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An Audit of Cardiovascular Risk Management of A1c, Blood Pressure and Cholesterol (ABC) in a Diabetic Clinic: Identifying Gaps and Quality Improvement Implications

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ABSTRACT

Background: Type 2 diabetes increases cardiovascular disease (CVD) risk. Optimal management requires controlling blood sugar (A1c), blood pressure (BP), and LDL cholesterol (LDL-C). Quality improvement (QI) initiatives to track these factors are essential; however, resource limitations hinder optimal care in low- and middle-income countries (LMICs). Care audits aid in identifying gaps and guide QI initiatives. Methods: A retrospective cross-sectional audit (2019 data) of 362 type 2 diabetes patients' files at Kenyatta National Hospital (Nairobi) was done using systematic random sampling. Data on demographics, diabetes duration, comorbidities, and CVD risk factors (A1c, BP, LDL-C) were extracted comparing them to Kenyan, European, and American Diabetes Association guidelines, to assess adherence and data use for decision-making. Results: Most participants (68%) were female, aged 50-59, with diabetes duration under 10 years. CVD risk stratification was not documented. We categorized patients into cardiovascular risk strata: very high (28.7%), high (57.7%), and moderate (13.5%). Only 50.6% had one risk factor controlled, and none had all three controlled, with 42.3% missing documentation for these factors. BP was the most frequently recorded parameter (99%). Clinic visit frequency was low, with 47.8% attending twice and 26.2% attending once in the year under consideration. Conclusion: We revealed deficiencies in documentation and suboptimal control of CVD risk factors. Absence of CVD risk stratification during care highlights the need for QI initiatives to improve documentation and translate guidelines into effective management practices. Addressing socioeconomic factors influencing follow-up visits and access to necessary tests is crucial for optimizing care in LMIC settings.

Keywords: Type 2 diabetes, CVD risk factors, Quality improvement (QI) initiatives, Clinical practice guidelines, Risk stratification, LMICs.

BACKGROUND

Among individuals living with type 2 diabetes, up to two-thirds will develop atherosclerotic cardiovascular disease (ASCVD) throughout their lifetime [1-3]. In such individuals with diabetes who develop ASCVD, the vascular disease is more extensive, less amenable to treatment, and tends to have worse outcomes than in the general population [1,4-6]. However, intensive glycaemic, blood pressure (BP), and LDL cholesterol (LDL-C) control in accordance to recommended evidence-based treatment targets has been shown to reduce cardiovascular outcomes and death [7, 8, 9]. The ability to measure and track clinical performance and outcomes, linked to a quality improvement (QI) program, is essential for ensuring the provision of the best level of care desired. Approximately 80% of adults living with diabetes worldwide live in low-income and middle-income countries (LMICs) [10]. The health systems in LMICs are limited in their capacity to deliver optimal care for non-communicable diseases (NCDs), of which diabetes is one, and this has resulted in substantial excess mortality [11,12]. The recommended comprehensive approach to clinical care of type 2 diabetes consists of pharmacological and non-pharmacological treatment and treatment targets for glycaemic control and other key cardiovascular disease (CVD) risk factors, namely, hypertension, elevated cholesterol, and obesity [3,4,13,14]. High-quality cohort studies have demonstrated the benefit of multiple risk factor reduction among people with type 2 diabetes mellitus (T2DM) [13]. Consequently, the pharmacological treatments that result in the most effective improvement in diabetes outcomes include glucose-lowering medications, antihypertensive medications, and LDL-cholesterol-lowering medications [15]. The complex requirements of diabetes care necessitate that a health system promotes and creates long-term chronic disease management rather than episodic care [14,16,17,18]. In LMICs, fewer than 10% of people living with diabetes receive guideline-based comprehensive diabetes treatment. Enabling health systems to deliver comprehensive treatment to lower glucose and address cardiovascular disease risk factors, such as hypertension and high cholesterol, are urgent global diabetes priorities, especially in LMICs [19].

Clinical audits have demonstrated their value in informing initiatives for improving care processes [20]. Clinical audits also assist in the scrutiny of healthcare provision and help in identifying any shortfalls in the care of patients [21]. Conducting audits and improvements based on them are found to be feasible even in resource-limited settings [22]. This audit was performed to evaluate the level of assessment and control of glycaemic, blood pressure and cholesterol parameters in the care of patients with type 2 diabetes by the clinical team at the outpatient clinic setting of the hospital. What was not documented was not done, as the dictum goes! The experts have acknowledged the centrality of the main cardiovascular risk factors in patients with T2DM and the serious morbidity and mortality attributable to CVD. Consequently, multiple guidelines and standards of medical care for diabetes mellitus patients have been developed. These standards of care in the form of clinical practice guidelines (CPGs) are supported by the highest level of evidence available at the time. Different regions/countries around the world tend to contextualize their own guidelines. However, most guidelines surrounding cardiovascular risk management in individuals with T2DM tend to cover the key risk factors of hypertension, dyslipidaemia, obesity/overweight, smoking cessation, lifestyle modification (including diet, exercise and alcohol use) and the use of anti-platelets. CPGs for cardiovascular risk management in type 2 diabetes (T2DM) are dynamically revised based on evolving evidence and are tailored to specific contexts globally. Our audit standards are dictated by the dynamic nature of these guidelines.

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METHODS

This was a retrospective file audit performed at the diabetes clinic at the Kenyatta National Hospital (KNH). The KNH is a tertiary, public teaching hospital in Nairobi, Kenya's capital city. The study areas were the diabetes outpatient clinic (DOPC) and its decentralized records department. The decentralized records department at the diabetic outpatient clinics stores physical files for patients with diabetes mellitus. These physical files act as the main form of data entry and storage of patients' clinical information. The patient files were chosen by systematic random sampling. The inclusion criteria for the T2DM patients was files of patients diagnosed with T2DM on follow-up at the KNH DOPC for at least one year (the target period of the audit was as of January 1st, 2019, to December 31st, 2019). File numbers of patients with a diagnosis of diabetes mellitus were identified from the KNH electronic database using 2020 international codes of disease (ICD-10 codes E11-). The records officers then used the files numbers to retrieve them physically from the records office store. Once retrieved in manageable batches of approximately thirty to forty per day, the principal investigator (JSO) carefully perused each file for inclusion in the study. The files were then carefully studied by the PI and two research assistants to obtain predefined study-specific targets that were adapted from the relevant guidelines, which were the 2018-Kenya National Clinical Guidelines for the Management of Diabetes Mellitus[23], the European Society of Cardiology (ESC) Guidelines/European Association for Study of Diabetes (EASD) Consensus Report on Management of Cardiovascular Disease in Type 2 DM[24] and American Diabetes Association (ADA) Guidelines[25,26] on the Management of Cardiovascular Risk in DM. When there was a lack of consensus in the guidelines above, we adhered to our local guidelines. The study tool was a questionnaire in the form of a checklist with 5 core sections covering each of the cardiovascular risk factors whose management we sought to audit. The following data were extracted from the files: patient study number, demographic details, duration of type 2 DM, comorbidities and CVD risk stratification. Stored data from Excel were exported to STATA version 14 and R version 4.3.1 for statistical analysis. The demographic and clinical characteristics of the study population were described. For continuous variables, appropriate measures of central tendency (mean/median/mode) were reported. Categorical variables are summarized as percentages and proportions. Interventions not documented were considered not done and were documented as such, and an arbitrary target score of 100% was used. This study was carried out after presentation and approval by the Department of Clinical Medicine and Therapeutics, University of Nairobi, KNH and the Ethical Review Committee. The data collected from the files were kept under lock and key with access controlled by the principal investigator.

Table 1: Guideline targets with respect to key areas of cardiovascular risk management in T2DM patients.

Risk Factor/Standard of care	Kenya Diabetic Clinical guidelines Target
Risk stratification *ADA and ESC have different methods of quantifying variables while stratifying risk however treatment targets based on risk stratification are similar	Kenya guidelines borrow aspects of risk stratification heavily from ESC: moderate, high, very high
Hypertension *ESC and ADA target 130/80 for most hypertensive diabetics.	Target <140/80 mmHg

Dyslipidaemia *Largely based on risk stratification, similar to ESC guidelines	Target LDL Moderate risk = <2.6 mmol/l High risk = < 1.8 mmol/l Triglycerides <1.7 mmol/l
Glycaemic control	HbA1c target <7% Less stringent in elderly < 8%

RESULTS

Five hundred and eighty-one (581) files were scrutinized via a systematic sampling approach, with every third file being comprehensively reviewed for inclusion and exclusion criteria at the beginning of every data collection session until the sample size was met. Of the initial 581 patients, 41 files were excluded because of a diagnosis of type 1 DM, three because of a diagnosis of gestational diabetes, and one hundred and seventy-five (175) files were excluded because they had incomplete or missing data, leaving 362 files that met the target sample size. The files that were selected were duly coded. Once the target sample size was met, data collection was stopped. See Figure 1.

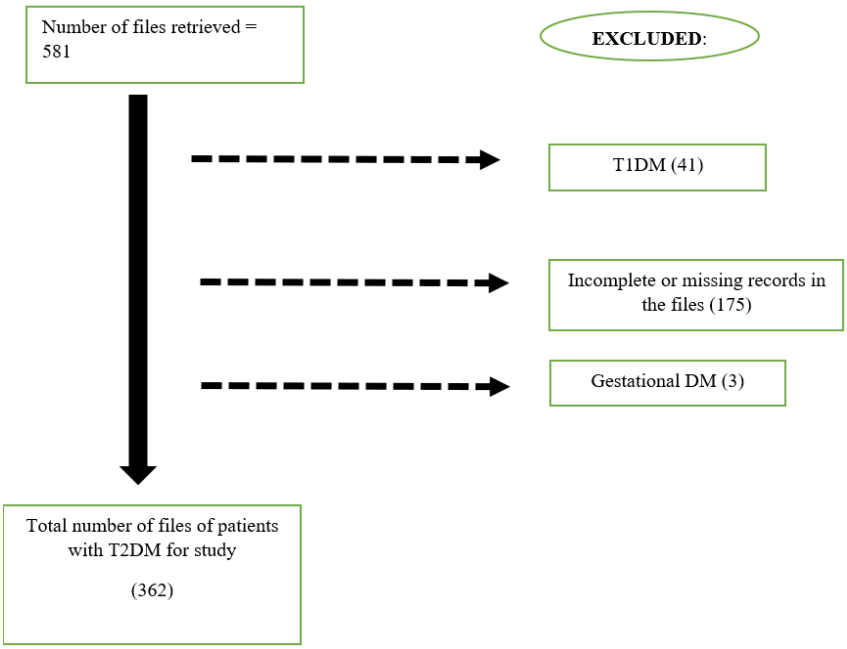

Figure 1: Flow chart showing the recruitment of patient files

There was no evidence of deliberate risk stratification of patients during the clinical encounters in any of the 362 patients' records. Therefore, we risk stratified all the patients according to their clinical records in files based on contemporary guidelines. According to the CVD risk stratification, 104 (28.7%) patients met the criteria of very high risk, meaning DM plus either established CVD or target organ damage or 3 or major risk factors; 209 (57.7%) were classified as high risk, meaning DM duration of 10 years or more, without target organ damage, plus any other additional CVD risk factor; and 49 (13.5%) were classified as moderate risk, meaning T2DM patients less than 50 years of age, with a DM duration of 10 years or less, without any other additional risk factors[24]. See Tables 2 and 3.

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The Documented Cardiovascular Risk Factors Among the Study Subjects:

The analysis of the data from the files showed that out of the 362 patients, 302 (83.4%) presented with at least one or more major cardiovascular risk factors, namely, hypertension (HTN), dyslipidaemia, obesity, chronic kidney disease (CKD) or documented established atherosclerotic CVD. See Table 4.

Table 2: Population characteristics of the study subjects

	Overall (N=362) N (%)	Female (N=246) n (%)	Male (N=116) n (%)
Age categories in years			
30-39	13(3.6)	9(69.2)	4(30.8)
40-49	69(19.1)	50(72.5)	19(27.5)
50-59	113(31.2)	79(70.5)	33(29.5)
60-69	95(26.2)	59(62.1)	36(37.9)
70-79	55(15.2)	38(69.1)	17(30.9)
80+	17(4.7)	9(56.3)	7(43.8)
Duration of diabetes (in years)			
≤10	223(61.6)	148(66.4)	75(33.6)
11-20	105 (29.0)	76(72.4)	29(27.6)
21-30	29(8.0)	20(69.0)	9(31)
>30	5(1.4)	2(40)	3(60)
Clinic visits (within the year of study)			
1	95(26.2)	59(62.1)	36(37.9)
2	173(47.8)	129(74.6)	44(25.4)
3	78(21.5)	49(62.8)	29(37.2)
4	15(4.1)	8(53.3)	7(46.7)
5	1(0.3)	1(100)	0(0)

*n represents a percentage of the overall N

Table 3: Cardiovascular disease risk stratification

CVD Risk stratification (at enrolment)		Female	Male
Very high risk	104(28.7)	62(59.6)	42(40.4)
High risk	209(57.7)	156(74.6)	53(25.4)
Moderate risk	49(13.5)	28(57.1)	21(42.9)

Table 4: Documented distribution of major CVD risk factors plus established ASCVD

CVD Risk factor/indicator	Overall population (N=362)	Female (N=246) n (%)	Male (N=116) n (%)
Hypertension	295	205(69.5)	90(30.5)
Dyslipidaemia	6	2(33.3)	4(66.7)
Cardiovascular disease	33	17(51.5)	16(48.5)
Obesity	7	4(57.1)	3(42.9)
Chronic kidney disease	15	11(73.3)	4(26.7)

*n represents a percentage of the overall N

There was a notable discrepancy in risk factor control based on cardiovascular (CV) risk stratification. Specifically, individuals classified as having high or very high CV risk had a greater

proportion of off-target CVD risk factors than did those classified as having moderate CVD risk. See Tables 5, 6, and 7. Notably, three patients in the moderate-CVD-risk group had undiagnosed hypertension with blood pressure readings that were above the cut-off and one patient in the high-CV-risk group had no recorded blood pressure readings. Two hundred and ninety-five (295) patients in the combined high- to very high-risk group were documented to have hypertension, while 18 were not documented to have hypertension. See Table 5.

The parameters assessed in terms of the adequacy of management of the above three cardiovascular risk factors were achieving target blood pressure, target glycaemic control, and testing and managing any dyslipidaemia. The documented evaluation of each of the CV risk factors is as documented below. See Tables 5, 6 and 7.

Table 5: Evaluation of the control of hypertension

CVD Risk factor indicator N (%)	**CVD Risk strata**					
(Hypertension)	Moderate CVD risk N = 104		High CVD risk N = 209		Very high CVD risk N = 104	
Documented blood pressure recordings n = 361; BP within target = 154 (42.7)						
Blood pressure off-target = 207(57.3)	3(1.4)		134(64.7)		70(33.9)	
Use of RAAS blockade among documented hypertensive patients	Yes	No	Yes 170(84.2)	No 32(15.8)	Yes 89(96)	No 4(4)

Table 6: Evaluation of glycaemic control levels

	CVD Risk strata					
CVD Risk factor indicator Glycaemic control N (%)	Moderate risk (N =49)		High Risk (N = 209)		Very High Risk (N=104)	
HbA1c test within 12months	Yes	No	Yes	No	Yes	No
	33(67.4)	16(32.6)	148(70.8)	61(29.2)	81(77.9)	23(22.1)
Guideline directed HbA1c testing	25(51)	24(49)	103(49.3)	106(50.7)	53(51.0)	51(49.0)
Documented HbA1c N = 158 HbA1c within target N = 55 (34.8%)						
HbA1c off-target N= 103 (65.2%)						
	10(9.7)		62(60.2)		31(30.1)	

Table 7: Evaluation of control of lipid levels

Lipids control	CVD Risk strata					
CVD Risk factor indicator N (%)	Moderate risk (N =49)		High Risk (N = 209)		Very High Risk (N=104)	
	Yes N (%)	No N (%)	Yes N (%)	No N (%)	Yes N (%)	No N (%)
Adequate use of statins N (%)	20(40.8)	29(59.2)	8(3.8)	201(96.2)	9(8.7)	95(91.3)
Documented LDL levels = 97 LDL within target = 36 (37.1%)						
LDL level off-target = N (%), 61(62.9%)	4(6.6)		23(37.7)		15(24.6)	

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According to the available documentation in the files, 183 patients had at least one of the risk factors controlled, 26 patients had two of the risk factors controlled, and none of the patients had all 3 of the risk factors controlled. The rest were unaccounted for due to poor documentation and lack of available test results. See Figure 2.

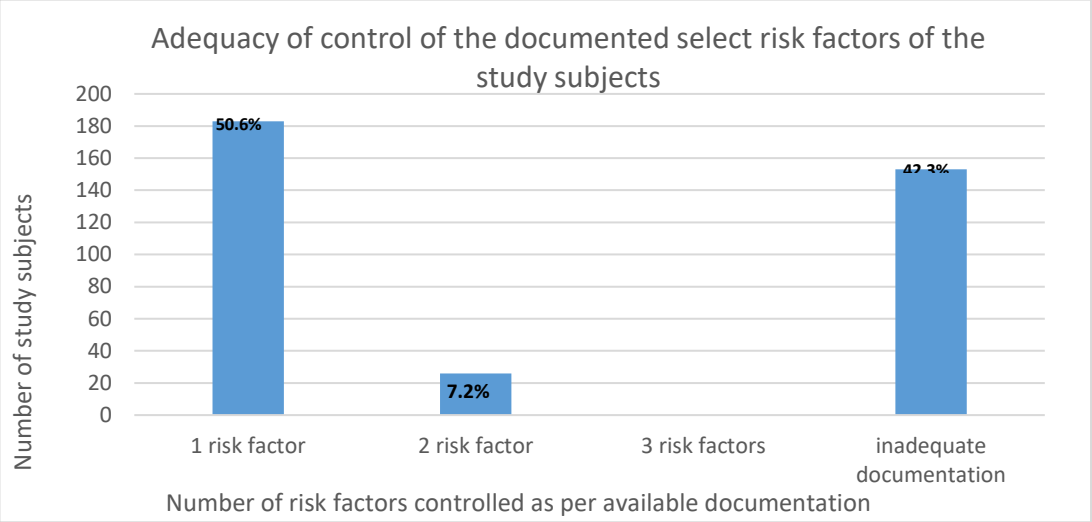

Figure 2: Adequacy of control of the documented selected risk factors for the study subjects.

On further analysis of the data, a logistic regression model for 2 controlled risk factors showed that CV risk stratification was a significant predictor, with higher risk stratification associated with decreased odds of controlled risk. Conversely, the number of clinic visits was marginally significant in predicting control of 2 risk factors, meaning that a greater number of clinic visits was associated with increased odds of controlled risk factors. Age, gender, and duration of DM were not significant predictors. See Figure 3. In comparison, the logistic regression model for 1 risk factor controlled showed that cardiovascular risk stratification was a significant predictor, whereas age, gender, duration of DM, and clinic visits were not significant predictors. See Figure 4.

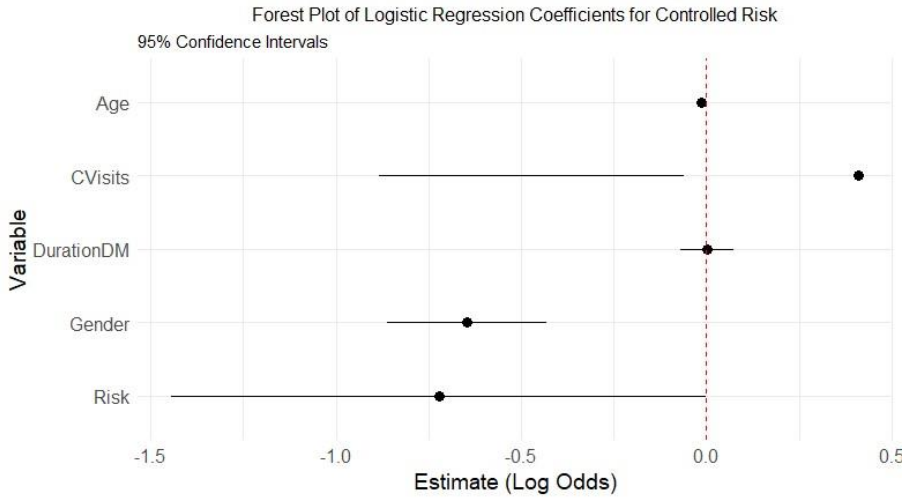

Figure 3: Plot of logistic regression coefficients for controlled risk for at least 2 risk factors.

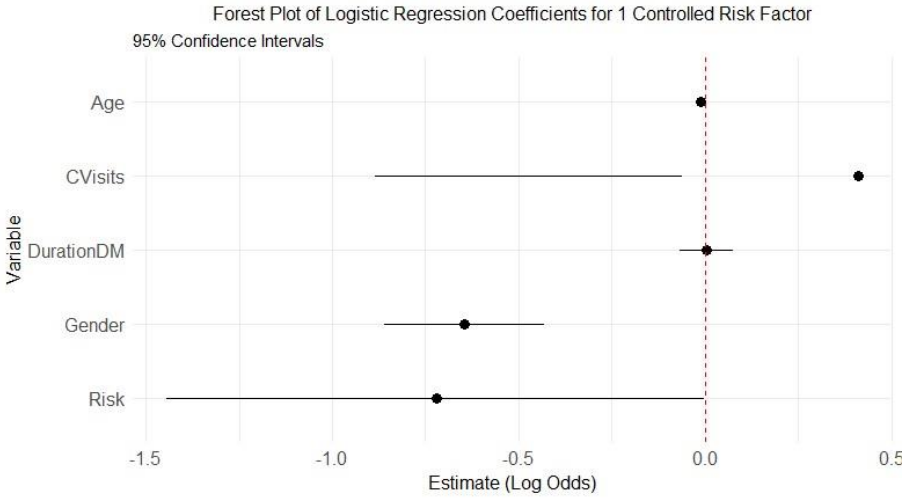

Figure 4: Plot of logistic regression coefficients for controlled risk for at least 1 risk factor.

DISCUSSION

Generally, there is a scarcity of data on studies that holistically audit the adherence or fidelity to guidelines on CV risk management in T2DM patients, especially with respect to LMICs such as ours. Instead, the data available are often from studies assessing particular aspect(s) of cardiovascular risk management.

Regular checks and recording of blood pressure readings, HbA1c levels, and periodic cholesterol assays (process measures) and intermediate outcome measures such as the achievement of good blood glucose, blood pressure and lipid control are indicators of good quality of care. Support to manage patients with type 2 diabetes optimally by their health care professionals should ideally be provided by updated local, national, and international guidelines. However, some studies have noted that process improvements may have a limited influence on hard outcomes of clinical care[27-32]. Additionally, the appropriateness of guidelines has been questioned in relation to treatment goals by respected professional bodies in their earlier publications[33] and the management of specific situations such as multiple comorbidities in older people who have diabetes as well[34]. More recent CPGs are now segmenting certain special groups for targeted clinical attention. Despite certain limitations, guidelines (CPGs) provide both evidence-based practical guidance and tools for measuring quality of care against agreed-upon standards. It is therefore imperative for physicians to recognize that there are diabetes-associated complications that dictate the need to provide appropriate and targeted clinical care to achieve optimal control of diabetes.

Understanding the factors that influence quality of care can assist in identifying strategies for improvement. A range of such factors has been previously identified, such as the duration of diabetes [35], management by specialists or non-specialists[36] and socioeconomic differences[37, 38, 39]. Enhancement of resources and better technical performance from redesigned care teams have been shown to produce improved outcomes[40]. Evidence shows that social determinants of health (SDOHs) are key drivers of diabetes outcomes and disparities in diabetes care. Targeting SDOH at the individual, organizational, and policy levels is an essential step in improving health equity for individuals living with diabetes[41].

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The primary objective of documenting information in patients' medical records is to record what is being done to support the delivery of good care and clinical decision-making, communication with other healthcare providers and continuity of care. Additionally, medical records are a valuable resource for research, quality assurance and transparency of the delivered care. Healthcare providers are mandated to record patient data as evidence of the medical services that they provide. The quality of the recorded information in patient records seems to be a predictor of the quality of care. Sufficient documentation of patient information could contribute to safer healthcare and better patient outcomes. Missing patient record components and poor quality of the available patient information may betray different underlying challenges in the hospital: first, administrative and process issues, and second, possibly reflects the performance of healthcare providers themselves—the diligence with which individual healthcare professionals record patient information and follow the record-keeping guidelines for documenting patient information[42]. Patient records are rarely compiled in a satisfactory way, yet the clinical documentation, particularly medical records (MRs), is the central means of communication among healthcare professionals[43,44,45].

We also asked ourselves, "Is deliberate CVD risk stratification of type 2 diabetes to direct the level of care needs of the individual patients, based on the CVD risk stratum often performed in our routine care?" We found that there was no evidence of deliberate CVD risk stratification during this clinical audit to suggest that this approach was used to direct the level of care needs of the individual patients, based on a determined CVD risk stratum.

The identification of both CVD risk factors and accurate CVD risk stratification tools in this cohort of patients with T2DM must therefore be a priority. The literature has shown that risk stratification among T2DM patients not only improves the accuracy of predicting subclinical cardiovascular events such as silent ischemia but also prevents future cardiovascular events[46]. However, there are knowledge gaps regarding cardiovascular disease (CVD) risk factors and the actual risk stratification of people with type 2 diabetes during care in the course of their disease. Therefore, how should we approach cardiovascular risk stratification in people with type 2 diabetes during their disease course? The patients in the highest CVD risk category are those with type 2 diabetes who have established CVD or other target organ damage (evidenced by any proteinuria, renal impairment defined by an eGFR <30 ml/min/1.73 m^2, left ventricular hypertrophy or retinopathy), or three or more major risk factors (age, hypertension, dyslipidaemia, smoking, obesity)[24]. Probably, we could also use risk scores QRISK2, UKPDS, etc. which involve calculations. However, when 22 cardiovascular risk scores were compared in a primary care setting, all the scores were demonstrated to perform universally poorly in patients with diabetes, but the diabetes-specific scores were not superior either[47]. The clinical practice guidelines should empower healthcare practitioners (HCPs) as clinicians to engage with patients in data-driven individualized risk discussions for interventions. By segmenting them into risk categories and adding risk enhancers as decision aids, the recommendations on clinical interventions can be strengthened. Suboptimal control of the selected CVD risk factors for ABCs was observed to be a major challenge in our clinic. The effects of multiple risk factors are more likely to be additive or synergistic; therefore, the assessment of CVD risk on the basis of the combined effect of multiple risk factors is a more practical and accurate approach[48,49,50]. The risk of structural and functional cardiac impairments in type 2 diabetes mellitus patients is greater in patients with concomitant uncontrolled metabolic risk factors[51].

It has already been demonstrated that among at-risk patients with type 2 diabetes, intensive intervention with multiple drug combinations and behaviour modification has sustained benefits for vascular complications[52]. Similarly, intensive multifactorial, target-driven treatment of type 2 diabetes demonstrated a long-term outcome of an increased lifespan in the study patients[53]. Moreover, patients with type 2 diabetes who had five risk factor variables that were within the target ranges of treatment appeared to have little or no excess risk of death, myocardial infarction, or stroke compared with the general population[13]. This underscores the increased value of deliberate efforts to achieve good control of multiple risk factors simultaneously over a long time for the benefit of patients. However, the reality is that, comprehensive control of ASCVD risk factors on the global stage is not being achieved in most patients with the greatest need. Indeed, there is wide variability among countries that is unaccounted for by patient and site differences[54]. Locally, we have demonstrated significant shortfalls in the proportions of patients at high CVD risk who do not attain treatment targets[55]. Better country-specific strategies are needed to implement comprehensive and consistent cardiovascular risk factor control in patients with T2DM to improve long-term outcomes. Therefore, risk stratification should be a quality initiative to target the individuals with the highest levels of need to segment them for more focus.

On average, people who are socioeconomically disadvantaged have greater levels of cardiovascular disease (CVD) and/in diabetes. A low socioeconomic status (SES) is more consistently associated with a worse profile of diabetes among women than among men[56]. Women composed the majority of our study population. Low SES limits one's ability to respond to the needs of diabetes care, including attending clinics and doing laboratory tests that are part of care processes that, in turn, indicate quality of care.

From this clinical audit, quality improvement initiatives should therefore target documentation of the care provided as an initial deliverable through formal data capture mechanisms. Medical record keeping is indeed an essential component although an overlooked activity of quality of care in resource-limited settings[57]. Consequently, the data summary will provide the levels of treatment targets (HbA1c, blood pressure, and LDL-cholesterol) achieved by the interventions. These levels would aid cardiovascular risk stratification to inform the care needs of individual patients and possibly, resource needs in the course of follow-up. It is also probable that the modest socioeconomic status of our study patients negatively influenced their capacity to respond to diabetes care needs, most likely in attending follow-up visits and funding the required laboratory tests. In that regard, the context of the health system of diabetes care should factor in the socioeconomic status of patients living with diabetes for equity. Significant national engagement needs to focus on the reality of structural inequalities within multiple societal domains, including healthcare.

List of abbreviations

- **CVD:** Cardiovascular Disease
- **ASCVD:** atherosclerotic cardiovascular disease
- **LMICs:** Low- and middle-income countries
- **HbA1c:** haemoglobin A1c (glycated haemoglobin)
- **PI:** Principal Investigator
- **eGFR:** estimated glomerular filtration rate
- **CPGs:** Clinical Practice Guidelines
- **ESC:** European Society of Cardiology

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- **T2DM:** Type 2 diabetes mellitus
- **T1DM:** Type 1 diabetes mellitus
- **DM:** Diabetes mellitus
- **BP:** Blood Pressure
- **LDL-C:** low-density lipoprotein cholesterol (LDL cholesterol)
- **QI:** Quality improvement
- **NCDs:** Non-communicable diseases
- **KNH:** Kenyatta National Hospital
- **DOPC:** Diabetes Outpatient Clinic
- **EASD:** European Association for Study of Diabetes
- **ADA:** American Diabetes Association
- **HTN:** Hypertension
- **CKD:** Chronic kidney disease
- **RAAS:** Renin Angiotensin Aldosterone System
- **SDOH:** Social Determinants of Health
- **HCPs:** Healthcare practitioners
- **SES:** Socioeconomic Status
- **MR:** Medical Records

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