

## Nepal Vaccine Support for JAPANESE ENCEPHALITIS (JE)

**This Decision Letter sets out the Programme Terms of a Programme.**

<b>1. Country:</b> Nepal														
<b>2. Grant Number:</b> 16-NPL-26a-X / 16-NPL-08i-Y / 16-NPL-22a-Y														
<b>3. Date of Decision Letter:</b> 16 July 2015														
<b>4. Date of the Partnership Framework Agreement:</b> 22 August, 2014														
<b>5. Programme Title:</b> NVS, Campaign														
<b>6. Vaccine type:</b> Japanese Encephalitis (JE)														
<b>7. Requested product presentation and formulation of vaccine:</b> 5 dose, LYOPHILISED														
<b>8. Programme Duration<sup>1</sup>:</b> 2016														
<b>9. Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):</b>														
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;"></th> <th style="width: 35%;">2016</th> <th style="width: 35%;">Total<sup>2</sup></th> </tr> </thead> <tbody> <tr> <td>Programme Budget (US\$)</td> <td style="text-align: center;">US\$1,921,000</td> <td style="text-align: center;">US\$1,921,000</td> </tr> </tbody> </table>		2016	Total <sup>2</sup>	Programme Budget (US\$)	US\$1,921,000	US\$1,921,000								
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<b>10. Vaccine Introduction Grant:</b> US\$157,500 payable up to six months before the introduction.														
<b>11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):<sup>3</sup></b>														
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<b>12. Procurement agency:</b> UNICEF														

<sup>1</sup> This is the entire duration of the programme.

<sup>2</sup> This is the total amount endorsed by Gavi for the entire duration of the programme.

<sup>3</sup> This is the amount that Gavi has approved.

<b>13. Self-procurement:</b> Not applicable	
<b>14. Co-financing obligations:</b> Not applicable	
<b>15. Operational support for campaigns:</b>	
	2016
Grant amount (US\$)	US\$2,374,000
<b>16. The Country shall deliver the following documents by the specified due dates as part of the conditions to the approval and disbursements of the future Annual Amounts:</b> The Country shall deliver the following documents by the specified due dates as part of the conditions to the approval and disbursements of the future Annual Amounts.	
<b>Reports, documents and other deliverables</b>	<b>Due dates</b>
Annual Progress Report or equivalent	To be agreed with Gavi Secretariat
Technical Report for the Campaign	3 months after the end of the campaign.
Post campaign coverage survey report	As soon as the report is available
<b>17. Financial Clarifications:</b> The Country shall provide the following clarifications to Gavi*:  <i>*Failure to provide the financial clarifications requested may result in Gavi withholding further disbursements</i>	
<b>18. Other conditions:</b>	
<ul style="list-style-type: none"> <li>• Please provide the EVM improvement plan prior to shipment (latest by September 2015 to launch on-time).</li> <li>• Please provide the finalised NHSP III and related timeline for waste management when complete.</li> </ul>	

Signed by,  
**On behalf of Gavi**



Hind Khatib-Othman  
Managing Director, Country Programmes  
16 July 2015

**Independent Review Committee (IRC) Country Report**  
**Gavi Secretariat, Geneva •16-27March 2015**  
**Country: Nepal**

**1. Type of support requested**

Table 1

Type of support requested	Planned start date (Month, Year)	Duration of support	Vaccine presentation(s) (1 <sup>st</sup> and 2 <sup>nd</sup> choice, if applicable)
<b>JE - Campaign and introduction in RI</b>	Campaign: April 2016; Introduction in RI: July 2016	1 year (2016)	5 doses per vial, Lyophilised
<b>HSS</b>	2015 (Fiscal Year Jul-15 – Jun-16)	5 years (2015-2019)	

The Government of Nepal is applying for

- Japanese Encephalitis (JE) campaign operational support: US\$ 2,373,858
- Japanese Encephalitis (JE) vaccine introduction grant (VIG): US\$ 157,341
- Health Systems Strengthening (HSS) through sectoral pooled fund arrangement in a Sector-Wide Approach (SWAp): US\$ 36,540,000

**2. In-country governance mechanisms (ICC/HSCC) and participatory proposal development process**

**JE application related process.** Nepal has an active ICC in place since many years, providing oversight on immunisation activities and new vaccines introduction. Terms of reference, composition and minutes of ICC meetings have been provided with the proposal. The membership includes the relevant national actors from the public sector and international partners, while it lacks a consistent representation of the civil society. Civil Society is involved in some aspects of situation analysis and implementation. The Gavi application for JE campaign and introduction was developed by Ministry of Health (MoH) staff from several departments, discussed in the ICC – including the implementation plans and training, safe injection and AEFI – and finally approved by the ICC.

There is a NITAG in Nepal, the National Committee on Immunisation Practice (NCIP), responsible for providing technical guidance to the Ministry of Health & Population (MoHP) on optimal immunisation policies, norms and practices. Minutes of the meeting deliberating on JE were provided.

**HSS application related process.** The HSS proposal was discussed and endorsed by the HSCC, chaired by the MoHP, with wide representation of stakeholders; minutes of this meeting were provided. According to the application documents, the proposal development built on the previous experience and current dialogue, going through a wide consultative process within and outside the MoHP, with regional and district health authorities, local governments, community stakeholders and health facility management committees. DPs - especially WHO and UNICEF - were involved in each step of the proposal process. The Civil Society was active in the

consultative process and attending the HSCC meeting (Rotary International, its Nepal chapter, and the Nepal Red Cross Society), although not represented in the official membership.

The content of the HSS proposal is actually part of the National Health Sector Plan 2015-2020 (NHSP III, provided as a draft): this is the government's strategic plan for the next 5 years and the basis of cooperation between the MoHP and other ministries, CS, private sector and DPs. Coordination and alignment to NHSP III by all health sector stakeholders will be essential to reach the desired goal and outcomes. It is not clear what the role of the HSCC is in the health sector governance, this body is not mentioned in the NHSP III. Under the SWAp mechanism a Joint Consultative Meeting (JCM) is regularly convened and there seem to be other bodies and technical groups to support the sector programme.

The outcome 5 of the NHSP III is "Improved sector management and governance". The strategic approach presented in this plan requires harmonization of existing national, regional and NHSP review processes that existed under NHSP II, and changes in structure and functions at different levels linked to changes in roles and responsibilities, authority, decision making and accountability. A better understanding of the health sector governance mechanisms will be important for Gavi to be an active partner in the SWAp.

### **3. Situation analysis – Status of the National Immunisation Programme**

Nepal is expected to reach the MDG 4 and 5 targets. The 73+ million US\$ provided by Gavi in several grants since 2002 have contributed to the expansion of immunisation activities, which was instrumental to the reduction of child mortality. Immunisation coverage (DPT3) has been consistently improving and the target set by the NHSP II to maintain coverage levels above 90% is being met (latest data is 93%). Nepal performs well also against the other Gavi's goal-level HSS indicators, with a drop-out rate of less than 1% in 2012/13 (Gavi's 2015 target is 9%) and equity in immunisation coverage at 10.8%<sup>4</sup> (Gavi's threshold is 20%). This latter figure, however, still signifies wide socio-economic differences, also reflected in geographic differences. In fact, the 2011 DHS showed that 3% of children had never received any vaccination and 13% did not receive full immunisation. The current plans – both under EPI and the NHSP III – acknowledge and address these issues.

Administrative data (in the NHSP M&E framework) are consistent with WUENIC and surveys (DHS and MICS) data. The EPI programme, launched in 1979, is solid and well performing. Four new vaccines are being introduced, IPV and PCV already launched in September 2014 and January 2015 respectively, Measles and HPV demo in 2015. JE vaccine was introduced in 31 high risk districts, the current proposal is to expand to the other 44 districts, for a nationwide coverage in routine EPI.

With regard to HSS: Gavi has been providing HSS support to Nepal through a pooled funding mechanism since 2010, as an endeavor of the Health System Funding Platform (IHP+) and building on the growing experience of the SWAp in Nepal: Gavi HSS 1 and HSS 2 (until 2013) performed well. The current HSS proposal is within the country's NHSP III, its implementation plan and M&E framework. Immunisation is a priority programme of the GoN and various other regulating authorities also monitor the activities at community level. The health systems constraints are well analyzed and addressed, the bottleneck analysis is

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<sup>4</sup>This is the difference between DTP3 coverage between lowest and highest wealth quintiles

sound and directly linked with activities and results, aligned to the cMYP. The goal to further increase immunisation – and PHC – coverage can only be achieved by addressing inequalities in access to services, through strengthening the systems at different levels. The access to quality care is a clear and explicit focus of the health sector plan, through improving availability and quality of services, aiming at reducing – and even eliminating – geographic and socio-economic barriers to quality health care, including immunisation.

These key features of the NHSP, i.e. high priority given to immunisation and a clear effort to reduce inequalities, are relevant assets to further motivate Gavi support.

#### 4. Overview of national health documents

The Nepal National Health Sector Programme 2015 – 2020, NHSP III, is the basic document for the proposal. Although still a draft, it is a sound programmatic document that builds upon previous plans (NHSP II) and consistent in depth reviews; it consolidates the alignment of all other programmatic documents including the cMYP. The NHSP really represent the “one plan” for health sector development.

The JE vaccine introduction has been incorporated into the current cMYP 2011-2016, with an addendum under the section on eradication, elimination and control of vaccine preventable diseases, including updated costing information and logistic issues.

All related technical and programmatic documents provided with the proposal are reasonably consistent and suggest a solid and competent work behind them.

#### 5. Equity

<b>Gender Inequality Index for Nepal<sup>5</sup></b>	47.9%
<b>Female adolescents currently married<sup>6</sup>/ in union (%)</b>	28.8%

The Nepal National Health Sector Programme 2015-2020 notes that the Interim Constitution (2007) and other high-level policy frameworks recognise that “women, Dalits, Adibashis, Janajatis (indigenous and ethnic people), Madhesis, Muslims, people living with disabilities, sexual and gender minorities, and people in geographically remote areas have experienced barriers to benefit from the nation’s development and warrant affirmative action”. In relation to gender issues, while there is little difference in vaccine coverage between boys and girls, it is noted that mother’s low education and women’s need to ask permission from a husband or family member are barriers to quality health care. In addition, internal migration from the more distant ecological zones (mountains, hills) to urban areas is a challenge to full immunisation of children. Relevant information from recent DHS and MICS were included in the package. It should be noted that CSOs seem minimally involved in immunisation.

Overall the issue of equity and social exclusion in relation to accessing health services is well addressed in the documents provided.

<sup>5</sup> The Gender Inequality Index (GII) is a composite measure which captures the loss of achievement within a country due to gender inequality. The GII is interpreted as a percentage and indicates the percentage of potential human development lost due to gender inequality.

<sup>6</sup> Generally early marriage indicates that girls are being taken out of school and married to significantly older men. This raises questions around inequality within these relationships and the ability of young women to make decisions about their own and their children’s wellbeing.

## 6. Proposed activities, budgets, financial planning and financial sustainability

**JE campaign and vaccine introduction in RI:** Activities are described and detailed in the appropriate documents (introduction plan), with a realistic budget and the government's financial commitment to provide for JE vaccine once in routine immunisation. For the campaign, the target population is 3,652,089 (corresponding to 4,053,900 doses of vaccine at the indicative 10% wastage rate) and the Gavi contribution requested is US\$ 0.65 USD per target person; a detailed budget is provided (whole cost US\$ 2.373.858) and financial management procedures are well described. The country plans to involve administrative infrastructures at provincial and district levels to support monitoring, supervision and media related activities. Support from WHO and UNICEF is also expected.

**JE routine immunisation:** A single dose JE vaccine will be integrated into the routine immunisation schedule at 12 month. The vaccine will be procured through UNICEF SD. The introductions will include the concurrent updating of immunisation cards, tally sheets, and immunisation registry. The application indicates several ways in which the proposed JE campaign is expected to strengthen routine immunisation including improving the capacity of health workers, further strengthening M&E and improving equitable access to vaccines, building upon efforts already initiated in identifying and reaching hard-to-reach populations.

**Training** for JE campaigns will equip health workers with better knowledge on appropriate use of vaccine, micro-planning skills and processes, AEFI surveillance and vaccine safety. A crisis communication strategy to respond to perceived and/or actual severe adverse events will be defined.

Advocacy & Social Mobilization will increase awareness on immunisation and JE campaign, working closely with community leaders, village chiefs, religious authorities and CBOs.

The country plans to conduct post campaign and post introduction evaluations.

**HSS:** The HSS activities actually consist in the implementation of the NHSP III. The modality is the contribution to the health sector pooled fund, within the Nepal health SWAp. The contribution requested corresponds to the Gavi HSS ceiling for the country, of US\$ 36,540,000 (ceiling for budgeting). The guidance for HSS application with pooled funding arrangements, provided by the Gavi secretariat to the country, provides for additional flexibility and a different set of documents and information to be attached to the application. Therefore, the NHSP III is the basic document, detailed description and budget of Gavi funded activities are not required, the health sector M&E framework is used. The NHSP III implementation plan and annual work plans will detail activities and budget in line with agreed country priorities. The Nepal application proposes a summary of major fields of activities related to immunisation that are included and prioritized in the NHSP III, with a roughly estimated budget defined as "indicative, for preliminary discussion".

SN	Major Activity	Estimated Budget
1	Updating the knowledge and skills of health workers, especially on immunisation including enhancement of training facilities	3,217,500
2	Implementation of "reaching Every Community" including strengthening of Immunisation outreach services	20,612,500
3	Support integrated diseases surveillance including VPD	4,917,500

## 7. Specific comments related to the requested support

**JE vaccination campaign and introduction in routine immunisation.** Nepal requests support for these appropriate measures, based on sound elements. The JE disease burden in Nepal is significant in terms of morbidity, mortality, and permanent disability, especially in children. Nepal has a solid experience of JE vaccination campaigns since 2006, and JE vaccine has been introduced into routine immunisation in 31 highest risk districts, targeting children 12-23 months of age, achieving 79% coverage in 2014. Current JE surveillance is supported by 132 sentinel sites and two reference laboratories<sup>7</sup>. The AEFI surveillance is operational and will be expanded in all districts. The proposed activities will use the same vaccine already in use in the country and, once in the routine, the same arrangements for vaccine procurement, fully financed by the Government. Finally, the proposed activities are well planned and aligned to the health sector strategic plan, where the national immunisation programme has high priority.

**Vaccine management and cold chain capacity.** According to the EVM 2014 report, cold chain capacity should not be a constraint for JE. Building on the experience of past campaigns and the ongoing routine use, JE will not pose any additional problem.

The main challenge for the overall EPI, already being addressed, relates to national cold chain store and vaccine management. The country has put a lot of thinking and long term analyses in the cold chain part of the proposal. The recent EVM assessment (end of 2014) is being used to inform the strategic approach in national documents, although a EVM improvement plan is not finalized yet. Despite some improvement since 2011, Nepal's immunisation supply chain is still facing considerable challenges in areas like temperature monitoring, maintenance, distribution, stock management of vaccines and supplies, and a lack of sufficient supervision at all levels. Whilst storage capacity would not appear to be a major issue, storage quality of the cold and dry storage is of major concern regarding introduction of other new vaccines.

The NHSP III IP addresses these challenges and adequately defines actions. A budget (2015-2019) for Cold Chain purposes plan was provided. It seems to be linked to the 2011 EVMA report rather than to the recent EVM and NHSP III. The specifications of Cold chain equipment are not included in the application and it is unclear if they comply with the PQS policy approved by the Gavi Board in June 2014.

**Waste management.** A waste management strategy for the immunisation programme is not mentioned and no satisfactory system seems to be in place. However, efforts of health waste management for the whole sector are ongoing – a model is being piloted in hospitals – and the NHSP draft IP includes an output (2.3) dedicated to this matter.

### HSS

**Linkages to immunisation outcomes, results chain and M&E Framework.** This HSS proposal from Nepal is unequivocally focused on supporting the country health sector, through the sectoral pooled fund that finances the implementation of the NHSP III. Immunisation activities have high priority, since long, within the country strategies and plans, they receive investments in terms of capacities, resources and political commitment, representing a key contribution for Nepal to reach the MDGs 4 and 5 targets.

<sup>7</sup> NPHL: National Public Health Laboratory. BPKIHS: B.P. Koirala Institute of Health Sciences (BPKIHS).

	surveillance	
4	Empowering community for “not to miss any child”	3,792,500
5	Strengthen vaccine logistics system	4,000,000
	<b>Total</b>	<b>36,540,000</b>

This draft description will be consolidated in the NHSP work plans. On those bases and related M&E and Joint Annual Reviews, the Gavi PBF will apply.

The importance of ensuring sustainability of health sector financing is recognized. The dependence on donor funding is significant, since the GoN’s contribution to the total health expenditure ranges between 57 and 66% (data 2011-2014). The fee for service (out-of-pocket expenditure) may affect the access to health care and therefore the achievement of the NHSP III objectives. A basic health care package should be provided free of charge, and this would imply an increased government allocation. These issues remain for further discussion between the GoN and the health SWAp partners.

Some weaknesses of the government systems are recognized, especially in the management of resources, both human and financial (the PFM system needs further development). However, the recent country evaluation of Gavi support to HSS (March 2015) highlighted important elements of the pooled fund arrangement:

- There is an increasingly streamlined single process for overseeing the flow of pooled funds to the MoHP.
- The role of the World Bank as the responsible party for fiduciary review of financial management controls and arrangements is adequate;
- There is greater alignment with government planning cycles and procedures;
- Partners meet to discuss overall progress against results and targets for the previous fiscal year, therefore putting an emphasis on the achievement of results.
- Increased harmonisation has meant that the government can concentrate on delivering activities and achieving results; and
- There are established EDP groups that meet regularly to exchange information and ensure strategic coordination, as well as technical working groups to facilitate dialogue on technical issues.

The Evaluation report concludes that partners are in general satisfied with the accomplishments of the pooled fund arrangements. The focus on results and the predictability funds make planning and budgeting easier for the GoN, also facilitating flexibility and allocation to priority areas. The Nepal Pooled Fund arrangement is now considered to be a fairly mature one. This and its relative successes to date have no doubt inspired the general confidence on the part of the government – and the donors as well – that the joint planning, monitoring, management and review will significantly contribute to shared responsibility and risk avoidance. The regular reviews at district, regional and the central levels, are expected to address and solve most problems.



Based on the documents provided, objectives and activities of the NHSP III adequately cover immunisation; intermediate results (outcomes and outputs) are clearly indicated and can be measured by the six mandatory indicators, all included in the “NHSP III Results based M&E Framework”. The country health sector reviews, evaluations and the population based surveys will also serve the immunisation programme. Information for decision making will come from sector-wide processes.

**Engagement of civil society, including for implementation.** The engagement of the Civil Society seems very limited or nonexistent in the official bodies. The proposal mentions active involvement of the CS is consultations and in implementation; in fact, the 2014 Joint Annual Review (JAR) included significant discussion on CSOs’ role and contribution in the health sector programme and saw a wide participation of NGOs and CSOs. In perspective, a greater contribution from CS is foreseen with mechanisms of PPP in the new NHSP III.

**Technical assistance needs.** WHO and UNICEF have professionals working closely with the Government’s EPI program. In a SWAp environment the major donors / partners are present with technical expertise and work closely with (or within) the MoHP; in fact a joint Technical Assistance arrangement was proposed in the 2014 JAR. No additional assistance seems to be required at the moment.

## **8. Country document quality, completeness, consistency and data accuracy**

The proposal forms for JE and HSS support were well prepared, clear and complete. There was adequate consistency between them and all required documents. The key programmatic documents provided include cMYP, JE introduction plan and JE Plan of Action for Campaign, as well as the wider health sector documents where the HSS proposal builds on: the draft NHSP III, the result based M&E framework and the draft NHSP III Implementation Plan. The latter, besides health systems issues, addresses the challenges and barriers to improve vaccine management and adequately defines key actions.

## **9. Overview of the proposal**

### Strengths:

- The proposal builds on previous well consolidated experiences on immunisation campaigns, new vaccine introduction and HSS through SWAp.
- The proposal is fully aligned to the national health plan. Objectives and activities are logically linked and clearly described. It uses the NSHP M&E framework.
- Two key features of the NHSP, high priority to immunisation and a clear effort to reduce inequalities are strengths to further motivate Gavi support.
- The evaluation recently conducted on the previous Gavi grants to the country provides a good analysis and strong recommendations toward continuing support.
- This is a very good opportunity for Gavi to provide support with modalities fully complying with the international commitments on aid effectiveness, in a context already tested that earned high donor confidence.

### Weaknesses:

- The perspectives for absorption and sustainability of human resources, as well as for the overall sustainability of health sector financing, are not considered in the documents provided.

**Risks:**

- The country may fail in reaching the unimmunized children, and therefore in increasing the immunisation coverage, due to persistent inequalities in access to health care.
- Unforeseen changes in priorities within the NHSP could affect the immunisation activities. In this case, the Gavi funds diluted in the pooled fund and not earmarked would not support immunisation.

**Mitigating strategies:**

- Need for close follow up and contribution to technical assistance if needed. Gavi should be more present in the country, with frequent missions or through partners.

Table 2

Comments for consideration
1. A meaningful involvement of the civil society in health sector and immunisation in the JE and HSS proposals processes is lacking. Good intentions and some strategies (PPP) are suggested in the NHSP III. It would be important to follow up on how these are realized and to encourage / support the country in using the potentials of CS and private sector for health.

**10. Conclusions**

Nepal application for JE demonstrates good planning, coordinated efforts for JE campaign and introduction, and adequate justification and documentation. The HSS proposal from the government of Nepal is sound, building upon the history of the country health sector development – in programmes and modalities – its immunisation activities, and its long term relationship with Gavi. The proposal complies with requirements and with the checklist for pooled fund proposals.

**11. Recommendations**

**JE Campaign and JE VIG : Approval**

Table 3a

Issues to be addressed	Action points
1. The EVM improvement plan is not available, since the EVMA was completed very recently.	1. Provide a timeline for the EVM improvement plan, its preparation aligned to the NHSP III and its implementation.
2. Immunisation equipment (CCL) funded by Gavi must be PQS pre-qualified; the proposal does not provide details.	2. Ensure that CCL equipment procured under this grant is PQS pre-qualified and communicate to Gavi.
3. Waste management is an issue to be addressed, and there is no waste management strategy in place.	3. Prepare a roadmap for the health sector waste management strategy – including immunisation waste – to be included in the NHSP III along with the roadmap implementation documents, and related timeline.

**Issues for follow-up by the Gavi Alliance:**

Follow up on the actions points and provide support.

## HSS: Approval

Table 3a

Issues to be addressed	Action points
1. In a SWAp environment and contributing to a sectorial pooled fund, Gavi should be more informed and engaged in the governance structures and mechanisms.	1. Provide further information about the health sector governance – any SWAp body, DP group, sector coordination mechanism, JCM, JAR, MoHP dept. in charge of coordination, etc – and suggestions for greater Gavi involvement.

### Issues for follow-up by the Gavi Alliance:

- Review the guidelines for application for HSS support, considering the details of requirements and the provisions for contribution to pooled funds.
- The Gavi secretariat will have the task to follow closely the definition of NSHP III annual work plans and budget, and related M&E.
- Gavi should explore modalities for greater engagement in the country health sector governance mechanism, in order to properly perform the role of SWAp partner and to exercise the related responsibility.
- The HSS support to Nepal, in a context with limited risks and high donor confidence, should be treated as a learning exercise for Gavi, with regard to aid effectiveness, incremental use of country systems, funds “on budget”. Consistent observation, technical contributions and documentation will be needed.

**Table 4: Approved budget for HSS**

	Year 1	Year 2	Year 3	Year 4	Year 5	<b>TOTAL</b>
	July 2015 – June 2016	July 2016 – June 2017	July 2017 – June 2018	July 2017 – June 2018	July 2018 – June 2019	
5-year annual ceilings for budgeting <sup>8</sup> provided by Gavi (US\$)	8,700,000	6,960,000	6,960,000	6,960,000	6,960,000	<b>36,540,000</b>
Budget request from Country Proposal (US\$)	8,700,000	6,960,000	6,960,000	6,960,000	6,960,000	<b>36,540,000</b>
Budget approved by IRC - if different from proposal budget (US\$)	The requested budget is approved					

<sup>8</sup>The actual 5 year total ceiling for Nepal is \$43,500,000, while the ceiling for budgeting is \$36,540,000.