlled trial. Journal of diabetes and its complications, 31(5), 891–897. https://doi.org/10.1016/j.jdiacomp.2017.01.022

(49) Höchsmann, C., Walz, S.P., Schäfer, J. et al. Mobile Exergaming for Health—Effects of a serious game application for smartphones on physical activity and exercise adherence in type 2 diabetes mellitus—study protocol for a randomized controlled trial. Trials 18, 103 (2017). https://doi.org/10.1186/s13063-017-1853-3

(50) Basu, S., Yudkin, J. S., Kehlenbrink, S., Davies, J. I., Wild, S. H., Lipska, K. J., Sussman, J. B., & Beran, D. (2019). Estimation of global insulin use for type 2 diabetes, 2018-30: a microsimulation analysis. The lancet. Diabetes & endocrinology, 7(1), 25–33. https://doi.org/10.1016/S2213-8587(18)30303-6

(51) Daly, A., & Hovorka, R. (2021). Technology in the management of type 2 diabetes: Present status and future prospects. Diabetes, obesity & metabolism, 23(8), 1722–1732. https://doi.org/10.1111/dom.14418

(52) National Institute for Health and Care Excellence (NICE) Technology appraisal guidance (TA151). Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. Available from: http://nice.org.uk/guidance/ta151 (Accessed March 12th 2022)

(53) Davies, M. J., D'Alessio, D. A., Fradkin, J., Kernan, W. N., Mathieu, C., Mingrone, G., Rossing, P., Tsapas, A., Wexler, D. J., & Buse, J. B. (2018). Management of hyperglycaemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetologia, 61(12), 2461–2498. https://doi.org/10.1007/s00125-018-4729-5

(54) Pickup, J. C., Reznik, Y., & Sutton, A. J. (2017). Glycemic Control During Continuous Subcutaneous Insulin Infusion Versus Multiple Daily Insulin Injections in Type 2 Diabetes: Individual Patient Data Meta-analysis and Meta-regression of Randomized Controlled Trials. Diabetes care, 40(5), 715–722. https://doi.org/10.2337/dc16-2201

(55) Reznik, Y., Cohen, O., Aronson, R., Conget, I., Runzis, S., Castaneda, J., Lee, S. W., & OpT2mise Study Group (2014). Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (OpT2mise): a randomised open-label controlled trial. Lancet (London, England), 384(9950), 1265–1272. https://doi.org/10.1016/S0140-6736(14)61037-0

(56) Lynch, P. M., Riedel, A. A., Samant, N., Fan, Y., Peoples, T., Levinson, J., & Lee, S. W. (2010). Resource utilization with insulin pump therapy for type 2 diabetes mellitus. The American journal of managed care, 16(12), 892–896.

(57) Pullano, S. A., Greco, M., Bianco, M. G., Foti, D., Brunetti, A., & Fiorillo, A. S. (2022). Glucose biosensors in clinical practice: principles, limits and perspectives of currently used devices. Theranostics, 12(2), 493–511. https://doi.org/10.7150/thno.64035

(58) Najafi, B., & Mishra, R. (2021). Harnessing Digital Health Technologies to Remotely Manage Diabetic Foot Syndrome: A Narrative Review. Medicina (Kaunas, Lithuania), 57(4), 377. https://doi.org/10.3390/medicina57040377

(59) Frykberg, R. G., Gordon, I. L., Reyzelman, A. M., Cazzell, S. M., Fitzgerald, R. H., Rothenberg, G. M., Bloom, J. D., Petersen, B. J., Linders, D. R., Nouvong, A., & Najafi, B. (2017). Feasibility and Efficacy of a Smart Mat Technology to Predict Development of Diabetic Plantar Ulcers. Diabetes care, 40(7), 973–980. https://doi.org/10.2337/dc16-2294

(60) Madanagopalan, V. G., & Raman, R. (2020). Commentary: Artificial intelligence and smartphone fundus photography - Are we at the cusp of revolutionary changes in retinal disease detection?. Indian journal of ophthalmology, 68(2), 396–397. https://doi.org/10.4103/ijo.IJO_2175_19

(61) Carinci, F., Štotl, I., Cunningham, S. G., Poljicanin, T., Pristas, I., Traynor, V., … Benedetti, M. M. (2021). Making Use of Comparable Health Data to Improve Quality of Care and Outcomes in Diabetes: The EUBIROD Review of Diabetes Registries and Data Sources in Europe. Frontiers in Clinical Diabetes and Healthcare, 2. https://doi.org/10.3389/fcdhc.2021.744516

(62) Lu, J. B., Danko, K. J., Elfassy, M. D., Welch, V., Grimshaw, J. M., & Ivers, N. M. (2018). Do quality improvement initiatives for diabetes care address social inequities? Secondary analysis of a systematic review. BMJ open, 8(2), e018826. https://doi.org/10.1136/bmjopen-2017-018826

(63) Golay, A., Lagger, G., Chambouleyron, M., Carrard, I. and Lasserre-Moutet, A. (2008), Therapeutic education of diabetic patients. Diabetes Metab. Res. Rev., 24: 192-196. https://doi.org/10.1002/dmrr.798

(64) Windrum P, Schartinger D, Waring J. Co-creation of social innovations and new professional institutions: diffusion of therapeutic patient education (TPE) for diabetes in Austria. Ind Innovat. 2018;25(6):570–93. https://doi.org/10.1080/13662716.2017.1295363

(65) Correia, J. C., Waqas, A., Golay, A., & Pataky, Z. (2022). Évolution et efficacité de l'éducation thérapeutique du patient pour l'obésité et le diabète [Evolution and effectiveness of therapeutic patient education for obesity and diabetes]. *Revue medicale suisse*, *18*(774), 512–515. https://doi.org/10.53738/REVMED.2022.18.774.512

(66) Assal, J. P., Albeanu, A., Peter-Riesch, B., & Vaucher, J. (1993). Coût de la formation du patient atteint d'un diabète sucré. Effets sur la prévention des amputations [Cost of training a diabetes mellitus patient. Effects on the prevention of amputation]. *Diabete & metabolisme*, *19*(5 Suppl), 491–495.

(67) Golay, A., Buclin, S., Ybarra, J., Toti, F., Pichard, C., Picco, N., de Tonnac, N., & Allaz, A. F. (2004). New interdisciplinary cognitive-behavioural-nutritional approach to obesity treatment: a 5-year follow-up study. *Eating and weight disorders : EWD*, *9*(1), 29–34. https://doi.org/10.1007/BF03325042

(68) Simmons, D., Bunn, C., Cohn, S., & Graffy, J. (2013). What is the idea behind peer-to-peer support in diabetes? Diabetes Management, 3(1), 61–70. https://doi.org/10.2217/dmt.12.80

(69) Anna Davies,Victoria Boelman (2015) Policy Paper: Social Innovation In Health And Social Care. The Young Foundation. https://www.si-drive.eu/wp-content/uploads/2016/02/social_innovation_in_health_and_social_care_january_2016.pdf (Accessed March 12th 2022)