Screening Strategies to Detect Gestational Diabetes Mellitus in AIC Kijabe Hospital, Kenya

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Abstract Gestational DM has been associated with increased risk of perinatal mortality and morbidity however, screening recommendations are not clearly described in Kenyan guidelines. Kenyan studies have shown wide-ranging prevalence rates for GDM between 1.1% - 16.7% which reflects inconsistences in GDM screening strategies. The purpose of this study is to assess the utility of the selective and universal screening strategies in detecting GDM in AIC Kijabe Hospital. **Methods** This was a cross-sectional retrospective and prospective study. Study participants between 24- and 32-weeks' gestation had a risk factor screening questionnaire administered, followed by a 75g oral glucose tolerance test (OGTT) if appropriate. **Results** A total of 343 were selectively screened for GDM from the retrospective data, while 38 women were universally screened for GDM in the prospective arm of the study. The detection of GDM was 13.2% and 2.6% in the universal and selective screening strategies, respectively (p=0.016). Forty-three percent (42.9%) of GDM cases were diagnosed in the absence of risk factors for GDM. **Conclusion** Universal screening detects a significantly higher rate of GDM than the selective screening strategy. **Recommendations** The Ministry of Health in Kenya should consider adopting the universal screening strategy for GDM, for early diagnosis and prevention of maternal and neonatal complications amongst pregnant women in Kenya. The true prevalence of GDM in Kenya will be clearly defined once universal screening is widely adopted.

Keywords: Gestational Diabetes Mellitus, Selective Screening, Universal Screening

Introduction

Pregnancy causes an increase in insulin levels and resistance which predisposes pregnant women to develop diabetes in pregnancy. Gestational diabetes mellitus (GDM) is a hyperglycaemic condition in pregnancy that develops during the 2nd or 3rd trimester (Riddle et al., 2018).

Women with hyperglycaemia before 12 weeks of their pregnancy are categorized as those with overt type 2 diabetes that was present prior to pregnancy. GDM usually resolves after pregnancy, however, pregnant women may develop adverse events during pregnancy and/or long term sequelae affecting the mother and infant (Mwanri, Kinabo, Ramaiya, & Feskens, 2015). Perinatally, pregnant women with GDM are at risk of hypertension in pregnancy, preterm delivery, and caesarean section delivery. The foetal complications include macrosomia, shoulder dystocia, hypoglycaemia and hyperbilirubinemia of the new-born (Kim, 2010).

The IDF reported a worldwide prevalence of hyperglycaemia in pregnancy as 16.2% by the year 2015, of which 85.1% was due to GDM (Ogurtsova et al., 2017). Low and middle-

income countries have reported a higher prevalence of GDM than high-income countries. A systematic review by Macaulay et al., (2014) that had a representation of only 6 African countries described a prevalence as high as 13.9% (Macaulay, Dunger, & Norris, 2014). Kenyan studies have described a GDM prevalence ranging from as low as 1.1% to high rates of 16.7%. These variations in Kenyan data are mainly due to the paucity of good data in the country and the different screening strategies that have been used in these studies.

The International Association of Diabetes and Pregnancy Study Groups (IADPSG) was created to develop a unified international approach to GDM screening and diagnosis because different screening strategies were being used in different countries. The IADPSG recommended high-risk women should be screened for pre-existing DM using random or fasting glucose levels or haemoglobin A1C (HbA1C) in the first obstetric visit. Subsequently, all women are universally screened for GDM at 24 to 28 weeks of pregnancy using a 2-hour OGTT (International Association of Diabetes and Pregnancy Study Groups [IADPSG], 2010). Nevertheless, these recommendations for universal screening are yet to be adopted internationally and countries continue to screen according to their preferences or not screen at all.

This study aims to assess the utility of the selective and universal screening strategies in detecting GDM in pregnant women from the peri-urban community that AIC Kijabe Hospital serves.

The Problem

GDM cannot be taken lightly as it results in several complications such as an increased risk of gestational hypertension and caesarean deliveries for pregnant women and birth trauma and macrosomia for the foetus perinatally (Buchanan, Xiang, & Page, 2012). Additionally, GDM predisposes a significant number of women (up to a 60% chance) to type II DM in the next decade of their lives (Centers for Disease Control and Prevention [CDC], 2011). Children of women with GDM have are more likely to have DM and cardiovascular disease due to subsequent obesity (Krishnaveni, 2010). Therefore, preventing and managing GDM in pregnancy will aid in halting the rise of obesity and metabolic syndrome in the overall population. This is one of the global targets of the World Health Organisation (WHO) for prevention and control of NCDs (World Health Organization [WHO], 2013b).

Screening enables early detection and management of GDM and therefore prevents the associated adverse events from occurring in both the mother and child. A number of studies on prevalence of GDM in Kenya have been done describing a prevalence as high as 16.7% (Adelaide, Ogutu, & Munguti, 2011). However, less research has been done to assess which screening strategy best detects GDM in our population; the risk factors observed in women of child-bearing age and those who eventually develop GDM. Screening and diagnostic criteria have also remained controversial despite the IAPDSG recommendations. There has been debate on which screening approach (universal versus selective) best diagnoses GDM. Studies looking at the prevalence of risk factors in the general population and women who develop GDM have helped inform several countries on the appropriate screening strategies. The Endocrine Society of United States of America adopted the IADPSG universal screening recommendations, however, the United Kingdom NICE guidelines recommend selective screening (Blumer et al., 2013; National Institute for Health and Clinical Excellence [NICE], 2015).

Screening for GDM has not been a routine requirement in most Kenyan health facilities possibly attributed to the fact that the Kenya national guidelines provide minimal data on whom and how to screen and diagnose GDM (Ministry of Medical Services & Ministry of Public Health and Sanitation, 2010). Failure to screen and manage GDM in Kenya can result

in higher rates of maternal and foetal morbidity and directly increase the rates of diabetes and other non-communicable diseases in the future.

Study Objectives

Amongst pregnant women between 24-32 weeks' gestation attending antenatal clinic in AIC Kijabe Hospital over a 4-month screening period, the following constitute the research objectives for this study:

1. Assess the utility of the selective screening strategy in detecting GDM using the IADPSG diagnostic criteria.
2. Assess the utility of the universal screening strategy in detecting GDM using the IADPSG diagnostic criteria.
3. Compare universal and selective screening strategies in detecting GDM.

Literature Review

Prevalence of GDM

GDM prevalence has been studied for several years now, however, in the last 2 decades, the prevalence has increased by up to 10 to100 per cent and therefore become a global health concern. Increase in prevalence has been demonstrated amongst the Asian, Hispanic and African American populations, with a lower prevalence in Caucasian populations (Ferrara, 2007). This highlights the association between race and ethnicity and GDM prevalence.

The trend in prevalence in the low- and middle-income countries, where these ethnicities are prevalent, has not been clearly reported as fewer studies have been done over the years in these regions. However, the International Diabetes Federation (IDF) described a global rise in GDM, with 91.6% of GDM cases being in the LMIC (Ogurtsova et al., 2017).

The scarcity of good, quality data from Africa reveals that little is understood about the prevalence and burden of GDM in the continent. Two systematic reviews on GDM prevalence in Africa have been published in the last 5 years. One review had a representation of 6 of the 54 African nations, and only 14 articles qualified to be included in the review. The authors, using this minimal data, described a prevalence ranging from 0% (Tanzania) to 13.6% (Nigeria) and emphasised the need for further African studies to describe the GDM burden in Africa (Macaulay et al., 2014). Another review described a similar median prevalence of 14% from 6 African countries. Half of the articles included were from West Africa (Mwanri et al., 2015).

A small prospective study was done in Kenyatta National Hospital, the largest referral hospital in Kenya, demonstrated a GDM prevalence of 16.7%, however, it was not clear what diagnostic criteria were used in the study (Adelaide et al., 2011). In Aga Khan University Hospital, a hospital that serves the urban, wealthier Kenyan population in Nairobi, Muriithi et al. (2014) described a much lower GDM prevalence of 1.1% using plasma glucose readings and the IADPSG diagnostic criteria (Muriithi et al., 2014). In Western Kenya, a multicentre study including the second largest referral hospital in Kenya revealed a lower prevalence of 2.9% using the IADPSG diagnostic criteria and HbA1C (Pastakia et al., 2017). These disparities in the Kenyan data make it difficult to define the GDM prevalence in Kenya. Significant differences in methodology, mainly screening and diagnostic criteria and blood sampling sites (venous versus capillary), between these four Kenyan studies, may explain the wide range in the prevalence described.

Screening & Diagnosis of GDM

Screening and diagnosis for GDM are done after 24 weeks' gestation because insulin resistance develops during the second trimester of pregnancy. Women who have features suggestive of pre-gestational DM or high-risk factors can be screened before 24 weeks for early diagnosis of pre-existing DM. Most guidelines recommend GDM screening to occur between 24 to 28 weeks gestation, however, it is not clear why the specific cut-off of 28 weeks gestation. Many studies were done in the African population extend the screening period to 32 weeks due to late presentation of women to ANC clinic compounded with difficulties of access to healthcare (Muriithi et al., 2014; Olagbuji et al., 2015).

The OGTT is the diagnostic test for GDM. The IADPSG panel recommended one or more glucose levels above or equal to of 5.1 mmol/L (fasting), 10.0 mmol/L (at 1 hour), 8.5 mmol/L (at 2 hours) as OGTT cut-offs that were diagnostic for GDM. These glucose cut-offs were informed by the hyperglycaemia and adverse pregnancy outcome (HAPO) study that revealed a directly proportional increase in predefined adverse pregnancy outcomes to each plasma glucose value (fasting, 1 hour and 2-hour) in the OGTT. Most international bodies such as the WHO (2013), Endocrine Society of the USA and FIGO have implemented the IADPSG criteria to diagnose GDM (Blumer et al., 2013; Simeoni & Sobngwi, 2015).

In Africa, most countries do not have national guidelines for the management of GDM and therefore no diagnostic criteria unique to the African population exists (Utz, Kolsteren, & De Brouwere, 2016). Kenya's National Guidelines for Quality Obstetric and Perinatal Care only describe the screening and diagnostic criteria for overt/pre-gestational diabetes mellitus. Most GDM studies done in Africa use screening and diagnostic criteria from other guidelines developed in high resource settings. There is an increased burden of healthcare cost and health resource associated with the IADPSG recommended criteria due to the increased prevalence associated with the criterion. Concerns have been raised on whether low- and middle-income countries could sustain the IADPSG recommendations.

Universal and Selective Screening Strategies for Gestational Diabetes Mellitus

Now that several factors have been associated with developing GDM, a few studies have evaluated the efficacy of a risk factor-based approach to the screening of GDM rather than screening all women between 24-28 weeks gestation (universal screening). The selective screening approach would be a more cost-effective, resource-saving strategy towards GDM screening that could be more practical to adopt than the universal approach in middle- and low- income countries with inadequate health resource.

A single centre, cross-sectional study in Sri Lanka assessed the detection rates of GDM using selective screening and universal screening strategies. They also compared the IADPSG and WHO diagnostic criteria. In spite of the diagnostic criteria used, universal screening detected higher rates of GDM in comparison to the selective screening strategy (23.2% versus 20.1% in the IADPSG criteria group and 18.2% versus 15.7% in the WHO criteria group). The authors of the study summarized that selective screening had a lower detection rate than universal screening (Meththananda Herath et al., 2016).

A similar study comparing universal and selective screening strategies in South Africa screened 554 pregnant with 75g - OGTT and GDM were diagnosed by the IADPSG criteria. The study showed that if selective screening alone was conducted, 10.6% of women with GDM would have been left undiagnosed (Adam & Rheeder, 2017). In Nigeria, 20% of women would have remained undiagnosed for GDM when selective screening is done (Olagbuji et al., 2015). Similarly, at the Aga Khan University Hospital, Muriithi e*t al.* illustrated that 48.1% of GDM diagnoses were identified in women without any risk factors

(Muriithi et al., 2014). These findings from the above named studies emphasize the relevance of screening strategies used in diagnosing GDM.

Methodology

The study is a cross-sectional study design from October 2019 to April 2020. The study included a retrospective arm (October 2019 to January 2020) and a prospective arm (February 2020 to April 2020). This cross-sectional study sought to establish the frequency of, and risk factors associated with GDM in the antenatal clinic at AIC Kijabe Hospital.

The study population included adult (>18 years) pregnant women between 24 to 32 weeks gestation attending AIC Kijabe Hospital antenatal clinics. Gestational age was calculated from the patients last normal menstrual period or obstetric scan estimation. Pregnant women with type 2 diabetes; HIV infection; on current medications that alter glucose metabolisms; women of Caucasian, Asian and Hispanic ethnicities and ill patients requiring admission were excluded from the study.

In the retrospective arm, all medical records of women attending ANC at Kijabe Hospital were reviewed for risk factors and GDM screening results. On the prospective arm, study participants were consecutively sampled over a 3-month period.

The Cochran formula modification for small sample size was used to calculate the final sample size. Based on the GDM prevalence in Africa, the prevalence in the study population was assumed to be 9%. A sample of 108 pregnant women between 24 and 32 weeks gestation was targeted in this study.

The research protocol was reviewed and approved by the Kabarak University and AIC Kijabe Hospital ethics committees. All participants provided written informed consent prior to being enrolled in the study.

In the retrospective arm of the study, the principal investigator audited the electronic medical records (EMR) of all women who attended Kijabe ANC for a 4-month period between October 2019 to January 2020. Data on their risk factors of all pregnant women attending ANC were collected and the OGTT results of those who met the criteria for testing were collected and analysed. The retrospective OGTTs were done based on the selective screening strategy and GDM diagnosis of both the retrospective and prospective data was based on the IADPSG diagnostic criteria.

In the prospective arm, all pregnant women meeting the diagnostic criteria were enrolled in the study based on the universal screening strategy. A data collection tool was used to collect demographic data and evaluate risk factors and symptoms for GDM. At the end of the questionnaire, the 75g OGTT results using the IADPSG cut-off points were documented.

Pregnant women enrolled to the prospective arm of study, were booked for an OGTT one visit prior to the testing date. This was to ensure that participants could be contacted and reminded to fast for a minimum of 8 hours prior to testing. First, a fasting blood sugar reading was taken and then the participant was given a 75g glucose load solution to ingest within 10 mins. A random blood sugar reading from venous plasma was collected at 1 and 2 hours following the 75g glucose load. Timing and results were documented in the data collection form by the laboratory research assistant.

One or more glucose levels above or equal to 5.1 mmol/L (fasting), 10.0 mmol/L (at 1 hour), 8.5 mmol/L (at 2 hours) were diagnostic for GDM.

Results

This cross-sectional study consisted of a retrospective and prospective arm, where a total of 381 women underwent GDM screening. The retrospective arm represented the selective

screening strategy, which is the AICKH GDM screening protocol, while the prospective arm represented the universal screening strategy that was adopted as a new intervention during this study. Three hundred and forty-three (343) were screened in the retrospective arm and 38 women in the prospective arm of the study. Forty-nine out of the 343 selectively screened women had an OGTT done to diagnose GDM in the retrospective arm. While all 38 women were tested for GDM based on the newly implemented universal screening strategy in the prospective arm of the study (figure 1).

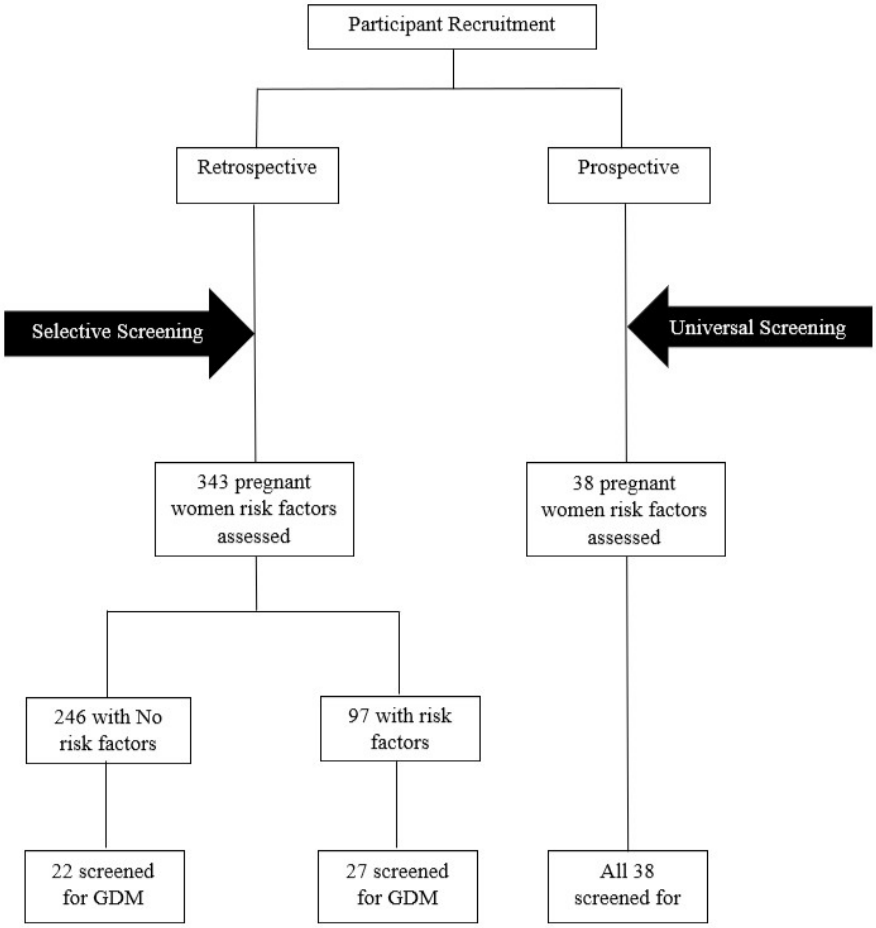

Figure 1. Participant recruitment flowchart for the Study.

Thirty-eight women were universally screened on the prospective arm of the study, of which 5 screened positive for GDM and 1 for overt DM resulting in a frequency of 13.2% for GDM cases and 2.6% for overt DM cases detected according to the universal screening approach. Three hundred and forty-three women in the retrospective arm of the study were screened for GDM using the selective screening criteria. Nine women screened positive for GDM, and 3 women had overt DM out of the total population of 343. The selective screening strategy detected a frequency of 2.6 % cases of GDM and 0.9% cases of overt DM.

The universal screening strategy detected a significantly higher proportion of GDM at 13.2% in comparison to the selective screening strategy at 2.6% (p=0.016). No significant difference was found between the cases of overt DM detected by the two screening strategies. See table 1.

Table 1. Frequency of GDM and Overt DM using Universal and Selective Screening Strategy

	Screening Strategy		P-value
	Universal	Selective	
GDM, n (%)	5 (13.2)	9 (2.6)	0.016
Overt DM, n (%)	1 (2.6)	3 (0.9)	0.927

A total of 381 women had their risk factor profiles reviewed and the frequency was calculated. Two hundred and sixty-nine had no risk factors (70.6%) while 112 (29.4%). A large proportion of women (24.9%) had at least one risk factor, 4.2% had two risk factors and only 0.3% of women had three risk factors (table 2).

Table 2. Presence and Absence of Risk Factors of all women attending ANC at Kijabe Hospital

	All Pregnant Women Attending ANC N=381
No Risk Factors, n (%)	269 (70.6)
Risk Factors present, n (%)	112 (29.4)
1 risk factor	95 (24.9)
2 risk factors	16 (4.2)
3 risk factors	1 (0.3)

A total of 14 pregnant women from both arms of the study tested positive for GDM using the IADPSG diagnostic criteria. Of the women who screened positive for GDM, 6 had no history of any risk factors; 6 had only 1 risk factor and 2 had 2 risk factors. None of the women who tested positive for GDM had more than 3 risk factors as shown in figure 2.

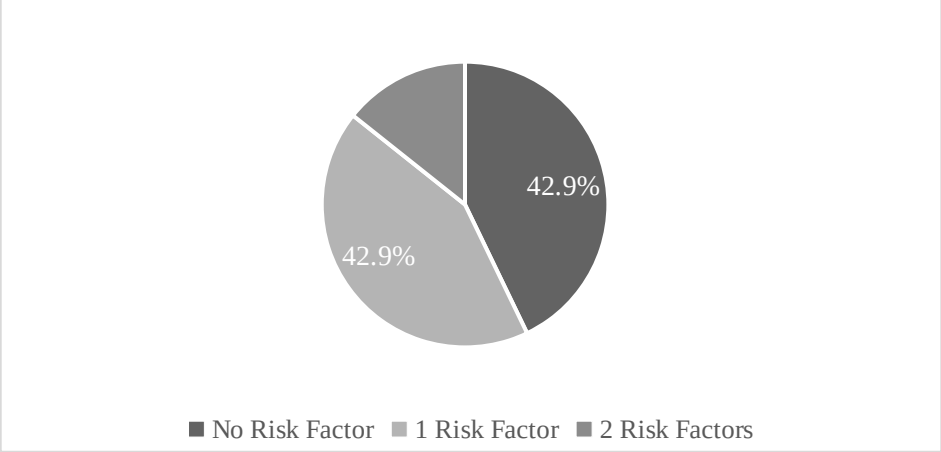

Figure 2. Frequency of Risk Factors associated with GDM.

Discussion

This study was not powered for prevalence, and therefore the GDM cases diagnosed in the study can only be described as proportions/frequencies of GDM using the different screening strategies. Nevertheless, the frequencies of GDM in both arms of the study are similar to the prevalence rates of GDM described in other Kenyan studies. In the retrospective arm of the study, where selective screening strategy was used, the proportion of women with GDM of

2.6% falls within the range of other prevalence studies done in AKUH (1.1%) and Western Kenya (2.9%) (Pastakia et al, 2017; Muriithi et al. 2014). Unlike this study, both of these studies had all pregnant women undergo a 50g glucose challenge test, and only those with impaired glucose tolerance would proceed to have the diagnostic OGTT for GDM. The frequency of GDM of 13.2% in the universal screening strategy also lies within the range of two studies done in Kenyatta National Hospital (KNH) that showed a prevalence of 11.6% and 16.7% (Bosire, 2012; Adelaide et al., 2011). Both these studies used the universal screening approach to determine GDM prevalence.

The USA was one of the first countries to compare the two screening strategies and found that selective screening added significant complexity to the screening process, and therefore opted for universal screening of all pregnant women (Danilenko-Dixon, Van Winter, Nelson, & Ogburn, 1999). Similarly, Berger et al. (2009) in Canada found that selective screening implementation was more complex than universal screening as it increased the burden on the healthcare provider during assessment on whom to screen. The retrospective data collected in this study reveals that the current selective screening method being used at AICKH has proven difficult to implement correctly and therefore not reliable to detect GDM due to the complexities of accurate GDM risk factor assessment by the healthcare workers.

As a result, a significantly lower frequency of GDM was detected using selective screening strategy at 1.2 % in comparison to universal screening strategy at 13.2% ($p=0.016$). This significant difference in frequencies between the two screening strategies has been described in several studies. In Ireland, a predominantly Caucasian, low-risk country detected prevalence in universal and selective screening was 2.7% and 1.45% ($p<0.03$), respectively and concluded that universal screening was superior to selective screening (Griffin et al., 2000). In South Africa, universal screening detected a 25.8% prevalence of GDM while selective screening detected 15.2%. Ten percent of women would have been missed if the risk factor-based screening strategy were used. Based on these findings, Adam et al. (2017) concluded that selective screening is a poor strategy to diagnose GDM.

Fourteen women screened positive for GDM, of which 8 (57.1%) had at least one risk factor and 6 (42.9%) had no risk factors at all. This finding coincides with an AKUH study where 48.1% of women who screened positive for GDM had no risk factors. This significant finding resulted in a change in the GDM screening approach from risk factor-based screening to universal screening of all pregnant women attending antenatal clinic at AKUH (Muriithi et al., 2014). Still, one of the recognised risk factors for GDM found in international guidelines is ethnicity (NICE, 2015). African, Hispanic and Asian women are reported to have a higher risk of developing GDM than Caucasian women, deduced from the higher prevalence rates of GDM in non-Caucasian countries. The high proportion of women developing GDM without risk factors in this study and others like it supports the presumption of African ethnicity being a possible risk factor for GDM.

Conclusion

This study reveals that universal screening is significantly better at diagnosing GDM than the selective screening strategy and women who screen positive for GDM can present without any risk factors. Therefore, universal screening for GDM would be the most reliable screening method to diagnose GDM. Larger, multicentre, trans-county studies should be done to clearly define the GDM prevalence in Kenya using the universal screening strategy. Furthermore, the Ministry of Health should consider adopting the universal screening strategy for GDM, for early diagnosis and prevention of maternal and neonatal complications amongst

pregnant women in Kenya. The true prevalence of GDM in Kenya will be clearly defined once universal screening is widely adopted.

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