Final Report – The DIAMIND Study

Postpartum SMS reminders to women who have experienced gestational diabetes to test for type 2 diabetes: the DIAMIND randomised trial

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Executive Summary

Background

Clinical practice guidelines recommend that women who have had gestational diabetes mellitus (GDM) have glucose screening for prediabetes and type 2 diabetes in the postpartum period [1-3], due to their increased risk of type 2 diabetes [4-6]. However, postpartum screening rates are often reported to be low, and vary considerably between settings [7, 8].

A Canadian trial of postal reminders for type 2 diabetes testing in women who had GDM, found that postal reminders increased test completion (published 2009) [9]. In Australia, since 2012, women have had the option of joining the National Gestational Diabetes Register [10], which sends women postal reminders at 12-16 weeks after their expected due date. We hypothesised that given the past success of postal reminders, in combination with evidence that SMS reminders have been shown to increase attendance for healthcare appointments [11], and that there is decreasing use of post as a form of communication in Australia [12], that an SMS reminder system for postpartum diabetes screening may be more effective and/or more preferable to women who have experienced GDM.

This final report contains the findings of the DIAMIND randomised controlled trial (RCT) (n = 276), conducted at the Women's and Children's Hospital, Adelaide, Australia. This RCT examined the efficacy of an SMS reminder system, with reminders being sent to women who had recently experienced GDM, for increasing completion of an oral glucose tolerance test (OGTT) by six months postpartum [13]. We also report the findings of the six month postpartum follow-up questionnaire, which aimed to obtain the views of the women who participated in the DIAMIND RCT regarding their preferred type of postpartum reminder system, and barriers and facilitators to postpartum glucose testing.

Methods

Women were eligible for inclusion if they were diagnosed with GDM in their recent pregnancy, had a mobile phone and normal blood glucose profile prior to postnatal discharge. A computer-generated random number sequence and telephone randomisation were used; blinding thereafter was not feasible. Women in the intervention group (n = 140) were sent a text reminder to attend for an OGTT at six weeks postpartum, with further reminders at three and six months if required. Women in the control group (n = 136) received one text reminder at six months postpartum. The primary outcome was OGTT attendance within six months postpartum. A questionnaire, based on literature review, was sent to women who participated in the DIAMIND Study (n = 276) via post or email six months after the birth of their baby.

Results

A total of 268 women (97%) were followed up to six months. The intervention did not increase attendance for an OGTT within six months postpartum, with 104 (77.6% of 134) of women attending in the six week group and 103 (76.8% of 134) women attending in the control group (RR 1.01, 95% CI 0.89-1.15).

Most women in both study groups (≥87%) self-reported that they had been offered an opportunity to join the Australian National Gestational Diabetes Register and had joined (≥83%) [14], and therefore would have received postal reminders at 12-16 weeks after their expected due date from this register.

Over 98% of women in each group receiving public medical care had a discharge summary forwarded to their postpartum care provider, with no difference seen between groups. The majority

of these discharge summaries listed GDM in their problem list, although approximately 20% did not include recommendations of an OGTT in the follow-up plan.

208 women (75%) returned their questionnaires. 67% of women selected SMS reminders as their preferred reminder type, followed by email (17%), postal (12%) and voice call (1%). Common barriers to attendance for postpartum glucose testing included: *not having enough time* (73%), *inadequate or non-availability of childcare* (30%), and a *need to focus on the health of the baby* (30%). The most common facilitator for postpartum testing was *having a shorter test (33%)*.

Study Findings

The SMS reminder system did not increase completion of postpartum screening for prediabetes or type 2 diabetes within six months, although high rates of postpartum test completion were observed for both groups. For women unable to attend for the oral glucose tolerance test, time constraints and test inconvenience were the most commonly cited barriers, and doing a shorter test was stated to be the main facilitator. This suggests that changing from an OGTT to a more convenient test, such as the HbA1c test, might facilitate an increase in the rate of postpartum glucose testing that would be clinically important. However, further research into the use of HbA1c for this purpose is required.

Most women expressed a preference for SMS reminders over other methods of postpartum reminders, followed by email, postal and voice call reminders; women should therefore be given the opportunity to have electronic forms of postpartum reminders, where possible. Screening for T2DM needs to be coupled with provision of effective counselling on T2DM risk, and risk reduction. Further research into T2DM prevention programs specific for women who have experienced GDM is important.

Final Report: Detailed Version

Background

Women who have had GDM are at much higher risk of type 2 diabetes in the future; they are also at risk of recurrent GDM in future pregnancies [4-6]. Due to this increased risk of type 2 diabetes, clinical practice guidelines recommend screening for prediabetes and type 2 diabetes in the postpartum period [1-3]. Women identified with prediabetes can then be counselled regarding type 2 diabetes prevention options [15-18]. Identification of previously undiagnosed type 2 diabetes prior to a subsequent pregnancy allows treatment to prevent early pregnancy hyperglycaemia. This can reduce the risk of several complications for the mother and her baby [3, 19-21].

Postpartum screening rates are often reported to be low, and vary considerably between settings [7, 8]. For example, in England, a study which examined postpartum glucose screening rates in women with a history of GDM, using a nationally representative sample from 127 urban and suburban primary care practices, found that just 18.5% of women had glucose screening within six months of birth [22]. Similarly, a study from Boston, in the United States, found that just 23.4% of GDM affected women received any glucose test by six months postpartum [23]. Furthermore, a recent Australian study found rates of postpartum oral glucose tolerance testing of 25% in Indigenous women and 34% in non-Indigenous women at three years after birth [24].

In Australia, women who are eligible for Medicare now have the option of joining the National Gestational Diabetes Register [10], which sends women postal reminders at 12-16 weeks after their

expected due date. A previous Canadian trial of postal reminders for a postpartum oral glucose tolerance test (OGTT) in women who had GDM, found that postal reminders increased OGTT completion [9]. Short message service (SMS) reminders have been found to increase attendance for healthcare appointments in general [11]. It is possible that a short message service (SMS) reminder system may be preferable to women, given the greatly decreasing use of the postal system in Australia and other developed countries [12].

This final report contains the findings of the DIAMIND randomised controlled trial (RCT) (n = 276), conducted at the Women's and Children's Hospital, Adelaide, Australia. This RCT examined the efficacy of an SMS reminder system, with reminders being sent to women who had recently experienced GDM, for increasing completion of an oral glucose tolerance test (OGTT) by six months postpartum [13]. We also report the findings of the six month postpartum follow-up questionnaire, which aimed to obtain the views of the women who participated in the DIAMIND RCT regarding their preferred type of postpartum reminder system, and barriers and facilitators to postpartum glucose testing.

Methods

Study design and population

The protocol for this single centre parallel group randomised controlled trial was published in 2013 [13], and the methods used followed this protocol. Ethical approval was obtained from the Women's and Children's Health Network Human Research Ethics Committee (REC2200/8/2015).

Women were eligible for inclusion in the trial if they were diagnosed with GDM in their most recent pregnancy (positive 75 gram OGTT with fasting glucose ≥ 5.5 mmol/L and/or two hour glucose ≥ 7.8 mmol/L), had access to a personal mobile phone, and had normal capillary blood glucose profile measurements prior to postnatal discharge from hospital (fasting plasma glucose < 6.0 mmol/L and 2 hour postprandial blood glucoses < 8.0 mmol/L). Women were excluded if they had pre-existing diabetes mellitus (type 1 or type 2 diabetes), a triplet/higher order multiple birth, requirement for an interpreter (due to text reminders being written in English), or if they had experienced a perinatal death in their most recent pregnancy.

The daily postnatal midwifery coordinator was consulted about women's eligibility. Women who were eligible were then approached and provided with verbal and written information about the study. Women were enrolled if they gave written informed consent and had a normal blood glucose profile prior to discharge from hospital. Recruitment for the DIAMIND Study took place from June 2012 until January 2014, when the pre-specified sample size was reached, in the postnatal ward of the Women's and Children's Hospital, South Australia, with follow-up of study outcomes completed by September 2014.

Randomisation procedures

Women were randomised into one of two study groups: either the 'six week group' or the control group. Allocation to study groups was carried out using a telephone randomisation service. The randomisation schedule was prepared by an investigator not involved in recruitment or clinical care and used balanced variable blocks, with stratification by antenatal requirement for insulin therapy to treat GDM.

Treatment schedules

Women in the six week group were sent a SMS reminder at six weeks after the birth of their baby [13]. Messages were sent automatically based on the date of birth of the baby using Clickatell bulk SMS gateway. Participants who responded to say they had completed the test were not sent further text reminders. All other women in the six week group were sent a further identical reminder at three and six months postpartum. A single text message reminder, using the same text as for the six week group, was sent to women in the control group at six months postpartum.

Baseline variables

Data were collected to assess the similarity between the two study groups in terms of factors that may have influenced attendance for a postpartum OGTT. At trial entry, information was collected on demographic characteristics of the participants, as well as smoking history, body mass index (BMI) and previous pregnancy outcomes. Women were asked whether or not they were offered the opportunity to join the National Diabetes Services Scheme (NDSS) and therefore the National Gestational Diabetes Register, whether they joined, and where they intended to have their postpartum OGTT. Data were collected regarding the date and the results of the antenatal diagnostic OGTT, control of GDM (dietary control only or requirement for metformin or insulin), and maternal complications at birth relating to GDM (requirement for induction, caesarean section, perineal injury, blood loss). Health outcomes of the newborn(s), as specified in the study protocol, were also collected.

Breastfeeding status at hospital discharge was collected given the link between breastfeeding and reduced risk of type 2 diabetes [14] [25], as well as the influence that breastfeeding may have on the mother's ability to attend for an OGTT [26]. Inclusion of GDM in the problem list of the discharge summary and whether or not a follow up OGTT was recommended were also recorded.

Assessment of outcomes

The primary outcome was attendance for an OGTT by six months postpartum. Secondary outcomes were attendance for a fasting plasma glucose (FPG) test, or glycated haemoglobin (HbA1c) test by six months postpartum (if no attendance for OGTT recorded).

All women in the study were asked to complete a questionnaire at six months after the birth of their baby either by post or by email (using Survey Monkey), to ascertain whether an OGTT was undertaken within the first six months, or whether a FPG or HbA1c may have been undertaken instead. The questionnaire also asked for the date and results of these tests, where known. These results were confirmed by checking the participant's medical records. The questionnaire also asked women what their preferred reminder system was (either *Postal*, *SMS*, *Email*, *Voice Call*, or *Don't know*), as well as what barriers and facilitators to postpartum glucose testing they had encountered.

Women were contacted by telephone two weeks after the questionnaires were sent if no reply was received, and offered the opportunity to complete the questionnaire over the phone, or to have the questionnaire sent to them again. Non-responding participants were contacted again two weeks later, and offered the same options. A final reminder and copy of the questionnaire was mailed to the remaining non-responders after a further four weeks.

Statistical analysis

The sample size calculation used an estimated baseline rate of attendance for OGTT of 37%, at the lower end of the range in the review by Tovar and colleagues (2011) [7]. This was chosen because the health centres in the Tovar study often had reminder systems in place [7]. The Stata version 10.0 sample size calculator was used to estimate the target sample size needed. To detect an 18%

absolute improvement in attendance for OGTT from 37% to 55%, with 80% power, two-tailed significance level of 5%, and estimated 5% loss to follow up, it was estimated that 276 women would be required.

Baseline characteristics of all randomised women were compared descriptively between the study groups. Outcome comparisons were made according to the treatment group allocation at randomisation on an 'intention to treat' basis. The primary and secondary outcomes were reported as risk ratios, with corresponding 95% confidence intervals, calculated using Epi Info 7 Software. Differences between categorical postpartum factors that may have influenced OGTT attendance were assessed using χ^2 test.

For the six month follow-up questionnaire, paper and Survey Monkey results were entered in a Microsoft Access database using an electronic data entry form created using Epi Info 7.4 [39]. Statistical analysis was undertaken using Epi Info 7.4, to assess differences between questionnaire completers and non-completers.

Results

Recruitment and participant flow

A total of 554 women were assessed for inclusion in the trial. Of those women, 179 did not meet the inclusion criteria, 54 eligible women declined to participate, and 45 potentially eligible women were not counselled for other reasons.

276 women were randomised into either the six week group (n = 140) or the control group (n = 136). 137 women in the six week group received their allocated reminders; two did not, due to mobile phone repairs in the early postpartum period, and one woman's mobile phone was unable to receive the text messages. All three were included in the analysis according to intention to treat.

A total of 268 women (97%) were followed up to six months. Results for eight women (3%) were not available to be included in the analysis, due to being unable to be contacted after six months postpartum (n = 5), being no longer interested in the trial (n = 1), moving overseas (n = 1) or moving interstate (n = 1).

Sociodemographic characteristics of included women

There were no notable sociodemographic differences between the allocated study groups at trial entry. The majority of women in each study group were between 30-39 years of age, and were being treated within the public health system. At trial entry, most of the women were either overweight (BMI 25.0-29.9 kg/m^2) (~30%), or obese (BMI ≥ 30.0 kg/m^2) (~40%), with only a fifth of the women being normal weight. Ethnicities were similar between study groups as was socioeconomic status.

Perinatal factors that may have influenced postpartum healthcare seeking: A comparison of study groups

There were no differences between the study groups with regards to perinatal factors. Although, fewer women in the six week group had experienced a previous preterm birth (4/66, 3%) than women in the control group (15/67, 11%); the national rate of preterm birth in women with GDM in Australia in 2005-7 was reported as 10% [40].

Outcomes and estimation

Primary and secondary outcome data were available for 268 participants (97%). Women in the six week group did not increase their attendance for an OGTT within six months after birth, with 104

(77.6%) of women attending in the six week group and 103 (76.8%) women attending in the control group (RR 1.01, 95% CI 0.89-1.15).

Six women (4.5%) in the six week group, and five women (3.7%) in the control group attended for FPG tests; thus the intervention had no effect on the secondary outcome of FPG attendance within six months postpartum (RR 1.20, 95% CI 0.37 – 3.84). Only one participant had an HbA1c test as their primary screening test.

Finally, the SMS reminder for the six week group had no effect on the rate of completion of any of the tests combined (either OGTT or FPG or HbA1c) within six months postpartum, with 83% (n = 111) of the women in the six week group and 81% (n = 108) of the women in the control group having either test (RR 1.03, 95% CI 0.92 – 1.15).

Postpartum follow-up results: prediabetes and type 2 diabetes frequency

Overall, 11% of women were diagnosed with prediabetes and 2.3% diagnosed with type 2 diabetes by six months postpartum.

Additional postpartum factors that may have influenced OGTT completion

Most women in both study groups (≥87%) self-reported that they had been offered an opportunity to join the Australian National Gestational Diabetes Register and had joined (≥83%) [14], and therefore would have received postal reminders at 12-16 weeks after their expected due date from this register.

Over 98% of women in each group receiving public medical care had a discharge summary forwarded to their postpartum care provider, with no difference seen between groups. The majority of these discharge summaries listed GDM in their problem list, although approximately 20% did not include recommendations of an OGTT in the follow-up plan.

Questionnaire responders

275 women from the DIAMIND Study were sent the follow-up questionnaire (one participant requested that no questionnaire be sent due to time constraints), and 208 (75%) completed questionnaires either by email (n = 100) or post/telephone (n = 108).

Questionnaire results

207 women indicated their preferred postpartum reminder system, and there was little variation between the allocated treatment groups' responses. Most women (nearly 70%) selected SMS reminders as their preferred postpartum reminder type. Email was preferred by about 17% of women, postal by 12% and voice call reminders by less than 1%.

The most frequently indicated barrier to postpartum glucose test completion was *not having enough time (n = 24/33, 73%)*, followed by *inadequate or non-availability of childcare (n = 10/33, 30%)*, and a *need to focus on the health of the baby (n = 10/33, 30%)*. Some women believed the test was *too long (n = 6/33, 18%)*, that they were *at low risk of T2DM (n = 5/33, 15%)*, and some women did not seek testing because of their *concern or anxiety relating to the possibility of being diagnosed with T2DM (n = 5/33, 15%).*

A small subset of the women who did not complete a postpartum OGTT (n = 15/69, 22%), provided information on what may have facilitated their attendance for postpartum OGTT. A third of those women said that a shorter test would have made it easier for them to attend. Others suggested that having a health professional arrange the test, doing the test before discharge from hospital, or having a reminder for attendance would facilitate test completion.

Discussion

SMS reminders at six weeks and three months postpartum were not found to affect the rate of attendance for postpartum screening for type 2 diabetes by six months after birth, with either OGTT, FPG or HbA1c tests. This is in contrast to the results of a previous Canadian randomised trial of postal reminders for women who had GDM [9]. In their study, completion of OGTTs was higher in those women who were sent a reminder (42 of 76 (55%), compared with five of 35 women (14%) in the control arm.

Within our trial, overall attendance for an OGTT within both study arms was more than 20% higher than previously reported rates of postpartum glucose testing in South Australia [41], and much higher than the vast majority of studies conducted worldwide [8]. Only a small number of studies, focussed on assessing rates of postpartum glucose intolerance or type 2 diabetes in women with recent GDM, have reported higher rates [8]. High rates of postpartum testing shows the positive influence of raised awareness of the need for postpartum screening amongst health professionals and women alike. The increase observed in our study may partially reflect the transition from the South Australian GDM Recall Register (established in July 2002) to the Australian National GDM recall register, which occurred just prior to the beginning of recruitment for the DIAMIND Study. A key difference between the function of these two registers was much earlier postal reminders from the National GDM Register at 3-4 months after birth, compared with the South Australian GDM Recall Register that had provided reminders 15 months after birth [41].

The low use of HbA1c for type 2 diabetes screening is likely to reflect that, during the period of DIAMIND Study data collection, relevant Australian guidelines recommended use of an OGTT for postpartum type 2 diabetes screening[42], and that Medicare reimbursement for HbA1c was only possible in people with established diabetes [34].

It is noteworthy that a high proportion of women in the study received postal reminders from the national reminder scheme (≥83%). Furthermore, discharge summaries were completed and sent to the relevant clinicians in a very high proportion of cases (98% in each study group). Most summaries not only provided the diagnosis of GDM in the problem list (92%), but also recommended an OGTT in the follow-up treatment plan section (81%). This communication of the diagnosis of GDM is likely to have positively influenced rates of OGTT completion, as previous studies with clinicians' views have indicated that lack of communication of the diagnosis was a key factor preventing adequate postpartum healthcare provision for women with GDM [43]. Most women in the study planned to attend for postpartum care with their general practitioners in the community (64%) rather than at the hospital, highlighting the importance of communication of the diagnosis to the relevant postpartum care providers.

The postpartum glucose test results from our study indicate the importance of screening relatively soon after birth; although, the rates of prediabetes (11%) and diabetes (2.3%) are at the lower end of the range of those found in previous studies of testing up to six months postpartum (prediabetes was reported in 13-32% of participants, and type 2 diabetes detected in 1-25% [8]). These lower rates were expected given that the women in the DIAMIND Study were only eligible if they had had a normal blood glucose profile before discharge after giving birth.

Most women preferred SMS reminders, followed by email reminders over other forms of reminder systems. Whilst it may be argued that the women consenting to the DIAMIND RCT would be more likely to favour SMS reminders, the relatively low decline rate of women eligible for the DIAMIND RCT overall (<20%) would suggest that those recruited were a representative sample of women with GDM attending the hospital. Women's views on reminder systems have previously been elicited in a

small sample of women attending either of two tertiary care sites for GDM education (n = 51) in Ottawa, Canada, with data collected from November 2010 until February 2011. They found that women's first preferences for postpartum reminder types were home phone/landline (55%), followed by email (22%), postcard (10%), SMS message (8%) and voice message (6%) [44].

Just over half of the women in the DIAMIND Study were still breast-feeding at six months postpartum and several others had breast-fed for six months and only recently stopped. Breast-feeding as a barrier to undertaking postpartum diabetes screening was only reported by one woman in both the DIAMIND Study and in the Canadian study of postal reminders for postpartum OGTTs [26], and is therefore unlikely to be a barrier for most women.

Many of the barriers to OGTT completion were related to lack of time and to the test itself. Taking time out from caring for their new baby and other children, in the absence of readily available and acceptable childcare, was also difficult for many women, so a shorter test would be preferable for this reason as well.

Suggested facilitators were often related to OGTT convenience, with women suggesting that having a shorter test, not having to arrange a separate appointment for the test, and being able to do the test in a more convenient location (such as home), would facilitate their glucose test completion. This suggests that for many women, the OGTT itself does not pose a barrier to T2DM screening, but for a minority it is a significant barrier. Changing from a two hour OGTT to an HbA1c test for T2DM screening would therefore probably increase completion of a postpartum test. The HbA1c test has several advantages in comparison with the two hour OGTT, including not requiring the women to fast, consume a glucose drink, wait for two hours for final blood sampling and having more than one blood sample to be taken. Although, further research on HbA1c use for diabetes screening in the postpartum period is required.

Postpartum counselling and education regarding the risk of T2DM is important, given the range of perception of risk from anxiety and concern about the possibility of being diagnosed with T2DM to perception of low risk of future T2DM development, both of which posed barriers for some women in the study. It is important that T2DM screening is linked with T2DM prevention interventions for the majority of women, who would not yet have developed the condition. There is ongoing research into interventions specifically for women who have experienced GDM [45, 46], and positive results have been found for sub-groups of women with a history of GDM in previous diabetes prevention studies [16, 18, 47].

The low use of HbA1c for T2DM screening, was largely because during the period of DIAMIND RCT data collection, relevant Australian guidelines recommended use of an OGTT for postpartum T2DM screening [1, 48], and Medicare reimbursement for HbA1c was only possible in people with established diabetes [34]. Since then, the Australian Diabetes Society has submitted a proposal to Medicare to accept the measurement of HbA1c for diagnosis of T2DM outside of pregnancy [49], and this proposal was accepted.

Limitations and generalisability

Women in the DIAMIND Study were representative of women with GDM in South Australia and Australia. Rates of perinatal adverse outcomes known to be associated with GDM generally did not differ between study groups, indicating that the randomisation process was effective. As expected in GDM, women were slightly older [50], with higher BMIs [51] and more likely to be Asian [52], compared with the overall population of women giving birth in South Australia [53] or Australia [40]. Most women in the study had been educated beyond secondary school. Almost half of the women in

the study lived in either extremely disadvantaged (n = 64, 23%) or disadvantaged areas (n = 74, 27%), and a higher proportion of women in the study had received public rather (n = 264, 96%) than private care compared with other women giving birth in South Australia (71% public in 2011 [53]). This concurs with previous studies showing that socioeconomic disadvantage is linked with increased risk for GDM [54].

In any trial with behavioural outcomes, such as attendance for glucose testing, there is the potential for aspects of research participation to contribute to the observed frequency of the behavioural outcome [55]. Thus, it is possible that raised awareness of the risk of type 2 diabetes and the benefits of postpartum screening resulted from participation in the study, and that this contributed to an increase in attendance for postpartum glucose testing in both study groups.

The six month follow-up questionnaire was designed to be user-friendly and visually appealing, and it contained mainly short, easy to answer questions with tick box option answers to cater for women with low health literacy and for whom English was not their first language. The moderate response rate for the questionnaire indicates that the views of most women in the DIAMIND RCT on the questionnaire topics are likely to be accurately represented [56]. Our response rate was higher than the women's response rate in the follow-up survey of the Canadian RCT of postal reminders (63%, 140 of 223), the most comparable study to this one [26].

Conclusions: Implications

- Most women expressed a preference for SMS reminders over other methods of postpartum reminders, followed by email, postal and voice call reminders; women should therefore be given the opportunity to have electronic forms of postpartum reminders, where possible.

- For women unable to attend for the oral glucose tolerance test, time constraints and test inconvenience were the most commonly cited barriers, and doing a shorter test was stated to be the main facilitator. This suggests that changing from an OGTT to a more convenient test, such as the HbA1c test might facilitate an increase in the rate of postpartum glucose testing that would be clinically important, and the use of HbA1c for this purpose should be further investigated. New Zealand guidelines have already recommended use of HbA1c for this purpose.

- Screening for T2DM needs to be coupled with provision of effective counselling on T2DM risk, and risk reduction. Further research into T2DM prevention programs specific for women who have experienced GDM is important.

Dissemination of results

The results of this study will be disseminated to other researchers and clinicians via conference presentations and publications. The main results of the DIAMIND study will be presented (10 minute oral presentation) at the Perinatal Society of Australia and New Zealand conference in April 2015 in Melbourne, Australia, and the results of the follow-up questionnaire will be presented at the same conference as a poster and brief oral presentation. The DIAMIND Study trial results have been accepted for publication by the journal *Diabetic Medicine*, and the follow-up study is under review for publication by the journal *Primary Care Diabetes*.

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