National decision-making in the introduction of New Vaccines

Mini Engagement
Azerbaijan - Georgia

30 June 2022
Introductions
Problem statement – Azerbaijan
Experience sharing – Georgia
Q & A
Poll
Summarising
Presenters

- Khatuna Zakashvili - 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
NVI Introduction timeline

- **Penta Introduced**: 2010
- **Rota Introduced**: 2013
- **PCV Introduced**: 2014
- **Switch to Hexa**: 2015
- **HPV demo project**: 2017
- **Fully Self-financing**: 2018
- **HPV introduced countrywide**: 2019-2020

*Overview NIP in Georgia (2002-2021)*

Fully self-financing
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

**WHO- CO, Regional Office**

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

**NCDC**

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

**Professional groups**

Advocating for certain vaccines introduction, e.g. HPV vaccine (oncologists)
NVI National Decision-making, process

**Global evidence:** (WHO)

**Stakeholder Sensitization**
Global evidence dissemination (WHO)

**Problem identification:**
Local disease burden data generation; (WHO, NCDC)

**Policy recommendations / projections**
NITAG prepares recommendation on vaccine introduction
NCDC develops financial projections (vaccine introduction implication on program budget)
WHO supplies cost-effectiveness data

**Policy Formulation**
Deliberations at ICC (vaccine safety, effectiveness, cost-effectiveness, financial sustainability)

**Final decision**
ICC

**Several rounds**

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Rotavirus vaccine introduction
Rotavirus Introduction process

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

- 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

- 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

<table>
<thead>
<tr>
<th>Year</th>
<th>Rota inf %</th>
<th>Coverage %</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>35</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>29</td>
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<tr>
<td>2011</td>
<td>20</td>
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<td>2012</td>
<td>18</td>
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<tr>
<td>2013</td>
<td>20</td>
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</tr>
<tr>
<td>2014</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>10.1</td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>11.7</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>4.1</td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td>3.2</td>
<td></td>
</tr>
</tbody>
</table>
Rotavirus Introduction – Vaccine price

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

- Gov budget vaccines
- Gov budget other

Rota introduction
HPV introduction
HPV Introduction process

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

- 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

- 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

▪ Strong communication campaign based on research of public concerns and health workers knowledge and attitudes
▪ Continious training of health workers (primary care)
▪ Training of specialists (gynecologists particularly)
▪ Strong collaboration with education system
HPV Introduction – Vaccine price

Introduction Year – 2017 (demostration) 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

Gov budget vaccines  Gov budget other

- Rota introduction
- PCV introduction
- Hexa switch
- HPV introduction


Gov budget vaccines
Gov budget other
# NIP financing (2009–2021) in 1000 GeL, USD Government sources

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

**Fully self-financing**
Financial Sustainability

- 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
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**

- **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 of competitive and stable prices
  - Evidence on vaccine cost-effectiveness is available (desirable)
  - Previous vaccine introduction practices show positive impact
MoF – MoH negotiation process

- 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 providers spending units with information about assignations 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 assignations. **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

- **From September 1st 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 3rd 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?