Cost-effectiveness of skin-barrier-enhancing emollients among preterm infants in Bangladesh

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Objective To evaluate the cost-effectiveness of topical emollients, sunflower seed oil (SSO) and synthetic Aquaphor, versus no treatment, in preventing mortality among hospitalized preterm infants (< 33 weeks gestation) at a tertiary hospital in Bangladesh.

Methods Evidence from a randomized controlled efficacy trial was evaluated using standard Monte Carlo simulation. Programme costs were obtained from a retrospective review of activities. Patient costs were collected from patient records. Health outcomes were calculated as deaths averted and discounted years of life lost (YLLs) averted. Results were deemed cost-effective if they fell below a ceiling ratio based on the per capita gross national income of Bangladesh (United States dollars, US$ 470).

Findings Aquaphor and SSO were both highly cost-effective relative to control, reducing neonatal mortality by 26% and 32%, respectively. SSO cost US$ 61 per death averted and US$ 2.15 per YLL averted ($6.39, international dollars, per YLL averted). Aquaphor cost US$ 162 per death averted and US$ 5.74 per YLL averted ($17.09 per YLL averted). Results were robust to sensitivity analysis. Aquaphor was cost-effective relative to SSO with 77% certainty: it cost an incremental US$ 26 more per patient treated, but averted 1.25 YLLs (US$ 20.74 per YLL averted).

Conclusion Topical therapy with SSO or Aquaphor was highly cost-effective in reducing deaths from infection among the preterm neonates studied. The choice of emollient should be made taking into account budgetary limitations and ease of supply. Further research is warranted on additional locally available emollients, use of emollients in community-based settings and generalizability to other geographic regions.

Introduction

An estimated 4 million children worldwide die each year during the neonatal period, three fourths of them within the first 7 days.1 The overwhelming majority (99%) of neonatal deaths occur in low- and middle-income settings and are caused directly by infections and complications due to prematurity and birth asphyxia and indirectly by low birth weight (< 2500 g).1 Infants born very preterm (i.e. gestational age < 32 weeks) and with very low birth weight (< 1500 g) have mortality rates of over 50% in many low-resource settings2–5 and are at high risk for long-term disabilities and impairments.6

Premature infants have compromised skin barrier function, which increases their risk of infection7–9 and of hypothermia due to transepidermal water and heat loss.10,11 Undernutrition further impairs skin barrier function and compromises the immune system, increasing the risk of morbidity and mortality.12,13

Application of topical emollients has been practised traditionally in South Asia and sub-Saharan Africa for generations. It has a variety of perceived benefits, although some of the emollients used may be detrimental, depending on their composition and mode of application.14–16 Mustard seed oil is the most widely used emollient in South Asia owing to its fragrance, warming sensation and availability; however, it may be toxic to keratinocytes of the skin.15–17 Research on the impact of four natural oils and of Aquaphor, a synthetic emollient, on epidermal barrier function in mice has shown that mustard seed oil has deleterious effects on the epidermal barrier.14 By contrast, sunflower seed oil (SSO) and Aquaphor significantly accelerate barrier recovery.14

Aquaphor and SSO were tested in randomized controlled trials in Bangladesh and Egypt.4 In Bangladesh, massage with SSO resulted in a 41% reduction in sepsis and a 26% reduction in mortality,5,18 while Aquaphor treatment resulted in 32% lower mortality among treated infants relative to controls.3

The efficacy of this trial highlights the potential for low-cost, culturally acceptable alternatives to replace mustard seed oil for treating preterm, low-birth-weight infants in South Asia.5 The Disease Control Priorities Project (DCP2) has identified research on emollients as a global priority.19 In particular, evidence is needed to inform decision-making about how the use of emollients should be prioritized in health policy. This paper presents data on the cost-effectiveness of SSO and Aquaphor therapy versus standard care for preterm neonates at a tertiary hospital in Bangladesh.

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Une traduction en français de ce résumé figure à la fin de l’article. Al final del artículo se facilita una traducción al español.

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Methods

Study site and population
Bangladesh is characterized by high rates of maternal and neonatal undernutrition, prematurity (gestational age < 37 weeks) (19%),20 low birth weight (30%) and neonatal mortality (42 per 1000 live births).21 A prospective randomized controlled trial was conducted to ascertain the impact of topical emollients on rates of sepsis and mortality in preterm infants admitted to Dhaka Shishu Hospital in Dhaka, Bangladesh, between December 1998 and July 2003. With a total of 320 paediatric beds, Dhaka Shishu is the largest tertiary-level paediatric hospital in the country. It has extensive laboratory capabilities in addition to a 20-bed special care nursery, which generally operates at full capacity.5,18

A total of 497 preterm, low-birthweight neonates were randomly assigned to one of three treatment groups: SSO (n = 159 141 < 1500 g), Aquaphor (n = 157; 138 < 1500 g) and control (n = 181; 154 < 1500 g). Eligibility for enrolment in the trial was limited to preterm infants (< 33 weeks gestational age) presenting to hospital for care within 72 hours of birth. Infants were excluded if they had major congenital abnormalities, hydrops fetalis, conditions requiring major surgery, clinically evident skin infections, generalized skin disease or structural epidermal defects covering over 5% of the body, or if they were expected to die within 48 hours. This trial has been registered (MS# 2007-0213 Clinical Trials.gov #98-04-21-03-2) and additional information on the trial is detailed elsewhere.5,7,18,22

Description of interventions
The emollients tested in this trial were high-linoleate SSO (Omega Nutrition, Bellingham, WA, USA) and Aquaphor, a synthetic emollient consisting of petroleum, mineral oil, mineral wax and lanolin alcohol (Beiersdorf, Norwalk, CT, USA). Control infants received standard care without any oil or massage and were managed on an intention-to-treat basis. Study nurses supplied 4 g of emollient per kilogram of body weight (in 100 g gradations) three times daily for 14 days, then two times daily for every day thereafter. Risk factors for nosocomial infections were minimized through infection control practices,5 and blood cultures were obtained from infants suspected of systemic infection. Health complications were masked to treatment group assignment, although distinct differences in emollient consistency made complete assurance of masking uncertain.

Health outcomes
The primary health outcome measured was 28-day survival, adjusted according to hazard ratios between intervention and control groups.7 Deaths averted were translated to discounted years of life lost (YLL) averted,24 consistent with cost-effectiveness analyses of other neonatal care interventions.26 Reference case assumptions included an average life expectancy at birth of 62.6 years25 and a discount rate of 3%, in keeping with standard practice in economic evaluation for low- and middle-income countries.6 However, empirical evidence from developing country settings suggests that 6% may better represent social preferences, and this was tested in sensitivity analysis.37 Age-weighting was excluded from reference case calculations for consistency with the analyses presented in DCP2,26 but was also tested in sensitivity analysis.

Costing
Economic costs for the 20-bed nursery staffed with 6 physicians, 4 nurses and 1 laboratory technician were calculated from a provider and programme perspective through a retrospective review of individual patient records and project activities. Programme costs included activities required to initiate and implement the study and were distributed evenly across intervention arms. One-time start-up activities included administrative time required to prepare for the study, identification of emollient supply, investigator time to develop a manual on emollient application, and nurse orientation and training in emollient application and data collection. Implementation costs for the remainder of the project included costs associated with refresher training of nurses (half a day three times each year). Provider costs included emollient treatments, antibiotics and other medications, blood transfusions, medical supplies, laboratory tests, bed costs and food. Cost per bed-day was 300 Bangladeshi taka (US$ 5.95), calculated on the basis of hospital charges to patients; shadow prices were used for patients treated free of charge. Costs per day charged to patients were validated through costing by the health facility, including capturing of actual electricity and overhead costs. These costs were comparable to figures reported by the World Health Organization (WHO) Choosing Interventions that are Cost-Effective (WHO-CHOICE) project.28 All costs associated with research components of the trial were excluded, as were opportunity costs incurred by household members for lost wages and transportation. Costs were converted to 2006 base-year dollars using local consumer price indices. Start-up costs were expected to be amortized over two years and were annualized and discounted at 3%. All costs were converted from Bangladeshi taka to United States dollars (US$) using a 2006 exchange rate23 and were also converted to international dollars (IS) to make them comparable to WHO-CHOICE figures.26 International dollars have the same purchasing power as a US dollar in the United States. International dollar values were determined by dividing taka by the 2006 purchasing power parity (PPP) conversion factor.

Cost-effectiveness
The cost-effectiveness of each pair of strategies (SSO versus control, Aquaphor versus control, SSO versus Aquaphor) was evaluated according to incremental cost-effectiveness ratios (ICERs). Reference case calculations included all costs and YLLs calculated with a 3% discount rate and no age-weighting (3.0). The impact of uncertainty regarding patient-level costs and health outcome data was accounted for through probabilistic sensitivity analysis, using standard Monte-Carlo simulation resampling.20 In this method, data points were randomly sampled from original data, with replacement, and ICERs were calculated. This process was repeated to represent what results might arise if a large number of similar trials were performed. These calculations were performed in Excel (Microsoft, Redmond, WA, USA), using a Visual Basic-based macro to perform the resample automatically.

In total, 10 000 iterations were generated for each simulation and plot-
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Results

Results are presented in terms of 100 premature neonates, a number that approximates the number of premature neonates who might be treated at a similar facility per year.

Costs

Table 1 outlines programme costs for initiating study activities and maintaining a tertiary facility with 320 paediatric beds, Dhaka, Bangladesh, 1998–2003. All costs were comparable across arms. The average total cost per patient in the SSO arm was US$ 99.47, compared to US$ 125.35 in the Aquaphor arm and US$ 93.39 in the control arm.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Total annualized cost in US$ (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start-up</td>
<td>1023.15 (55.8)</td>
</tr>
<tr>
<td>Administrative set-up</td>
<td>9.14 (0.5)</td>
</tr>
<tr>
<td>Orientation for neonatal unit physicians and staff</td>
<td>178.45 (9.7)</td>
</tr>
<tr>
<td>Identification of emollient supplier</td>
<td>137.30 (7.5)</td>
</tr>
<tr>
<td>Manual on emollient application</td>
<td>274.59 (15)</td>
</tr>
<tr>
<td>Training of nurses</td>
<td>423.67 (23.1)</td>
</tr>
<tr>
<td>Implementation</td>
<td></td>
</tr>
<tr>
<td>Refresher training of nurses</td>
<td>810.67 (44.2)</td>
</tr>
<tr>
<td><strong>Total cost</strong></td>
<td><strong>1833.82</strong></td>
</tr>
</tbody>
</table>

US$, United States dollar.

Table 2 shows the distribution of provider costs per patient by study arm and component. Hospital stays were the most expensive component; costs were similar for all three treatment groups, with an average length of stay in days of 11.54 (SSO), 11.76 (Aquaphor) and 11.48 (control). Overall, Aquaphor cost about 20 times as much as SSO, with an average per patient cost of US$ 29 and a unit cost of US$ 0.76 for a single application of 4 g of emollient, or US$ 1.14 for each treatment of a neonate weighing 1500 g. SSO, by comparison, cost an average of US$ 1.55 per patient and had a unit cost of US$ 0.04 for 4 g, or US$ 0.06 for each treatment of an infant weighing 1500 g.

Health outcomes

The 26% reduction in mortality with SSO treatment corresponded to an adjusted probability of death of 52% and translated to 19 deaths averted per 100 neonates, or 523 YLLs averted given an average lifespan in Bangladesh of 62.6 years (discounted to 28.24 YLLs). Aquaphor reduced mortality by 32%; this outcome was associated with an adjusted probability of death of 48% and 23 deaths averted, or 649 YLLs per 100 neonates.

Cost-effectiveness

Per 100 neonates, the total cost of each arm was US$ 10 517 (95% confidence interval, CI: 10 138–10 878) for SSO, US$ 13 117 (95% CI: 12 722–13 509) for Aquaphor and US$ 9393 (95% confidence interval, CI: 9079–9699) for control (confidence intervals bootstrapped from Monte Carlo simulations). Reference case calculations for SSO relative to control found an incremental cost of US$ 1124 for 19 deaths or 523 YLLs averted. This translated to a cost-effectiveness of US$ 61 per death averted, or US$ 2.15 per YLL averted ($6.39 per YLL averted) (Table 3). Aquaphor cost US$ 3725 and averted 649 YLLs relative to control conditions, giving an ICER of US$ 162 per death averted, or US$ 5.74 per YLL averted ($17.09 per YLL averted). Comparison of the two emollients reveals that Aquaphor was more costly.
but more effective than SSO, with an ICER of US$ 586 per death averted, or US$ 20.74 per YLL averted (I$ 94.35 per YLL averted). Confidence intervals were not determined for ICERs because results extended beyond zero for two of the three comparisons, rendering results not meaningful.

**Sensitivity analysis**

The cost-effectiveness acceptability curves shown in Fig. 1 and Fig. 2 illustrate the degree of uncertainty around each comparison according to different valuations of YLLs. If YLLs are valued above US$ 5.33 (i.e. above the point at which the 95% probability of cost-effectiveness line intersects the x-axis), decision-makers can be 95% certain that using SSO was cost-effective relative to control. The certainty that SSO was cost-effective never fell below 6% at any YLL valuation as there remains a probability that it improves health at a lower cost. Aquaphor was also highly cost-effective relative to the control arm. Above US$ 9.55 per YLL averted it was 95% certain that Aquaphor was cost-effective; below US$ 3.45 per YLL averted, it was 95% certain that it was not. All of these results are well below the per capita gross national income in Bangladesh (US$ 470).25

When the two intervention strategies are compared, Aquaphor is more cost-effective, although a decision-maker can never be more than 77% certain of this result (Fig. 2). This finding is explained by the 21% chance that Aquaphor is more costly and less effective than SSO, coupled with a 2% chance that its cost-effectiveness is above the threshold YLL valuation.

If total arm costs are 25% higher than those found in the trial, the cost-effectiveness of each emollient relative to control remains below US$ 10/YLL (Table 4). Sensitivity analyses on YLL assumptions recommended by Fox-Rushby and Hanson (2001)24 have no effect on the interpretation of ICERs – all remain highly cost-effective.

**Discussion**

Repeated, gentle massage of neonates’ skin with SSO or Aquaphor was highly cost-effective in reducing neonatal mortality in the intervention groups relative to the control group, even at very low valuations of YLLs. Both emollients substantially improve neonatal survival, owing at least in part to marked reductions in risk of sepsis,4,5,18 although our results may be underestimates as costs associated with the treatment of complications following the neonatal period were not considered and are likely to have been higher in the control group.6 The choice between Aquaphor and SSO is more complicated because each is highly cost-effective, and there is not a significant difference between their efficacies (P = 0.2163). While the Arrow-Lind theorem advocates decision-making using expected values when results are uncertain,39 decision-making depends on a variety of economic and ethical factors, particularly available budget to reach target coverage levels.36

Public financing of emollient treatment may be warranted for both economic and ethical reasons. In addition to being cost-effective, it has notable externalities: it can prevent infectious disease from spreading to others and may also prevent disabilities that require lifelong medical treatment and support from caregivers. The expense of Aquaphor would presumably be catastrophic for most Bangladeshi households, which earn on average US$ 38.63 per month;25 at US $29 per patient, Aquaphor treatment would amount to 75% of the average monthly salary, which is well above the WHO definition for catastrophic cost (more than 40% of monthly income after subsistence needs have been met).34 From an ethical perspective, 50% of Bangladeshis live below the poverty

**Table 3. Deaths and YLLs averted and associated costs per 100 neonates, by study arm, in clinical trial comparing two topical emollients in preterm infants, Dhaka Shishu Hospital, Dhaka, Bangladesh, 1998–2003**

<table>
<thead>
<tr>
<th></th>
<th>Deaths averted</th>
<th>YLLs averted</th>
<th>Incremental cost (US$)</th>
<th>Cost per death averted (US$)</th>
<th>Cost per YLL averted (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSO vs control</td>
<td>19</td>
<td>523</td>
<td>1124</td>
<td>61</td>
<td>2.15</td>
</tr>
<tr>
<td>Aquaphor vs control</td>
<td>23</td>
<td>649</td>
<td>3725</td>
<td>162</td>
<td>5.74</td>
</tr>
<tr>
<td>Aquaphor vs SSO</td>
<td>4</td>
<td>125</td>
<td>2600</td>
<td>586</td>
<td>20.74</td>
</tr>
</tbody>
</table>

SSO, sunflower seed oil; US$, United States dollar; YLL, year of life lost.
line and would not be able to afford contributory insurance. With mortality rates in the intervention groups of 48% (Aquaphor) and 52% (SSO) relative to 71% percent in the control group, this intervention is clearly life-saving for a cohort with high mortality, meets the “rule of rescue” criterion and is vertically equitable.

Many of the same arguments apply to SSO. However, since SSO costs only US$ 1.55 per patient, or 4% of monthly household income, there is greater probability that it could be supported by the private market, which means that smaller incremental policy changes would be required. In Bangladesh and much of the developing world, patients often independently buy medicines recommended for patients from pharmacies. Asking already underresourced public health systems to provide additional interventions is difficult, particularly when an estimated US$ 37 million would be needed to provide Aquaphor to 1.3 million low-birth-weight infants per year41 – a sum that amounts to slightly less than 3% of total national health expenditure.

On one hand, investment by high-income countries in developing country health systems is increasing; however, sustainable change can be expected to occur gradually, and investors generally shun environments with high disease burdens. It could be argued that national governments have the capacity to determine how much revenue they raise through taxation and should finance all interventions deemed cost-effective,40 but experience shows that revenue targets are not always achieved in reality.41 While the choice of emollient will depend on the ease of maintaining a reliable supply and on local preference, Aquaphor will become more attractive when single-use ointment tubes are manufactured – which will avoid bedside contamination of the product42 – and when the cost falls through bulk purchasing.

Comparison to other studies

This is the first study on the cost-effectiveness of emollients to protect premature neonates in low-resource settings. The efficacy data generated by the clinical trial underlying this analysis5,18 are corroborated by a smaller study conducted in Egypt, which documented a 54% reduction in sepsis and found a trend in reduction in mortality, although statistical power was insufficient.4 Neither of these trials found adverse outcomes from the intervention, such as skin reactions, injuries, infections or phototherapy burns.4,5,18 Both studies suggest that with careful monitoring it is appropriate for these interventions to be replicated in comparable tertiary-care environments.

Justification for use of YLLs

The limitations of disability-adjusted life years (DALYs) are described elsewhere.43 However, some of the assumptions underlying the DALY can be justified, as some degree of modelling is a “fact of life” in clinical trial-based economic evaluation.44 Defining health outcomes as YLLs facilitates comparison with a wide spectrum of evaluations in large-scale evidence bases such as DCP2.26 There is precedent in the neonatal survival chapter of DCP2 for excluding the years of life with disability (YLD) component of the DALY, which is difficult to observe scientifically; moreover, data from low- and middle-income countries on disabilities stemming from neonatal conditions is lacking.45 However, the Global Burden of Disease study recognizes perinatal illness as the sixth largest contributor to YLDs in low- and middle-income countries.46 In further work, evidence from our trial will be used to inform a calculation framework useful for economic evaluation of neonatal health interventions, although such an analysis is not expected to have a significant effect on our already highly cost-effective results.

Generalizability of findings

The high prevalence of low birth weight (31%) and prematurity (16%) and the widespread traditional use of emollients in South Asia make it a priority.
area for research to evaluate the generalizability of our findings. Among the interventions recommended by DCP2 for South Asia, estimates of the cost per DALY averted range from US$ 8.00 for childhood immunizations to US$ 260.50 for a package of maternal and neonatal care services. SSO and Aquaphor both achieve better cost-effectiveness than all the interventions evaluated in DCP2 for this region. Converted into international dollars, the cost effectiveness of Aquaphor and SSO is IS 17 and IS 6 per YLL averted, respectively. These estimates compare favourably with maternal and neonatal interventions for South Asia evaluated by WHO-CHOICE, which range in cost effectiveness from IS 6 for support for breastfeeding at 50% coverage to IS 16 930 for a comprehensive package of maternal and neonatal care services at 95% coverage.

Further research is warranted for other regions of the world with high burdens of neonatal mortality. In both Africa and Asia, the potential benefits of emollient therapy for neonates, regardless of gestational age or birthweight, should be studied, as should its use for babies born at primary care facilities and at home. When costs from the tertiary hospital nursery in this study are scaled up, expected economies of scale in variable costs should be taken into account.

As the majority of neonatal deaths in low-resource settings occur outside the formal health care sector, it is important to understand the sociocultural and contextual factors that affect treatment-seeking behaviour. In many South Asian societies, new mothers enter a period of seclusion from society after delivery, which means that they often do not seek care from the formal health sector for themselves or for their babies. As community health workers (CHWs) have been shown to be effective providers in such circumstances and community-based care has been shown to improve the equity of care distribution, research on community-based delivery of emollients is recommended. However, the limitations of the CHW model should be recognized, and the sustainability of behaviour change in non-facility settings should be explored.

Conclusion

The perception exists that hospital care of premature infants is expensive and requires high technology and specialized medical attention. This study suggests that topical treatment with Aquaphor or SSO is highly cost-effective, resulting in significant health improvements among preterm infants, and can be integrated into existing hospital treatment protocols at low cost. This policy change would address two of three intervention objectives outlined by the Lancet Neonatal Survival Series for neonatal care by reducing the need for emergency care and strengthening care for low-birth-weight infants. Further research should be conducted on the impact of emollients in community settings so that they can be considered for inclusion in priority packages of community-based neonatal interventions. The high proportion of births occurring outside the formal health care sector in many high-mortality settings provides further impetus for expanding research on emollients to the community level; however, strategies are needed to address the use of potentially toxic emollients (e.g. use of mustard oil, mixing the emollient with potentially harmful additives) and harmful application techniques, such as too vigorous massage, which can damage the skin barrier, especially in preterm infants.

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Competing interests: None declared.
Resumen

Costeeficacia de la aplicación de emolientes cutáneos a los lactantes prematuros en Bangladesh

Objetivo: Evaluar la costeeficacia de los emolientes tópicos a base de aceite de girasol y del producto sintético Aquaphor en comparación con la ausencia de tratamiento como medida de prevención de la mortalidad de los lactantes prematuros (< 33 semanas de gestación) en un hospital terciario de Bangladesh.

Métodos: Los datos, obtenidos en un ensayo aleatorizado controlado de la eficacia, fueron evaluados mediante el método estándar de simulación de Montecarlo. Los costos de los programas se determinaron mediante una revisión retrospectiva de las actividades, y los costos para los pacientes se determinaron a partir de su historia clínica. Los resultados sanitarios se calcularon como el número de defunciones evitadas y de años de vida perdidos (AVP) descontados evitados. Se consideraron costeeficaces los resultados inferiores a un límite máximo basado en el ingreso nacional bruto por habitante de Bangladesh, 470 dólares estadounidenses (US$).

Resultados: Tanto el Aquaphor como el aceite de girasol fueron muy costeeficaces en comparación con la situación de control, pues redujeron la mortalidad neonatal en un 26% y un 32%, respectivamente. El costo del aceite de girasol fue de US$ 61 por muerte evitada, y de US$ 2,15 por AVP evitado (6,39 dólares internacionales, I$, por AVP evitado). El costo del Aquaphor fue de US$ 162 por muerte evitada y US$ 5,74 (I$ 17,09) por AVP evitado. Los resultados demostraron ser robustos en el análisis de sensibilidad. El Aquaphor fue costeeficaz en comparación con el aceite de girasol con un grado de certidumbre del 77%; cuesta US$ 26 más por paciente tratado, pero evita 1,25 AVP (US$ 20,74 por AVP evitado).

Conclusión: La administración tópica de aceite de girasol o Aquaphor fue muy costeeficaz como medida de reducción de las muertes por infección entre los recién nacidos prematuros estudiados. La elección del emoliente debería hacerse teniendo en cuenta las limitaciones presupuestarias y la agilidad del suministro. Se requieren nuevas investigaciones sobre otros emolientes disponibles a nivel nacional, sobre el uso de emolientes en entornos comunitarios y sobre la generalización a otras regiones geográficas.
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Research

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