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Efficient and Effective Diabetes Care in the Era of Digitalization and Hypercompetitive Research Culture: A Focused Review in the Western Pacific Region with Malaysia as a Case Study

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ABSTRACT

There are approximately 220 million (about 12% regional prevalence) adults living with diabetes mellitus (DM) with its related complications, and morbidity knowingly or unconsciously in the Western Pacific Region (WP). The estimated healthcare cost in the WP and Malaysia was 240 billion USD and 1.0 billion USD in 2021 and 2017, respectively, with unmeasurable suffering and loss of health quality and economic productivity. This urgently calls for nothing less than concerted and preventive efforts from all stakeholders to invest in transforming healthcare professionals and reforming the healthcare system that prioritizes primary medical care setting, empowering allied health professionals, improvising health organization for the healthcare providers, improving health facilities and non-medical support for the people with DM. This article alludes to challenges in optimal diabetes care and proposes evidence-based initiatives over a 5-year period in a detailed roadmap to bring about dynamic and efficient healthcare services that are effective in managing people with DM using Malaysia as a case study for reference of other countries with similar backgrounds and issues. This includes a scanning on the landscape of clinical research in DM, dimensions and spectrum of research misconducts, possible common biases along the whole research process, key preventive strategies, implementation and limitations toward high-quality research. Lastly, digital medicine and how artificial intelligence could contribute to diabetes care and open science practices in research are also discussed.

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Introduction

Worldwide, except in a few developed countries, the incidence and prevalence of pre-diabetes and diabetes mellitus (DM) continue to rise without much improvement in the achievement of treatment targets.¹⁻⁵ It was estimated that 206 million adult (20-79 year-old) DM live in the Western Pacific Region (WP) in 2021.² This constitutes about 12% of the regional prevalence of adults living with DM knowingly or unknowingly.

This is estimated to increase to 260 million by 2045. Furthermore, 300 million adults in WP have dysglycaemia, and this is projected to reach 335 million by 2030 and 350 million by 2045.² Approximately 110 million adults have undiagnosed DM in WP, and 1 in 7 live births were affected by hyperglycemia in pregnancy.²

In tandem with that is the increase in diabetes-related complications, morbidity, mortality, and healthcare cost.⁶⁻⁸ In 2021, the estimated total deaths related to DM was

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2.3 million deaths in WP and a total of about 240 billion USD was spent on healthcare for people with DM in this region.² The estimated total health-care cost for DM in Malaysia was .0 billion USD (45.4% of total costs) in 2017.⁷ Therefore, more concerted and preventive efforts are needed to reduce this burden, and to provide more efficient and effective diabetes care in prioritized healthcare settings.⁹ Sufficient and continuous investment in healthcare systems delivery includes healthcare professionals who are directly involved in diabetes care to have the right knowledge and skills that should not be compromised.¹⁰ Evidence has shown that healthcare professionals in primary care, by seeing people with DM at the earlier stages, with multimorbidity and have a lower risk profile,^{9,11,12} are more likely to contribute to significant cost-effective and health-promoting effects such as achieving disease targets control, self-efficacy, self-care, emotional wellbeing and quality of life,^{13–15} as compared to hospital-based specialty care.^{16,17} This has also been associated with enhanced access to healthcare services, better health outcomes, and a decrease in hospitalization and use of emergency department visits, and a more equitable distribution of health in populations.^{18,19} Therefore, primary medical care needs to be properly designed, supported, and invested in to bring about the greatest health outcomes in diabetes care for the country.^{20,21}

The challenges of effective and efficient diabetes care have been likened to a “Double Valleys” of uphill tasks that require patients and physicians to perform, behave and be assisted to climb their respective slopes to reach the peak of good outcomes.²² Patient’s health behaviors need continuous support with accessibility to health services such as personal coaching, psycho-educational programmes and timely medical emergency care, affordable medical and surgical therapies, availability of all required screening facilities, availability of the necessary laboratory tests with optimal turnaround time, and continuous accessibility to all types of medications.²² Many of these health behaviors likely to arise from aligned health beliefs, formed from good health knowledge (literacy) with that of their physicians, which in combination would affect the patient’s motivation in effective self-care.^{22,23} Most importantly, the attitude of trust in patients is affected by the attitudes of the treating physicians and delivery of the healthcare services.^{22,24} Physicians require regular trainings and updates on diabetes care and prescribing habits.^{25,26} They also require a conducive clinical environment for consultations with patients for an appropriate length of time, enabled by efficient appointment systems.^{27,28} Physicians also require adequate remuneration, incentives, and attractive career development paths.²⁹ While robust primary health care support requires the

presence of dedicated allied health team members in the management of both the medical and non-medical aspects of patient care.³⁰ This system also demands multiple risk factors management, supportive secondary care services, and a well administered registry that allows for periodic assessment of clinical performance.²²

This article proposes initiatives a country can take to tackle suboptimal diabetes care and control of comorbidities,^{31,32} and to institute dynamic and efficient healthcare services that are effective in managing people with DM. It is a multicomponent medical-health-social system with a multitiered societal and population-based prevention strategy, taking into account the effect of professional clinical care on society—population—community interacting with the environment—agent—host.³³ The plan envisions a five-year transformation and reformation initiatives at the primary care settings where certain parts can be adaptable to private clinic or hospital practice. It is also assumed that a better healthcare service (the supply side) would attract a positive change of health-seeking behaviors and health literacy in a population (the demand side). These proposed initiatives involve multiple stakeholders at administrative levels including non-medical institutions responsible for the social and welfare services.³³ The complexity of this initiative does not stop short of also requiring strong political will, public and health-related non-governmental organizations advocacy and/or counter-lobbyists to meet this health agenda. Until these transformation are executed and sustained,³⁴ efficient and effective diabetes care is expected to be sporadic at health clinics that adopt the suggested interventions and planned actions.³⁵ Notwithstanding, at any scale this plan is believed to return health benefits, a higher quality of life, greater economic productivity, reduced morbidity and mortality, and lower healthcare cost.³³

Accordingly, the objectives of this article were to explore how the healthcare system could be reformed to provide optimal diabetes care, identify the main challenges and key strategies for ensuring high-quality clinical research in DM amidst digitalization and hyper-competitive research culture, and examine the potential contributions of digital medicine, artificial intelligence, and open science practices to diabetes care and research.

Materials and Methods

This focused review of literature attempts to update and delineate practical recommendations to achieve an efficient and effective diabetes care at primary care setting based on the latest guidelines from major societies, overviews and different types of syntheses articles. A narrative synthesis was completed to answer these review questions: 1) How can the healthcare system be

reformed to provide optimal diabetes care? 2) What are the main challenges in conducting and key strategies to ensure high-quality clinical research in DM in the era of digitalization and hypercompetitive research culture? 3) How might digital medicine and artificial intelligence contribute to diabetes care? 4) What role does open science practices play in the context of diabetes research? Results were contextualized to the Malaysian healthcare system with specific time-based suggestion of improvements, and potential approaches in digital medicine and open science for diabetes care were presented broadly. As many clinical practice guidelines and treatment algorithms currently exist in varying details between countries, the aim of this focused review is not to provide new guidelines but to give more of “How to do” advice than “What to do” discussion, to get more patients to the recommended treatment targets. It strives to offer immediate suggestions that are useful in making important decisions to improvise existing services, and to prepare for the future of digital medicine with mobile technology, electronic- and internet-assisted healthcare.³⁶ Discussions are also provided on initiatives to encourage higher quality research in diabetes care.

Results and Discussion

Healthcare System Reforms to Provide Optimal Diabetes Care

Principles of Effective Diabetes Care

Effective diabetes care refers to achieving the desired, personalized, and important treatment outcomes through appropriate treatment strategies and psychosocial approaches.^{37,38} An efficient diabetes care will be the care process that is timely, safe and sustainable where evidence-based mechanisms overcome the contextual challenges leading to the best outcomes, and with an appropriately use of technology.³⁹ These features in diabetes care overlap to some extent as effective treatments would encourage efficient use of resources, and efficient delivery systems often enhance treatment effectiveness safe and cheap. It is a fact that on some occasions, in a selected group of patients fewer effective therapeutic interventions are all that is available and acceptable, or on other occasions, to limit damage and mitigate an extreme risk, a significantly less effective strategy must be employed.

Current Initiatives and Evaluations

There were many initiatives in the developed countries but few in the developing countries to improve primary diabetes care.^{40,41} The Enhanced Primary Healthcare (EnPHC) in Malaysia was an integrated care model

comprising multifaceted evidence-based interventions in 20 public primary healthcare clinics.⁴² The project compared the enhanced services and improved efficient utilization of existing infrastructure and human resources to 20 control clinics in the management and prevention of DM.⁴³ It improved only process of care but not disease control (HbA1c, low-density lipoprotein and blood pressure).⁴³ The process evaluation disclosed issues of human resources such as having a care coordinator to lead the team, having doctors or better trained healthcare providers to conduct health education,¹² and conducive physical infrastructure during implementation.⁴⁴ At post-intervention, the healthcare providers especially the nurses in the intervention clinics reported higher level of stress, experiencing more dissatisfaction at work, and were less likely to perceive their profession as well-respected,⁴⁵ and questionable sustainability.²¹ Beside EnPHC, there were smaller scale initiatives at the healthcare delivery system²⁰ and using psychological interventions,⁴⁶ which showed limited effects on the important clinical outcomes.

Strategic Interventions on Possible Causes

Tables 1,2 describe the possible causes, interventions, and a roadmap to improve diabetes care at primary care levels over a 5-year period. Table 1 offers a comprehensive framework for understanding the causes of suboptimal diabetes care and provides possible interventions to address these issues.⁶⁸ The suggested actions are elaborated in Table 2 underscoring the need for a multifaceted strategy that includes healthcare system improvements, ongoing healthcare professional training, and patient-centered interventions, all implemented over varying timeframes to enhance the quality of diabetes care.

Challenges to Ensure Quality Research and Strategies to Achieve Quality Research

Higher Quality Research in Diabetes Care

Optimal treatment of DM requires high-quality and translational research. These inevitably result from participation of people with DM in clinical research as the healthcare consumers in managing personal aspects of the disease. Healthcare consumers decide whether to adhere to prescribed medication and healthful lifestyles with more physical activity and cardio-metabolic friendly diets. Involving healthcare consumers in the self-management of diseases such as in monitoring their disease status and adjusting their medication dosage (e.g., insulin) can improve health outcomes.^{22,69} Accordingly, an important function of research on

Table 1. The possible causes of suboptimal diabetes care, interventions and planned actions²².

No.	Causes	Possible Interventions (Supported by literature)	Plan of Action (Refer to Table 2)
1	Healthcare system (including policymakers): costs of new medications, formulary limitations and health delivery or working system that does not facilitate and support proper use of screening services, and treatment/medication.	Improve medications availability, accessibility, and affordability. Care management interventions which include virtual coaching of patients by healthcare professionals including use of mobile applications, telemonitoring, point-of-care testing, and use of alerts, shared-decision-making tools, or embedded practice advisories in the electronic health record or other practice quality improvement programmes. Also empowering diabetes educators, nurses, dietitians, nutritionists and pharmacists in lifestyle/dietary intake and medication review and modification within acceptable and evidence-based scopes. Due attention to the organisation culture and working system that encourage intrinsic ability of healthcare professionals and best clinical performance.	<ul style="list-style-type: none"> • Item 2, 3 and 5 in the short-term (within one year) • Item 7 to 9 in the medium-term (within three years) • Item 10 to 13 in the long-term (three to five years)
2	Physician/Health professionals: competing priorities and lack of time, overconfidence in the quality of care and adherence to guidelines, lack of awareness of clinical inertia, delay in adopting new guidelines, discomfort, or lack of familiarity with prescribing new medications, and perceptions that patients will not be amenable or adherent to medication changes and healthy living recommendations.	Programmes delivered to physicians and other healthcare professionals who are involved in diabetes care including diabetes educators, dietitians, nurses, or pharmacists that are designed to influence their behaviour such as educational programmes, feedback or reminders, medication knowledge and management, medical audit of health records to improve prescribing habits, and trainings on patient-centred communication skills. Nurses, diabetes educators, dietitians and pharmacists are regularly updated on medications, treatment guidelines and diabetes lifestyle recommendations to provide professional support to patients on medication use and lifestyle changes.	<ul style="list-style-type: none"> • Item 1 and 4 in the short-term (within one year) • Item 6 in the medium-term (within three years) • Item 11 and 12 in the long-term (three to five years)
3	Patient-level factors: misperceptions about medication use, fear of unwanted side effects, and the impact of social determinants of health. This medication (non-) adherence may compound therapeutic inertia where medications are less effective, affordable or available.	Patient education or structured patient education programmes, family or peer support programmes, psychoeducation, or psychological interventions to improve health literacy, self-efficacy and practical self-care activities (a diabetes lifestyle intervention). These require a holistic approach including use of digital health technologies, non-medical interventions on social determinants of health.	<ul style="list-style-type: none"> • Item 6 and 8 in the medium-term (within three years) • Item 11 in the long-term (three to five years)

A part of Table 1 is adapted from Table 1. Causes and Possible Interventions for Therapeutic Inertia in Chew BH, et al. Overcoming Therapeutic Inertia as the Achilles' Heel for Improving Suboptimal Diabetes Care: An Integrative Review. DOI: <https://doi.org/10.3803/EnM.2022.1649>.

diabetes care services is therefore to acquire the best approaches that encourage and support people with DM to self-manage successfully by adopting healthy behaviors. Similarly, the engagement of clinicians and health facility staff in research would also improve healthcare performance.⁷⁰ However, the amount of information, encouragement, and support that can be conveyed during consultations by the physicians or educational classes by healthcare professionals or peer-supports within the existing service infrastructures or through other traditional media (such as leaflets), is limited. Moreover, the availability of high-quality scientific evidence in diabetes research to guide clinical practice is insufficient in many countries including Malaysia.⁷¹ Real-world observational studies should be used judiciously⁷² and upgraded accordingly with enhancement from big data.³³

There are some recent notable non-drug clinical trials in diabetes care in Malaysia but appeared to be incomplete in reporting or sufficiently thorough in the methods and analysis,^{10,73–81} sample size issue,

efficiency in the trial conduct,^{82,83} reported inconclusive negative results,^{46,84–86} and avoidable salami publication.^{82,87,88} The integrity of scientific research can be compromised by misconducts and biases, which have the potential to undermine the reliability and objectivity of research outcomes, risking public trust in science and incurring high-cost in their handling.⁸⁹ Biased clinical and biomedical research in DM may range from non-intentional errors to intentional frauds (Figure 1).⁹⁰ This may occur at any stage during the proposal, design, performance, recording, supervision, or review of research, or in the report of research results. Biased research (Figure 2)^{89,91–94} not only skews our understanding of diabetology but can also have profound consequences for decision-making, policy formulation, and the overall advancement in diabetes care. Table 3 enlists some of the common and serious biases in diabetes research and proposes preventive plans with discussion of potential implementation and limitations that researchers and institutional stakeholders can employ to avoid or minimize those

Table 2. A suggested roadmap to improving diabetes care at the primary care level.

(a) Short-term (within one year)	
1.	Train at least 1–2 doctors* in every health clinic to provide high-quality diabetes care, prevent/treat its comorbidities (hypertension and dyslipidaemia), and have the skills in managing obesity, metabolic syndrome and prediabetes from progressing to type 2 diabetes. All patients with sub-optimal control of diabetes (HbA1c > 8.5%) are to be seen at a shorter interval by these doctors. ^{47–49} Patients within good control could be followed-up by other doctors but must be reviewed at least annually by these designated doctors. Patients who still do not meet the personalised disease targets after being under the care of these doctors for at most 6 months should be discussed with or referred to the FMSs† for further management. Initiate and incorporate the “Stand Against Prediabetes: Don’t Sugarcoat It” [†] in routine diabetes care at the clinics. Allocate adequate budget for point-of-care testing in the clinic for testing of glucose, HbA1c, and urinalysis for initial screening.
2.	Make available most anti-diabetic, anti-hypertensive, anti-lipid and anti-obesity agents currently in the formulary for the designated doctors and FMSs. These doctors and FMSs to receive training in using newer agents. ⁵⁰
3.	Review and strengthen the existing Diabetes Medication Therapy Adherence Clinic (DMTAC). ⁵¹ Conduct a nationwide medical audit on the quality of DMTAC services, and act on the findings to improve or standardise the service. Re-audit after 1–2-year post-intervention.
4.	Reactivate and improve or develop a diabetes registry that includes important and relevant risk factors for DM. This would be an effective and efficient way of auditing diabetes care in each clinic. To include some patient-reported outcomes such as diabetes-specific symptoms, self-care activities, participation in social roles and activities, emotional wellbeing, health status and quality of life in the routine clinical practice.
5.	Make FMSs the responsible clinical specialist and the administrator of the clinics. ⁵² All allocated resources and activities at health clinics are governed by FMSs and team toward providing dynamic primary medical care and diabetes care.
(b) Medium-term (within three years)	
6.	Train at least 1–2 dedicated nurses in every health clinic to provide self-management support (clinical coaching) to patients with poor disease control. ^{49,51,53} At the same time to pay attention to the newly diagnosed patients making sure they achieve target control within 3–6 months. Also, these designated nurses are to support all follow-up patients in adhering to the treatment plan, ensure health screenings are up to date and conduct follow-up defaulter tracing. ⁵⁴
7.	Allocate adequate budget for laboratory testing of lipids, glucose, HbA1c and microalbuminuria for monitoring purposes; make available the screening tools at the clinics e.g., monofilament, fundus camera, echocardiography, ankle-brachial doppler and central aortic pressure measurement, and psychosocial measures such as illness perception, diabetes-specific symptoms, cognitive functions, participation in social roles and activities, diabetes distress, anxiety, depression, sleep and sexual functions. ⁵⁵ Begin benchmarking on quality of diabetes care by using the ABCW (A= HbA1c, B= blood pressure, C= low-density lipoprotein cholesterol, and W= weight) as four major modifiable cardiovascular risk factors as critical quality indicators. ⁵⁶
8.	Apply a continuous needs-driven approach and assessment in diabetes care service planning. ⁵⁷ This is to ensure evidence-based health workforce model is used to maintain the healthcare team (number of manpower and competencies) required to support best-practices in diabetes care at the clinic level. Create a diabetes health coaching team comprising a FMS, 1–2 doctors*, diabetes educators/dietitians or nutritionists/nurses/medical assistants, and have an organisational culture that makes this team thrive. ⁵⁸ Include trained physiotherapists and/or psychologists as a resident or visiting member to a clinic. Create, adopt and apply appropriate digital health technologies such as telemonitoring (mHealth and telephone communication) intermittently scanned glucose monitoring, continuous glucose monitoring, newer drug therapies (such as ultra-fast insulins, SGLT2 inhibitors, GLP-1 receptor agonists and GIP) to also reducing postprandial hyperglycaemia, glycaemic variability, and to extend as much as possible the time in range in near-normoglycaemia. ^{59,60} The same goes for other medications required to treat related comorbidity of DM.
9.	Begin to feedback to the healthcare team, before the end of year-two, on the clinical performance on the process measures, the prevalence of ABCW targets achieved and treatment profiles. This is best done through a registry. Review and improve on a structured training for the members of the diabetes health coaching team. This is to be done on a regular basis such as every 2–3 years.
(c) Long-term (three to five years)	
10.	Make available more drugs for the designated doctors and FMSs. Strengthen the educational classes with the inclusion of psychosocial/emotional support programmes, ^{61,62} peer-to-peer group support, realises important contribution from industry, academia and public health communities towards better patient empowerment and self-care. ^{9,63–65}
11.	Provide regular training courses for the designated doctors and nurses, or train new doctors and nurses to ensure non-disruption of these ‘diabetes’ doctors and nurses, and dietitians or nutritionists/nurses/medical assistant/physiotherapist/psychologist. Consider advanced or specialised courses in developing psychosocial competency as well as quality medical and non-medical management in diabetes care to enhance quality consultation and professional relationships with patients that facilitate the meeting and maintain clinical targets. ^{57,66} Consider recognising these courses as credentialing courses, from which the doctors and nurses will be awarded certificate and incentive in remuneration.
12.	Create permanent posts in chronic diseases for the nurses who are credentialled and elevate them to nurse practitioners or clinical nurse specialists. Create the posts of the sister or matron levels in parallel with the challenges of the service needs in managing chronic diseases at the primary care level. The diabetes coaching team is led by an experienced nurse, avoiding loss of trained nurses due to career advancement. ⁵⁸
13.	Consolidate all the above at each health clinic. Consider diabetes nurse prescribing protocols. Encourage innovation and adoption of more ehealth and digital medicine (wearables, mHealth or eHealth) approaches in diabetes care. ⁵⁷

ABC= A for HbA1c, B for blood pressure, C for LDL-cholesterol; FMSs= family medicine specialists; GIP= glucose-dependent insulinotropic polypeptide agonist; GLP-1= Glucagon-like peptide-1 receptor agonists; SGLT-2= Sodium-glucose cotransporter-2 inhibitors.

*qualified doctors with an undergraduate medical degree but not post-graduate training

† family physicians with post-graduate training in family medicine or general practice[‡] This programme conducted by a coalition of professional bodies led by the Malaysian Endocrine and Metabolic Society (MEMS) to promote prediabetes screening, diagnosis and management involving both lifestyle and pharmacological interventions by the inclusion and standardization of prediabetes diagnostic values in laboratory test reports nationally, equipping healthcare professionals with the skills and knowledge to address prediabetes effectively and raising awareness among the public on prediabetes.

biases.^{91,95} The biases are further classified into either Extrinsic or Intrinsic biases with the former are those external to the researchers while the latter are internal.^{96,97}

Strategies to Achieve Quality Research—Collective Actions

The first step in a collaborative effort toward improving diabetes care services and research would be creating

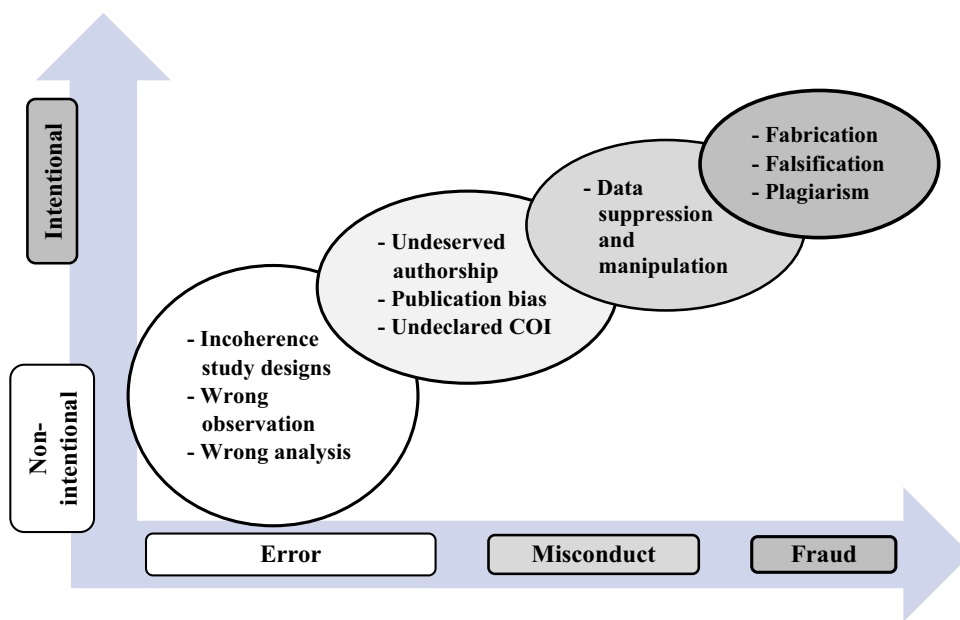


Figure 1. The dimensions and spectrum of misconducts. Modified from the figure in Nylenna M, et al. Scientific misconduct: a new approach to prevention. *Lancet*. 2006;367(9526):1882-4. Doi: [http://10.1016/S0140-6736\(06\)68821-1](http://10.1016/S0140-6736(06)68821-1). COI = conflict of interest.

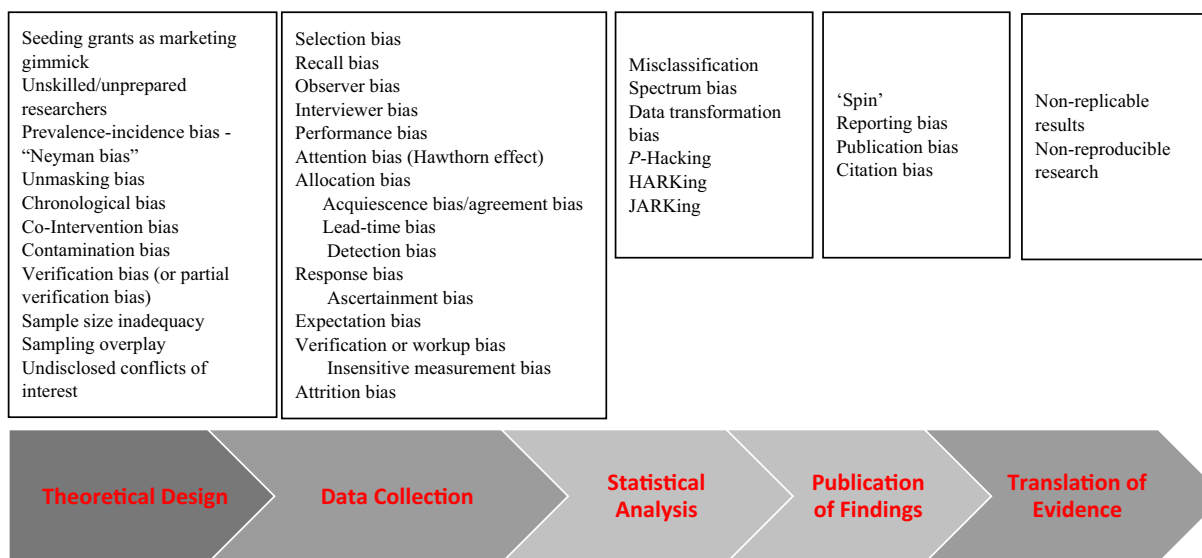


Figure 2. Possible biases along the whole research process. P-hacking= generating statistically significant results through repeated analyses. HARKing= Hypothesising After the Result is Known, a significant *p* value is retrospectively generated to match a hypothesis. JARKing= Justifying After Results are Known "Spin"= presenting results of study as more striking, "positive" or newsworthy than warranted Misclassification and spectrum biases in the statistical analysis may occur in the earlier stages. For other biases that are labeled differently, please see Bias in medical research by Justin Morgenstern in Evidence Based Medicine Front Page. Published July 2, 2018-Updated June 8, 2021. <https://first10em.com/bias/>.

a group of diabetes scientists, researchers and clinicians who are trained in clinical epidemiology and research misconducts and biases as described above. Compilation and synthetization of local evidence to establish the best latest available evidence on effective diabetes care would be

a good starting point. They would function as a consultation group to facilitate, coordinate and encourage higher quality clinical research and trials in diabetes care. The group could also assist in translating best evidence in practice in the shortest time possible by reviewing local and

Table 3. Common biases, key preventive strategies, implementation and limitations.

No.	Biases	Prevention/Detection	Implementation and limitations
Extrinsic			
1	Sponsorship bias ⁹⁸	<ul style="list-style-type: none"> (i) Sequestering investigators from private companies. (ii) Avoid engaging with industry-sponsored clinical research⁹⁹ and seeding trials¹⁰⁰ without rules and principles of integrity. (iii) <i>Disclosure of all relationships.</i> 	<ul style="list-style-type: none"> (i) Whenever possible. Otherwise, be utmost careful and sceptical with every step of the whole research process. (ii) Require awareness, experience and guts on the researchers to say 'No' to the 'easy' grants and to stand up to the pressure of obtaining research grant in research institutions for career advancement. (iii) <i>Limited by timing and disclosures by (un)involved people in a research project.</i>
2	Flawed incentive structures and researcher performance metrics that preferentially value 'aesthetics' over authenticity ¹⁰¹	<ul style="list-style-type: none"> (i) To prize authentic and robust research and their outputs whether their findings are positive or negative. (ii) To encourage or educate both investigators and research institutions to recognise the extent to which they are entangled in the major conflict of commitment and interest between conducting authentic science and being successful and enjoying the individual and institutional rewards of success in 'aesthetic' science. (iii) To show proof of inclusion or exclusion of research papers produced by the researchers or the research institutions from high-quality systematic reviews in the related topics, if available. Otherwise, may consider conduct or simulate one that apply risk of bias assessment and grading of the certainty of the evidence. (iv) Institutional leaders will need to take responsibility for eliminating the conflicts of interest that promote bias in research by having institutional metrics of professional success that align with good science,¹⁰²⁻¹⁰⁴ (v) Institution or a professional society to host a competition to develop the best prevention plan for respective department or discipline, respectively. (vi) Research institutions to sponsor audits of the work or outputs of their research teams 	<ul style="list-style-type: none"> (i) A challenging transformation given the extent to which both the investigators and research institutions flourished under the current rewards structures. (ii) Researcher's personal behaviours are often determined by the institution's policy that would risk career advancement if not complied. While the institution's policy is often determined by the high-level stakeholder or policymakers fixed and outdated concepts of research excellence. (iii) Limited by the availability of related systematic reviews. The alternative approaches are limited by competent and availability of reviewers. If this were achieved, the findings could result in insightful and decisive prevention plan. (iv) To convince the leaders that good science will lead to the desired outputs and research excellence,¹⁰⁵ more satisfied and motivated researchers and vibrant research culture.⁹⁷ Can draw on existing resources such as the published five Hong Kong Principles for assessing researchers: 1) responsible research practices; 2) transparent reporting; 3) open science (open research); 4) valuing a diversity of types of research; and 5) recognizing all contributions to research and scholarly activity.¹⁰⁶ (v) This requires sizeable interest, having critical mass of champions and participation from the institutional leaders. (vi) Systematic reviews that are available would be used to inform the audits. The audits could be conducted at random or only on teams that volunteer. The launch of the audits would need to be preceded by a communication effort that outlined the aim and value of the audits in order that they are not perceived or experienced as punitive.

(Continued)

Table 3. (Continued).

No.	Biases	Prevention/Detection	Implementation and limitations
3	Biased research practices have caused much scientific misconduct and diffused through the scientific community as an unhealthy condition to be handled <i>en masse</i> . ⁹⁰ To impose a heavier responsibility than currently applied on all institutions and their leaders for ensuring ethical and sound research environments and avoiding minor breaches of good scientific practice.	<p>(i) Acknowledge and address scientific misconduct</p> <p>(ii) Broad definition of biased research practices</p> <p>(iii) Simplify guidelines and improve training</p> <p>(iv) Establish independent investigation mechanisms</p> <p>(v) Reform academic system of reward and merit</p>	<p>(i) Scientific misconduct should not be downplayed, and its occurrence must be openly acknowledged. Regular seminars and discussions on the causes, outcomes, and consequences of scientific misconduct should be held by research institutions.</p> <p>(ii) While a strict definition is suitable for legal action, a wider definition that includes all breaches of accepted scientific practice should be used for preventive measures.</p> <p>(iii) Current guidelines and regulations should be simplified and readily accessible to researchers. Ethical and legal issues should be included in research training. Supervision of young researchers should be enhanced, with senior researchers serving as models for ethical behavior. Issues such as conflict of interest and guidelines for authorship should be addressed.</p> <p>(iv) National-level mechanisms for investigating suspected incidents of serious scientific misconduct should be established. Clear methods to manage whistleblowers should be in place, with designated individuals to receive complaints.</p> <p>(v) A thorough discussion is needed on the academic system of reward and merit. Emphasis on productivity and publication numbers should be reduced, while fostering a culture of transparency and ethics within academia. A wealth of resources is available on DORA (San Francisco Declaration on Research Assessment, https://sfdora.org/resource-library/)</p>
Intrinsic			
4	Biased design, conduct and reporting of preclinical studies	<p>(i) Peer reviewing the research proposal before study initiation (such as at the ethic committee or funding level), and manuscript for publication</p> <p>(ii) Reporting guidelines such as the ARRIVE (Animal Research: Reporting of In Vivo Experiments) guidelines.¹⁰⁷ Many similar reporting guidelines and checklists are available on EQUATOR (Enhancing the QUALity and Transparency Of health Research) network for different study designs https://www.equator-network.org/.</p>	<p>(i) Limited by availability of competent and fair reviewers.</p> <p>(ii) Ensuring transparency of critical methodological aspects of animal studies.</p>
5	Biased study designs due to incoherency in the whole research process	<p>(i) To provide field-specific courses focused on the fundamentals of research methodologies, techniques or tools such as experimental design and statistics, reproducibility, and other practical skills related to the robustness of different types of research.^{108,109}</p> <p>(ii) Having an introductory course on research integrity in a safe and non-punitive environment.¹⁰⁹</p> <p>(iii) Principal Investigators (PIs) could also lead an annual informal research integrity discussion with their team, demonstrating their commitment to instilling a culture of integrity in their group.</p> <p>(iv) Involvement of PIs and senior researchers as role models (iv).</p>	<p>(i) To convince researchers and institutional leaders that research knowledge and skills can be learned. Participation in courses and workshops may be a challenge to busy clinicians.</p> <p>(ii) Having competent trainers, dedicated and regular slots that are supported by all stakeholders may be a challenge if this topic is not valued more than the 'aesthetic' outputs.¹⁰¹</p> <p>(iii) A system change is likely to be needed to require and to record this practice. However, effectiveness of this within every team would depend on the passion and genuine interest and input of the PIs.</p> <p>(iv) This can be done quite easily with appropriate recognition to the role models.</p>

(Continued)

Table 3. (Continued).

No.	Biases	Prevention/Detection	Implementation and limitations
6	Cognitive biases ⁹⁵ : (i) Hypothesis myopia (ii) <i>p</i> -hacking (repeated tinkering with data and retesting) and HARKing (hypothesizing after results are known) (iii) Asymmetric attention (iv) Just-so storytelling/ JARKing (justifying after results are known)	(i) Use the strong inference approach to explicitly considering competing hypotheses, and if possible, working to develop experiments that can distinguish between them. (ii) Transparency in registering research protocols, or publishing research proposal on repository or journals to subject the research to public/open scrutiny. This is to reduce the unconscious temptation to warp the data analysis. Another approach is blind data analysis where important variables are hidden, or dataset is added with removable noises. (iii) Use team of rivals (an adversarial collaboration) to quickly spot flaws such as hypothesis myopia, asymmetric attention or just-so storytelling. (iv) To explicitly list alternative explanations for all observations to reduce tendency to tell just-so stories.	(i) Researchers are to be always on the guard and prepared to be impartial when facing with the data and results. (ii) Belief in pre-print and publishing research protocols before the initiation of the study require motivation and support. This could come from journals that accept publication of research protocol without or with minimal cost and practice open access. (iii) This may be easier said than done. Such a practice demands big and open heart among the academic rivals and strive to support good science as the ultimate end. (iv) Same to item (i).

Content of this table was adapted from an article by the author shared in RECRUS Research Newsletter on July 2023, Vol. 3 Issues 23, page 641. (https://hsaas.upm.edu.my/upload/dokumen/20230801091907Biased_Research_Prevention_Plan.pdf).

international evidence at a regular basis and producing updates annually. All research in diabetes care must adhere to epidemiologic principles of efficiency, validity, and precision in the whole research process, particularly in the measurement aspects of quantitative clinical research.¹¹⁰ Qualitative research on the right topics should also be encouraged. To improve the relevance and potency of clinical research, public and patient inclusion would be encouraged. These three attributes require proper use of study designs, participant, and control selection, along with the appropriate statistical strategies. Any diabetes research that is conducted without due diligence to the quality principles mentioned above, defeats the ultimate purpose of the research itself. Worse, the research contributes to research waste, results in missed opportunity and biased pooled estimates.

In addition, studies should be extended to assess any disparity between the effect size observed in clinical trials versus those observed in real-world settings. This bridges the gap between research and practice, enhancing the capacity to explain and promote the application, translation and implementation of research findings. In another perspective, meta-research initiatives or research on research should be given greater consideration, patients' participation and funding approaches in diabetes care research to be regarded with increased attention to safeguard high quality and public trust. This should include more capacity building and research into digital medicine in diabetes care. Broken systems in research training, guidance, funding, publication metrics and career promotion of researchers should

be mended and supported. If the research was not conducted with credibility and without conflicts of interest, the clinical evidence would not be regarded as credible.

Digital Medicine, Artificial Intelligence, and Open Science Practices to Diabetes Care and Research

Digital Medicine in Diabetes Care and Research

Technological advancement, the internet of things, machine learning and artificial intelligence (AI) will transform every aspect of human life including diabetes care.^{111,112} The use or intrusion of digital technology in medicine and diabetes care is already significant and expanding fast, but is not without its limitations and ethical issues.^{111,113–116} As human data are accumulating, big data analysis in diabetes care and for health behaviors may be the game-changer and ushering in the next paradigm shift in diabetes care delivery. Digital health interventions encompassing the e-health initiatives, telehealth programs, telemedicine and mobile health (mHealth) apps could contribute in the effort to address challenges that impede the attainment of health system goals. According to the Tanahashi framework published by WHO, these include: 1) accountability in coverage of the target population, 2) accessibility and availability of health facilities, and availability of human resources, 3) contact and continuous coverage of the target population for treatment, 4) effective coverage with quality medical and clinical care, and 5) affordability of app-based digital interventions.¹¹⁷

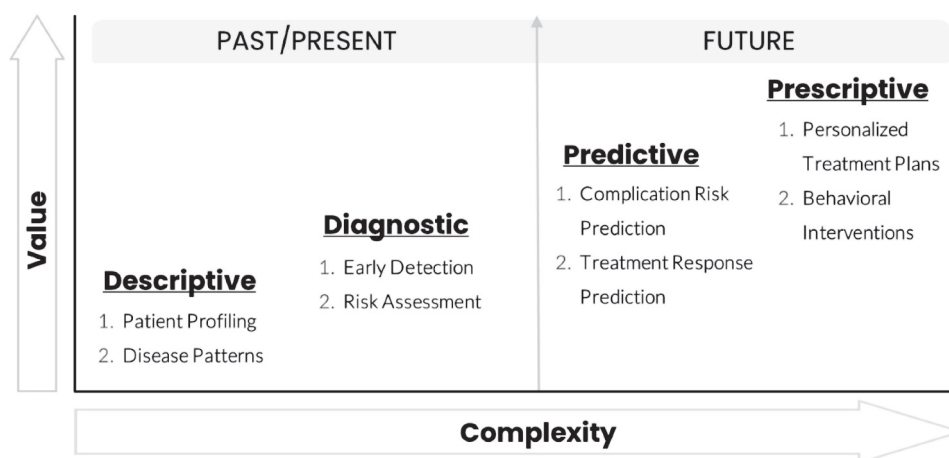
Recent mHealth interventions targeting type 1 and type 2 diabetes are diverse in their goals and components, which include insulin management applications, wearable blood glucose meters, automated text messages, health diaries and virtual health coaching for diabetes education, self-management and prevention.¹¹⁸ Effective apps would have a structured interface which contains a module on diabetes-related complications and prevention,¹¹⁹ while the clinical decision-making function needs further improvement and evaluation. Desirable apps are user friendly, encourage healthy eating, provide actionable reminders, consolidate data across peripheral health devices, provide news updates on developments in the field of diabetes, educational topics on problem solving, insulin pump therapy, signs of diabetes complication and transition from pediatric into adult care.¹²⁰ In low- and middle-income countries, there is a distinct lack of mHealth applications, a scarcity of formal outcome evaluations, and a relative lack of scalable services.¹²¹ The most documented use of mHealth was 1-way text-message reminders to encourage follow-up appointments, healthy behaviors, and data gathering.¹²¹

However, digital health utilizing the various channels of mHealth and eHealth should be viewed at best as channels or containers. These devices and their apps will require good content and easy interfaces to meet active, engaged or smart users for it to be effective.^{122,123} Therefore, for digital health interventions to be effective they first must be well created, tested, and maintained by the providers. This will then address the requirement of empowered patients who are supported by competent healthcare providers.^{122,124} The content development,

validation and deployment are to be sound for all kind of clinical interventions even more so for digital interventions infused with mathematical algorithms of AI.

AI is the cognitive capacity of machines made possible by mathematically designed neural networks.¹²⁵ The electronic neural networks are built to mimic human neuronal plexus and programmed to manage a myriad of data according to their categories and to assign different weights to different factors. The weights are determined based on provided data on specified outcomes, and this process is continuously enhanced with the registration of new data. The learning computer models are the machine learning (ML) version of the AI, whereas the deep learning (DL) version has multiple layers of neural networks.¹²⁶ Transformers exist when these deep learning models differentially weight the significance of each part of the input data and enable natural-language processing (for example, the ChatGPT stands for Chat Generative Pretrained Transformer).

When a vast quantity of data becomes interconnected, it generates new discoveries and opportunities at an individual level and in almost every aspect of diabetes care and research.¹¹² Augmented intelligence (AugI) is the application of artificial intelligence that complements and enhances human capabilities rather than substituting them. There are many FDA-approved software, applications, programmes and devices that use AI to interpret a broad range of imaging modalities, diagnostic and prognostic assistance, and helps outline possible treatments for clinicians.¹²⁷ The appropriate use of AI technology in healthcare is on the rise¹²⁸ and has the potential to be cost-effective, improved quality by reducing



AI= artificial intelligence; ML= machine learning

Figure 3. Potential aspects in diabetes care that artificial intelligence/machine learning could make a difference.

variation, safe and fast^{129,130} if potential biases and discriminatory data are minimized or eliminated, during the development or deployment to the intended users. [Figure 3](#) illustrates some of the potential aspects in diabetes care that AugI could make a difference.

A Full Development Process of Artificial Intelligence/ Machine Learning Tools

The following is a typical progression for the development and deployment of a new AI tool that could be applied in diabetes care and research.^{129,131,132} It is consistent with other frameworks and could be expanded to incorporate health economic assessment.¹³³ Healthcare professionals and clinicians with an understanding of the development process of AI tools would help improving the therapeutic potential of the tools,¹³⁴ and facilitate clinical adoption and monitoring of these tools in healthcare settings.¹³⁵ A fuller elaboration on these nine stages will be disseminated elsewhere.

Clinical Problem Identification

These are challenges that are rooted in facts, mechanical, repetitive and complex in nature due to the need to process multiple aspects of diabetes care services or individuals with DM in the health system. AI/AugI/ML is of no assistance in dealing with personal values, health beliefs and emotions. Decision must be made on the level of the problem for the AI technology to solve, either descriptive, diagnostic, predictive or prescriptive ([Figure 3](#)). These pertain to the estimation of a condition's prevalence, diagnostic probability, prediction of certain outcomes, and recommendation of the most likely effective treatment. The order denotes an incremental level of value and complexity to be anticipated during the tool's development.

Form Project Team or Collaborate with Experts

The team must consist of the qualified people with the required skillsets. This includes data scientists to conduct data validation/transformation/curation and data visualization for AI/ML models; data engineers to implement data workflows (such as storage); data architects to design system architecture for data repository; and a chief data officer to design the data governance structure and policies if one is not already available. Clinicians, healthcare administrators and related stakeholders including patient and public groups of individuals are indispensable for the proper project planning, development, deployment, adoption and maintenance of the AI/ML tool. Health informatics, business or industry partners should be considered if available.

Data availability, organization and curation

Relevant real-world sources of data must be explored, annotated and pre-processed. Different types of data will have to be processed through distinctive stages before it is useful for the AI algorithms. These are standardization (coding of structured and unstructured data) for interoperability, cataloging, de-identification (pseudo- or anonymization), cleaning/transformation (validation) and linking and combining multiple sources into single dataset. Significant quantities of high-quality data, shared within credible data governance structures, present real challenges to achieve this objective.¹³⁶

Infrastructure and Architecture for Data Repository and AI Technology

It is necessary to have adequate computer and server capacity, as well as the appropriate hardware, to process massive amounts of data with optimal speed. The operation of this data server includes robust cybersecurity, data privacy, controlled access and up-to-date regulatory policy on the proper use of the data, as well as supervised incremental learning of the AI/ML tools. In addition to security and proper governance, ease and speed of access to different users are of utmost importance. The infrastructure and architecture must be scalable to accommodate the growing needs and requirements of the tools.

AI Neural Networks on Open Access Platforms

Many AI algorithms are readily available on open access platforms. Applying the appropriate AI/ML models and methods to the required tasks to resolve the identified clinical problems. The creation of new AI neural networks is a time-consuming process that requires data scientists with advanced skillsets. The convolution neural network is ideal for images, while the recurrent neural network is best suited for text and numerical data.

AI/ML Models Validation

Mandatory non-clinical and clinical validation of the tools is required to determine their performance, integration into the routine clinical workflow, usability to those involved, and effects on clinical outcomes. This encompasses exploring and addressing the potential ethical and legal implications of having these tools in the healthcare services. Properly designed clinical research including a clinical trial on the tools is necessary to estimate its clinical effect in the real-world setting. The final step is to publish the report for broad dissemination and evaluation of the final product.

Registration

Register tools with relevant authority such as the medical device authority.

Clinical Deployment

Instructing clinicians and team members in the health-care facilities where the tools will be utilized or integrated into the electronic medical record system. Be prepared to explain the decision process of the AI/ML tools and be present to support its use. Continue to measure the tool's effect on diabetes care and supervise the incremental learning of the tool. Also, continue to monitor for any unwanted effect arising from its use, including performance degradation, algorithm drift and pipeline decay owing to data integrity, cybersecurity, impact mitigation in case of breach and function recovery.¹³⁷ Be vigilance and prepared to re-train the AI/ML algorithm if the performance is below expectation.

AI Ecosystem Improvement

Engage stakeholders and public actively regarding the tool, and to progress the AI ecosystem in the institution and country.¹³⁰ This aims to promote a broader and better perception of AI/ML technologies, increasing interest and training, and establishing central governance, trusted custodian, ethical value and adequate confidence to permit innovation and the implementation of more AI/ML tools.

Ethical considerations of data privacy and patient safety are well-known challenges lying ahead.^{111,138} Similarly, the traditional principles of medicine are here to stay because they uphold the dignity of patients, and mutual trusts between the doctor, the patient, and the society. A win-win partnership between technology companies as the technological know-how and health-care facilities as the data sources and expert input to the algorithms would be the greatest challenge ahead. This is to be regulatory compliant and economically beneficial to the two key stakeholders.¹³⁹

Open Science Practice for Diabetes Research

All stakeholders, including scientists, clinical and biomedical researchers, must have a better appreciation and adoption of Open Science (OS) in diabetes research.¹⁴⁰ OS encourages the practice of diabetes research that is "opened" from the beginning to the end throughout the whole research process. This includes sharing research protocols (in the safe preprint servers or by stages), making public research tools, involving public and patient in the research planning, transparent in the research undertakings, collaborative

with experts and conduct high-quality research with integrity. It advocates sharing and use of openly available, accessible and reusable research products for everyone, to facilitate scientific collaborations and sharing of information for the benefits of science and society, and to expand access to the processes of scientific knowledge creation, evaluation and communication beyond the traditional scientific community.¹⁴¹ It comprises all scientific disciplines and aspects of scholarly practices, including basic and applied sciences, natural and social sciences, and the humanities.¹⁴¹

OS system practice is compatible with intellectual property rights¹⁴² and not free of cost.¹⁴³ OS is to be as open as possible so that all stakeholders can appreciate its full meaning and benefit from science via the FAIR (findable, accessible, interoperable and reusable) principles,¹⁴⁴ but at the same time be as close as possible to the local problems, values, cultures and legal requirements via the CARE (collective benefit, authority to control, responsibility and ethics) principles.¹⁴⁵ OS does not mean indiscriminate openness, and consent of or license to use any open sources of a research product, as permission should be first obtained from the intellectual property rightsholder. Similarly, potential rightsholders are urged to advocate for the use of copyright and licenses to compel the openness of a free research/scientific products. OS does not mean free of cost. The initial transition to OS may necessitate investments in the infrastructures and capacity building, as well as ongoing maintenance costs. Nevertheless, with the OS practise, science will generate multiple returns on investment through accelerated high-quality research, innovation, and commercialization.

Diabetes researchers may practice OS on the Open Science Framework (<https://help.osf.io/article/576-tips-and-tricks>.) to improve sharing of research project's information (metadata) for discoverability, collaboration, and reuse of materials or products of the research project (tools, data management plans, software codes, datasets and publications) for self and by others.

Strengths and Limitations

This review offers several notable strengths that contribute to its value in the field of diabetes care and research. Firstly, the focus on Malaysia as a case study provides a detailed and in-depth analysis of the challenges and opportunities within a specific context. This specificity allows for a thorough examination of the issues and the development of targeted strategies that can be adapted by other countries facing similar challenges. While this approach provides detailed insights and concrete examples, it may limit the applicability of the findings and

recommendations to other countries in the WP. Each country within the region has distinct healthcare systems, economic conditions, and cultural contexts, which might affect the relevance and implementation of Malaysia-specific solutions elsewhere. To enhance the relevance and applicability of the review's findings for other countries in the WP, it is crucial to tailor strategies to fit specific needs and contexts including case studies from diverse countries and conducting comparative analyses can highlight common challenges and successful strategies for regional adaptation. Engaging stakeholders from various countries provides valuable insights and facilitates the adaptation of solutions, while promoting regional knowledge sharing and collaboration help disseminating best practices. Pilot programs could be conducted in diverse settings to test and refine interventions before broader implementation. Additionally, developing flexible frameworks that accommodate unique challenges and opportunities, ensures that proposed interventions are scalable and adaptable across different healthcare systems and resource settings.

The review emphasizes the importance of a comprehensive and multi-faceted approach to diabetes care, highlighting the necessity of concerted and preventive efforts from all stakeholders. It advocates for the transformation of healthcare professionals and the reform of healthcare systems with a holistic perspective, instituting effective interventions that encompass primary care, allied health professionals, health organization improvements, and support systems for people with diabetes. However, implementing the proposed transformation of healthcare professionals and the reform of healthcare systems requires significant resources, necessitate extensive training and education, which may not be available in all healthcare settings, particularly in low- and middle-income countries. Resistance to change among established professionals may also pose a barrier.

Additionally, the review's discussion on important roles of high-quality research for diabetes care, as well as the open science practices in research that adds value by promoting transparency, collaboration, and the sharing of knowledge. Conducting high-quality research involves significant investment in terms of time, funding, and expertise. Similarly, ensuring consistent application of open science practices can be challenging, especially in under-resourced settings. These are crucial factors for efficient and effective diabetes care and research that should be improvised within the country and promoted in collaboration externally with other countries in the WP or internationally.

Another strength of the review is its forward-looking approach, proposing a detailed roadmap for the next five years, and inclusion of digital medicine and AI as

potential contributors to diabetes care. Educated clinicians are pillars of healthcare transformation.¹⁴⁶ They could ensure digital solutions meet their unique needs and preferences, emphasizing patient safety and quality of care. Their involvement facilitates seamless integration into the clinical workflows,¹⁴⁷ supports adoption, drives innovation, and optimizes clinical outcomes.^{148,149} The availability, readiness and needs for these are again to be assessed at different levels in different countries.

Conclusions

For patients, physicians, healthcare systems, and their stakeholders in many nations, including those in the WP and Malaysia, diabetes care is often defined with descriptions such as difficult, complex, costly, and perplexing. The ultimate goal of diabetes care is to achieve patient-perceived outcomes as they progress through life's stages. The best investment for quality and cost-effective diabetes care will be at the primary medical care level. This could be achieved in three stages: Short-term (within one year), medium-term (within three years) and long-term (three to five years). This requires concerted efforts of multiple parties in the government agencies and non-government organizations to facilitate the transformation and sustain it. Until then, only health clinics adopting the suggested interventions and planned actions would provide the optimal diabetes care. For optimal healthcare performance, the transformation initiative calls for high-quality diabetes care research and clinical evidence.¹⁵⁰ Therefore, a working group is required to compile and synthesize local evidence to provide information on the best and most recent available evidence regarding effective diabetes care. In the absence of best evidence, the group will facilitate, coordinate, and encourage high-quality clinical research and trials in diabetes care that adhere to the epidemiologic principles of efficiency, validity, and precision, the appropriate use of digital technology, and the practise of open science throughout the research process.

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BHC wrote the paper, all authors provided critical inputs with PL, AG, MYBN and TSC provided focused input on allied health professionals, nutritional, dietetics and laboratory perspectives, respectively. WPF and CLC provided input on the Enhanced Primary Care initiative in Malaysia. SD and BNI commented on the overall draft from the aspects of technical and grammatical quality. NHZ, WPF and CLC also provided general overviews.

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