

# National decision-making in the introduction of New Vaccines

Mini Engagement  
Azerbaijan – Georgia

30 June 2022

# Outline

Introductions

Problem statement – Azerbaijan

Experience sharing – Georgia

Q & A

Poll

Summarising

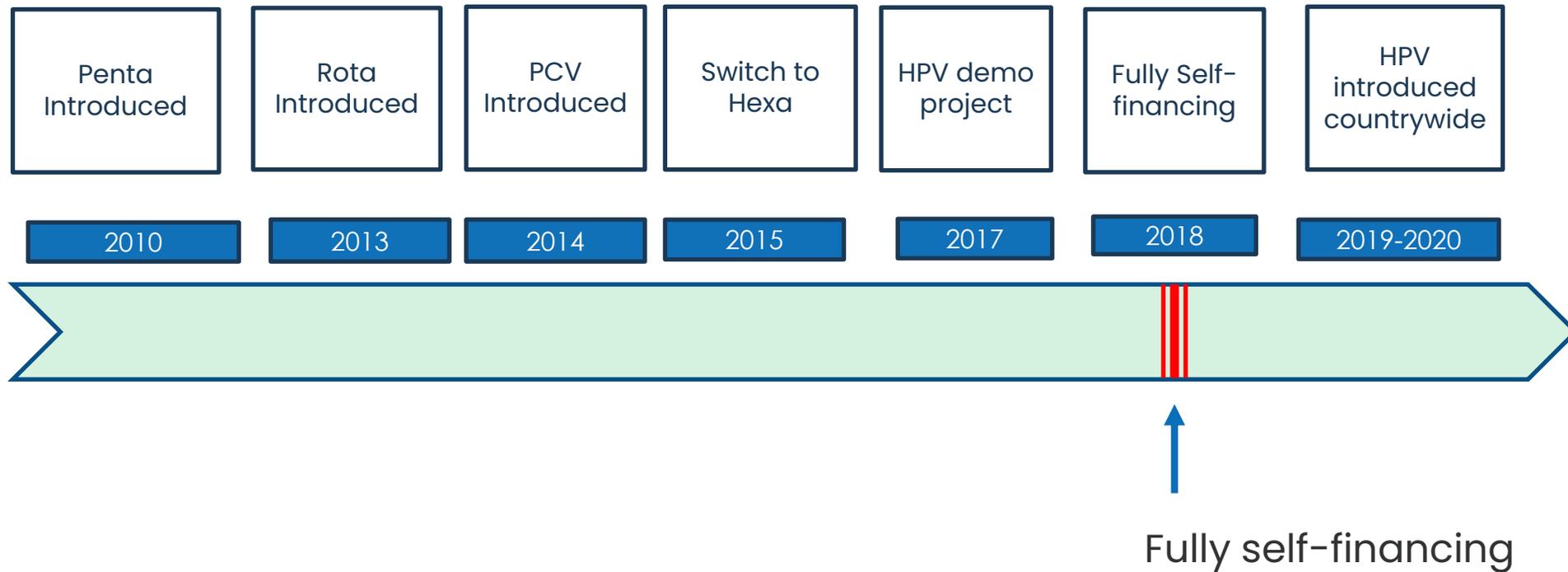
# Presenters

- Khatuna Zakhashvili – Head of the Communicable Disease Department, NCDC
- Vladimer Getia – Head of the Programs Department, NCDC
- Irine Javakhadze – Health programs budget curator, Budget department, Ministry of Finance

# Immunization Calendar

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# NVI Introduction timeline



# NVI National Decision-making

# NVI National Decision-making, *main players*

ICC

- Composition**
- Minister or Deputy Minister of Health (chair)
  - MoF
  - NCDC
  - In-country partners (WHO, UNICEF, USAID, Red Cross, other)
- Responsibilities**
- Discussions and Decision-making on new vaccine introductions
  - Endorsement of Gavi applications, Guiding Gavi funds

NITAG

- Composition (Core Group)**
- National experts in pediatrics and immunology
  - National CDC; MoH
- Responsibilities**
- Prepare Independent advise on national immunization policy including NVI
  - Does not have expertise in economic evaluations

NCDC

- Generating local epidemiological data
- Making Financial projections
- Advocating for NVI based on local and global evidence

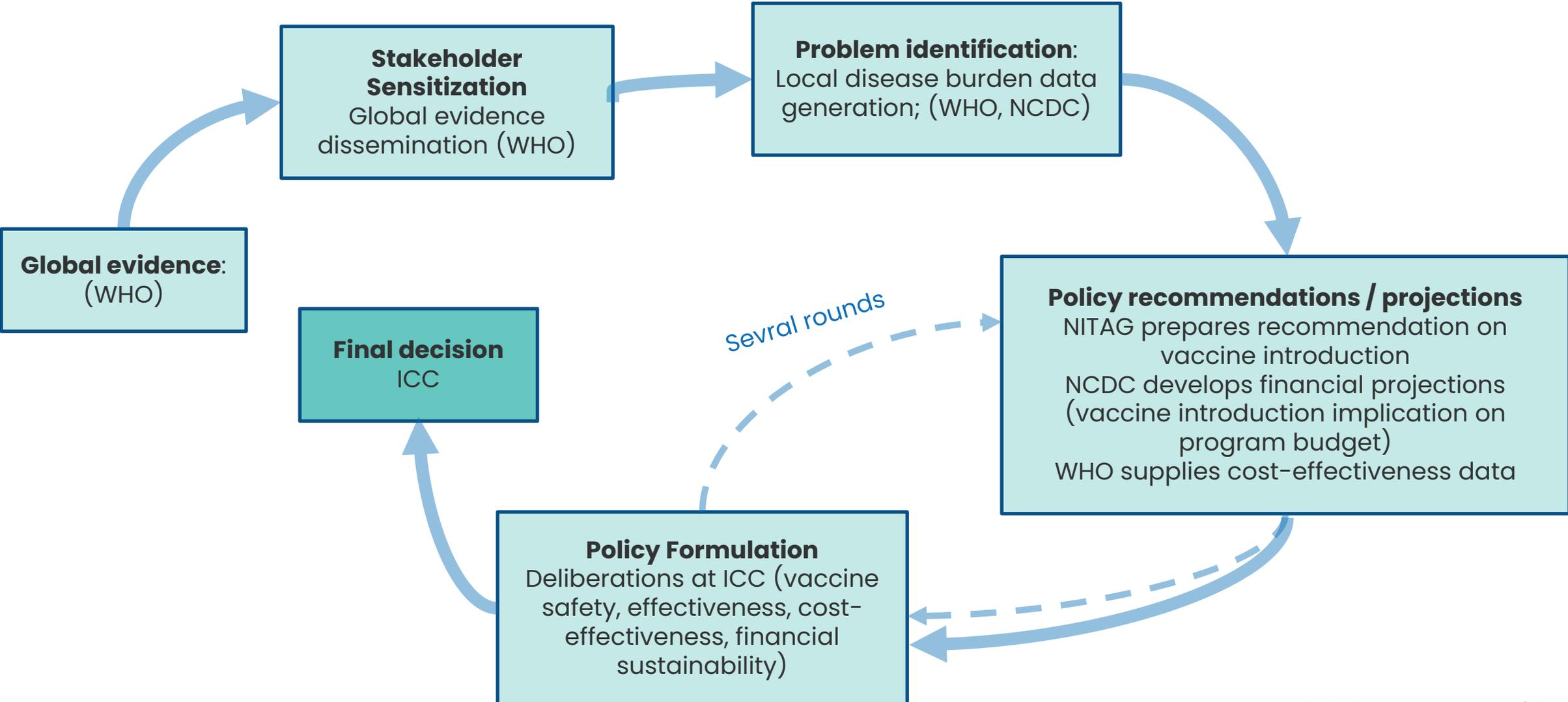
WHO-  
CO, Regional  
Office

- Support National sentinel surveillance studies
- Supply NITAG, NCDC with Disease burden data (global)
- Provide Scientific evidence on vaccine effectiveness, safety, cost-effectiveness

Professional  
groups

- Advocating for certain vaccines introduction. e.g. HPV vaccine (oncologists)

# NVI National Decision-making, process



# Rotavirus vaccine introduction

# Rotavirus Introduction process

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Questions to answer for policy decision

**Was is the disease burden? What is the benefit of the vaccine introduction?**

**Is there cold chain system capacity enough? What is the cost and can Georgia afford it?**

- Sentinel surveillance established in 2006 (WHO technical and financial support)
- Rotavirus disease burden was estimated as high – **40%** of diarrhoea cases in children 0–5
- Hospitalization reduction for severe gastroenteritis – 85%; outpatient visit reduction – 78%
- Cost-effectiveness study was not conducted in Georgia, however global and regional evidence suggested that vaccine was high cost-effective

# Common challenges during Rota decision-making

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- Prior to sentinel surveillance data Rotaviral infection was not considered a serious disease causing significant burden to children health in Georgia
- Relatively low risk of dying from Rotavirus among children 0-5 y. (16-per 100,000) made decision-makers sceptical about vaccine introduction
- However cost-effectiveness data (reduction of hospitalisations and OP treatment and thus health care costs) led to positive decisions
- Several ICC meetings were devoted for deliberations prior final decision was reached.

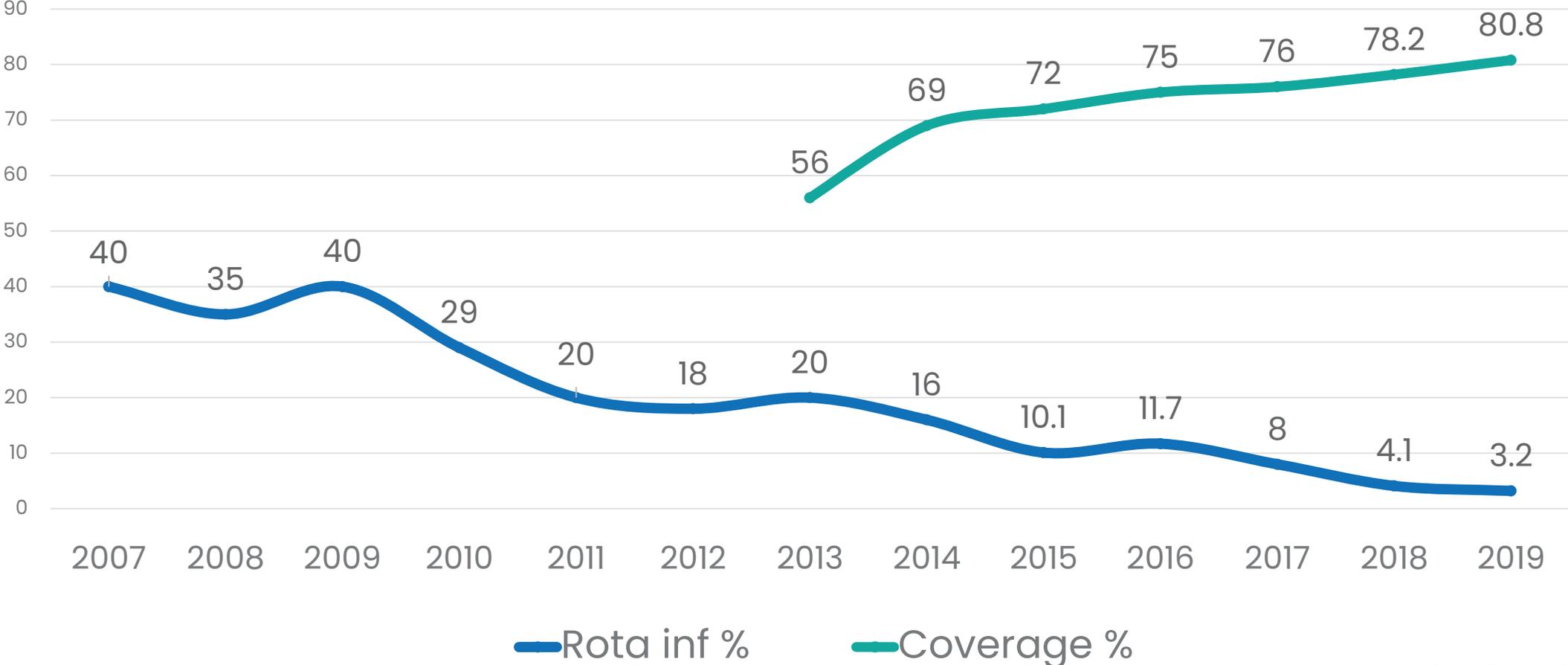
# Rotavirus vaccine pre & post-Introduction evaluation

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- Introduction was preceded by **formative research** of beneficiaries, personnel knowledge/attitudes towards vaccine and to plan communication activities
- **Post introduction evaluation** (2014) identified need of coverage increase through refresh trainings,
- **Hospital based sentinel surveillance** (2018) proved vaccine effectiveness – identified reduction from the baseline level among children 0–5 y.

# Rotavirus Sentinel Surveillance

% of rotavirus diarrhea and coverage, 2013–2019, Georgia



# Rotavirus Introduction – Vaccine price

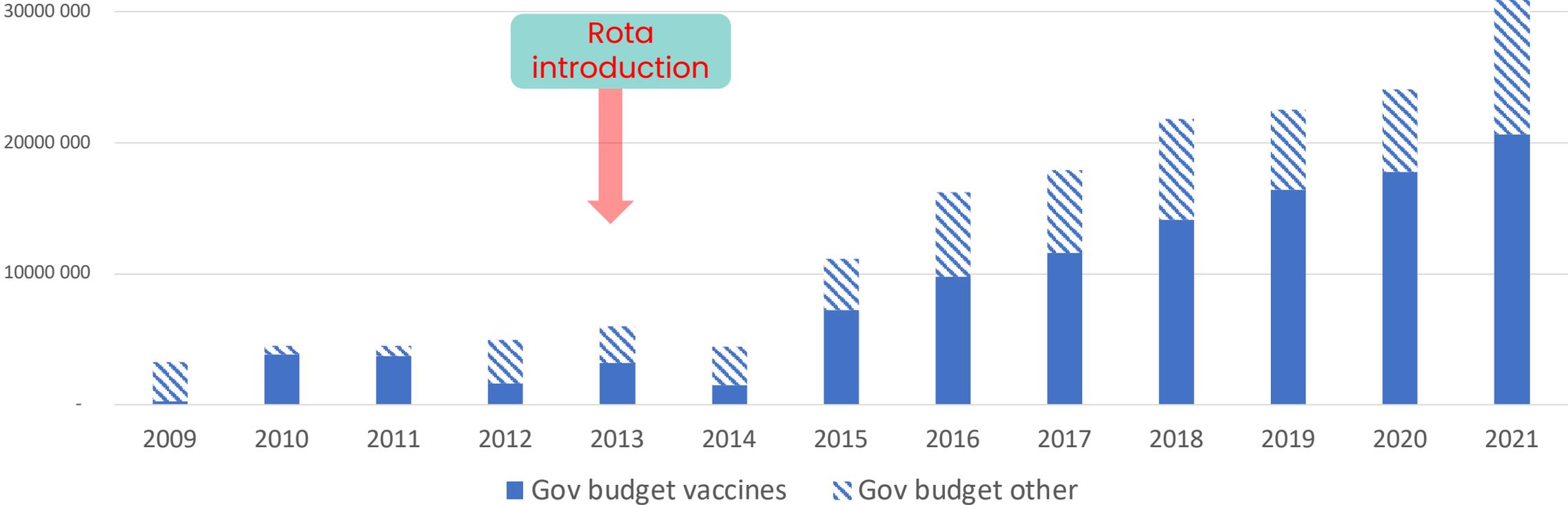
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Introduction Year – 2013

Procurement – through UNICEF SD

- GSk vaccine, Fixed Vaccine price – **1.88 Euro (1.97 USD)** – for 10 years after Gavi support (2016–2024) **vs 5.16 USD** market price
- Financial implications on EPI budget
  - With co-financing scheme (three years) Rota vaccine comprised from **5 – 23%** of EPI vaccine budget

# NIP financing (2009–2021) in GeL, Government sources



# HPV introduction

# HPV Introduction process

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## Questions for policy decision

**Was is the disease burden? What is the benefit of the vaccine introduction?**

**Is there cold chain system capacity enough? What is the cost and can Georgia afford it?**

- High cervical cancer burden in Georgia
  - Incidence -14.2. prevalence 76.6 per 100,000 population, third-leading cause of cancer among women, 40% of women diagnosed are diagnosed in late (III and IV) stages
  - Vaccine effectiveness global evidence: 80% reduction of HPV infection in teens, 71% reduction of infection in young females
- Last opportunity for Georgia to receive Gavi supported vaccine (in 2017 through demonstration project) with Gavi fixed price

# Common challenges during HPV decision-making

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- Prior unsuccessful experience in 2009 (pilot municipal program in Tbilisi) not supported by adequate preparatory work and communication campaign
- Vaccine safety concerns among medical workers and parents
- Complicated introductions in other countries (anxiety related AEFI, anti vaccination movements, religious groups)

# HPV vaccine pre & post-Introduction evaluation

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- Introduction was preceded by a **formative research** of beneficiaries, personnel to study knowledge/attitudes towards HPV vaccine and plan communication activities. Was found
  - low knowledge of parents and schoolteachers on HPV
  - concerns on vaccine safety and adverse effects
  - misinformation on infertility risks
- **Post introduction evaluation** (2018) identified
  - Lack of intersectoral collaboration (Education sector)
  - Lack of integration with preventive services (screening, adolescent health)
  - Low confidence among health workers, insufficiency of trainings

# HPV introduction key recommendations

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- Strong communication campaign based on research of public concerns and health workers knowledge and attitudes
- Continuous training of health workers (primary care)
- Training of specialists (gynecologists particularly)
- Strong collaboration with education system

# HPV Introduction – Vaccine price

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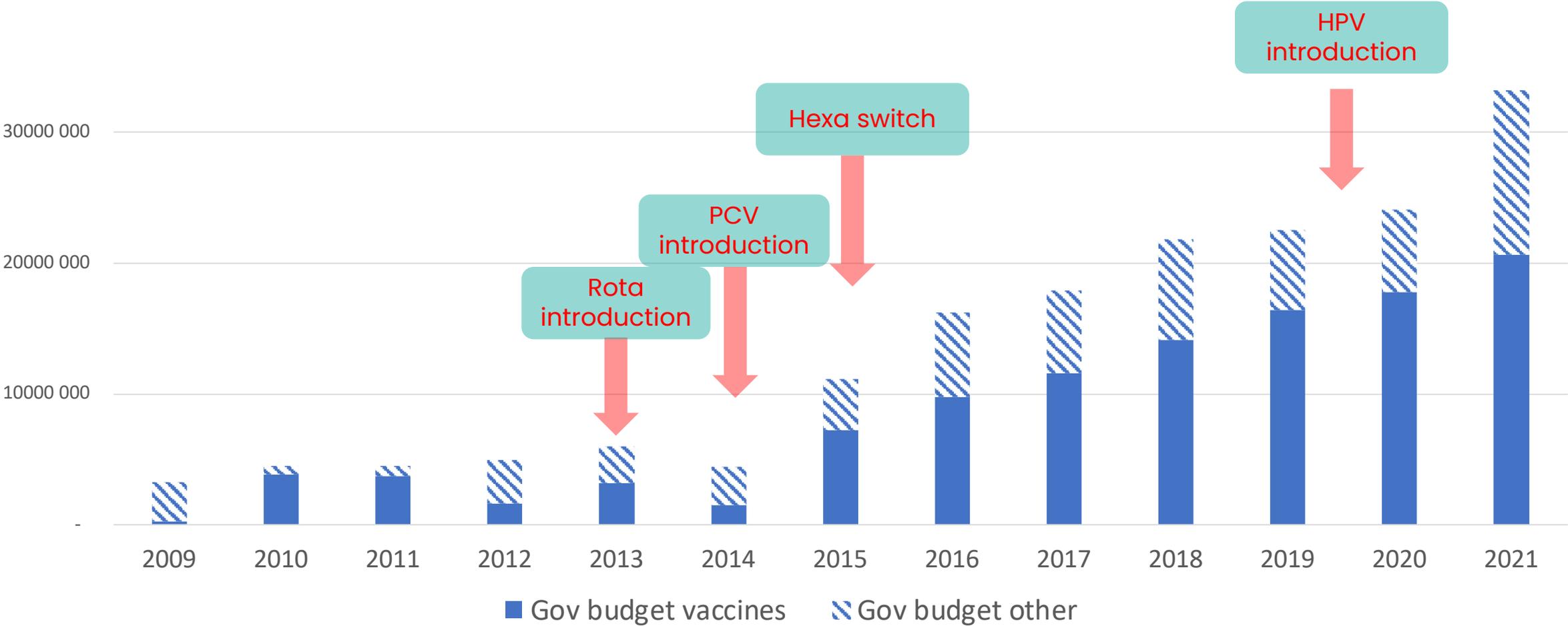
Introduction Year – 2017 (demonstration) 2019 (scale-up)

Procurement – through UNICEF SD

- Merck vaccine, Gavi Fixed price – **4.50 USD** – for 10 years after Gavi support ends (2020–2029) vs. **14.34 USD** market price
- Financial implications on EPI budget
  - HPV vaccine comprise about **4–5%** of EPI vaccine budget

# NVI introduction and EPI budget

# NIP financing (2009–2021) in GeL, Government sources



# NIP financing (2009–2021) in 1000 GeL, USD Government sources

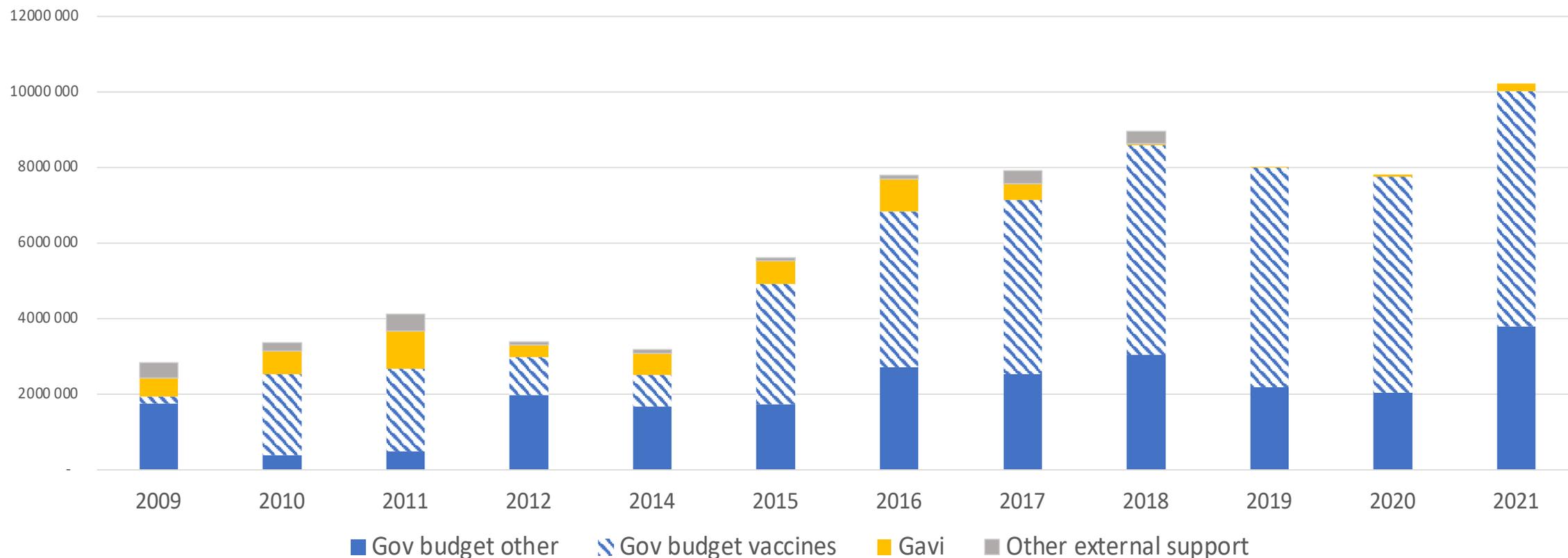
	2009	2010	2011	2012	2014	2015	2016	2017	2018	2019	2020	2021
									<b>Fully self-financing</b>			
NIP budget Gel	3,233	4,520	4,520	4,940	4,431	11,174	16,206	17,927	21,803	22,556	24,130	33,239
vaccine line	289	3,840	3,700	1,650	1,474	7,220	9,800	11,573	14,117	16,410	17,798	20,670
annual change %		40%	0%	9%	-10%	152%	45%	11%	22%	3%	7%	38%
NIP budget USD	1,936	2,532	2,681	2,976	2,510	4,922	6,847	7,146	8,602	8,001	7,760	10,029
vaccine line	173	2,151	2,195	994	835	3,180	4,141	4,613	5,570	5,821	5,723	6,237
annual change %		31%	6%	11%	-30%	96%	39%	4%	20%	-7%	-3%	29%

# Financial Sustainability

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- EPI budget projections (4 years) are reflected in Mid-Term Expenditure Framework
- After expiration of Gavi fixed price the following increase of EPI budget is projected (baseline 2021 budget)
  - For Rota vaccine – 3.8% increase in 2025
  - For PCV vaccine – 21.1% increase in 2027
  - For HPV vaccine – 29% increase in 2029

# NIP financing (2009–2021) in USD



The NIP budget covers costs for a) routine immunization vaccines and injection supply (60–70%), b) vaccines and other pharmaceuticals for epidemiological indication (rabies, tetanus); c) influenza vaccine and service costs (from 2014); d) cold chain support; and e) communication and information system support 1–0.2% (from 2020).

Supervision is covered from municipal budgets to municipal Public Health Centers

# MoF role in decision-making

# MoF in decision-making

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- **Role** – Member of ICC, participatory of all Gavi/ WHO /Sabin organised regional or local meetings dedicated to NVI & financial sustainability
- **Criteria for decision-making** on budget allocation for NVI
  - The disease burden is significant
  - The vaccine effectiveness is proved
  - The vaccine is available at competitive and stable prices
  - Evidence on vaccine cost-effectiveness is available (desirable)
  - Previous vaccine introduction practices show positive impact

# MoF – MoH negotiation process

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- The preparation of the annual budget project begins with the country's basic data and directions document (BDD)
- Within 5 days from approval of BDD document the MoF provides spending units with information about assignments and volumes of margins
- Considering actual limit, the MoH is sending a budget application with E-Budget (electronic programme of budget planning and management) by September 1st
- In case of need and respective justification the MoH has a right to request an increase in limits and/or assignments. **Justifications include:**
  - Introduction of new vaccine according to criteria listed above
  - Increase in coverage rates of existing vaccine (newly introduced vaccine)
  - Increase is hard to justify if previous year performance is not satisfactory

# MoF – MoH negotiation process

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- **From September 1<sup>st</sup> to – November 30** (the Gov is presenting a final version of state budget and respective BDD documents to the Parliament) **Revision process take place;**
- **The budget will be presented 3 times to the Government of Georgia; and 3 times the Parliament of Georgia;**
- In mentioned period the clarifications are possible, including
  - Consultations with MoF
  - Discussions within Government;
  - Discussion within Parliament Healthcare and Social Issues Committee
- **Not later than 3<sup>rd</sup> Friday of December – Parliament should vote for the Budget;**. Budget is approved within one hearing based on the votes of simple majority

# Questions?

Please ask questions to  
Georgia team?