The TSE Initiative is a multi-stakeholder effort. Current stakeholders are: WHO, UNICEF, Gavi, PATH, CHAI, JSI and Gates.

Total Systems Effectiveness (TSE)

Patrick Lydon (WHO)
WHO Product Development for Vaccines Advisory Committee (PD-VAC)
20-22 June 2017 Meeting
TSE builds on the following hypotheses:

• **Innovations will lead to more and more products and choices that will require more sophisticated decisions and frameworks for analyzing trade-offs beyond generalized CE analysis.**

• **Many existing and future product innovations have the potential to break coverage and equity limits that are currently beyond reach. In order to drive innovation, we need to understand country demands to better inform upstream product development and accelerate country adoption.**
The Problems

*TSE is about address the following problem statements:*

① **The innovation conundrum**
The supply of innovations is not always met with country level demand for it

② **The decision making bias**
Country decisions to introduce a non-vaccine innovation is often guided by purchase price without understanding
- Potential savings on service delivery costs, or from a safety perspective, or in terms of wastage
- Benefits in terms of coverage and health impact (reduction in disease) that could be achieved

③ **The coverage equity plateau**
Countries are often limited by procuring a single vaccine product for nationwide use when using a mix of presentations adapted to different in-country settings and delivery strategies could help break the coverage plateau
The Angle

*TSE is a deliberate attempt to link product innovation and broader immunization goals*

When progress towards goals is lagging . . . . . . evaluate solutions from a TSE perspective

- **Lagging GVAP Goals**
- **Identify Root Cause**
- **Evaluate Optimal Mix Of Innovations**

- Coverage
- Health Impact
- Equity

- Supply and Cold Chain
- Delivery strategies
- Programme Management

• Stimulate the development of the right transformative product innovations
• Optimize product presentations to delivery strategies
The Solution

TSE is an analytical framework that respond to the problem statements:

1) By defining the value proposition of new innovations for country decision makers much earlier in the vaccine and technology product development process

2) By paving the way for a future-state where countries:
   o Have the choice of multiple product presentations for different programmatic adaptations
   o Can comprehensively evaluate the tradeoffs of each beyond just the purchase price
   o Can apply “Systems” thinking to product decision-making with the context of coverage and equity improvements
The Users

Primary users for TSE decision making:

1. MANUFACTURERS
   - Understand demand and implementation trade-offs as input to cost benefit analysis of investment

2. PUBLIC HEALTH GOALS: WHO
   - Combine public health goal setting to programmatic suitability and implementation research

3. DONORS/INVESTORS*
   - Understand trade-offs and scalability early in a preclinical setting to determine level of investment
   - Assist in market shaping for priority vaccines

4. PROCUREMENT
   - Shift the decision-making format from cost of vaccine toward systematic considerations

5. COUNTRY MOH
   - Evaluate tradeoffs and make explicit how new presentations can help meet broader health goals

UPSTREAM

Chicken and egg discussion—manufacturers don’t know what countries will use--countries can’t evaluate a product they know nothing about

Country preferences feed into demand forecasts for manufacturers

TSE helps define the value proposition of new innovations for country decision makers much earlier in the vaccine and technology product development process
The Framework

Analyze trade-offs of a mix of product presentations to delivery strategy within their systems context:

CTE paves the way for a future-state where countries:
• Have the choice of multiple product presentations for different programmatic adaptations
• Can comprehensively evaluate the tradeoffs of each beyond just the purchase price
• Can apply “Systems” thinking to product decision-making with the context of coverage and equity improvements

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- Population density
- Cost per dose delivered

- Multi-dose vials
- Single dose vials/mono-multi-dose
- CTC/microarray patch/oral

- 10 Dose
- 5 Dose
- Uniject
- Uniject
- CTC
- MAP/Oral

increase in logistical complexity
The Framework

TSE will help understand the trade-off across a core set of components and make assumptions explicit.

5 core components

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<th>Component</th>
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Key

- Single product presentation
- Mix of product presentations
Healthy Markets Framework (HMF)

Healthy Markets Framework:
A Framework to explicitly and consistently articulate the characteristics of “healthy” market for vaccine innovations and the trade-offs between market-shaping objectives to make vaccines and other immunization products more accessible and affordable.

8 Building blocks of the HMF

Supply Efficiency: through total systems effectiveness and consider the benefits of longer term competition in a market and that it leads to product innovations that address gaps.

Supply Security: enough buffer capacity in the market to be able to manage unexpected shortages; management of risks associated with procuring from individual suppliers; and, lower reliance on one National Regulatory Authority (NRA) due to procuring too much from any one country.

Preferences: Markets meet country preferences for specific vaccine characteristics such as, vial size, packaging volume, schedule of doses and valency.

Foundation: Markets ensure developing countries have the vaccines required to meet their immunisation needs.

Markets with inadequate supply that does not meet demand cannot be healthy.
The Next Steps

TSE now has a critical mass of interested partners to take this forward*

Socializing Concept

- Defined stakeholder needs...
- R & D / MANUFACTURERS
- PUBLIC HEALTH GOALS: WHO
- DONORS/INVESTORS
- PROCUREMENT: GAVI
- COUNTRY MOH

Developing Use/Test Cases

- A Use Case describes the particular application of TSE framework for a defined set of users
  - i.e., the way in which a vaccine developer evaluates different vaccine presentations will be different than how a country will evaluate them

Developing Framework / Tools

- Carefully crafted Test Cases provide examples of TSE decision making and help understand...
- Test Cases are narrative problem-solving accounts in which stakeholders are grappling with challenges of decision making
  - e.g. country x evaluated MR 5 and 10 dose and chose 5-dose for the following reasons because it would have the most significant impact on coverage
- ...how tools, models and quantitative measures can help quantify or illustrate tradeoffs.

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The Summary

**TSE adds value by:**

- Offering **countries** a framework for assessing the full costs and impact for different vaccine products or program interventions.
- Helping **donors and procurement stakeholders** to prioritize future products that may help achieve immunization goals (coverage & equity).
- Assisting **vaccine and technology developers** in linking products to market demand and articulate product profile needs.