

Ranking Vaccines: Applications of a Prioritization Software Tool

Committee on Identifying and Prioritizing New
Preventive Vaccines for Development, Phase III

NVAC, 10 February 2015



INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

Advising the nation • Improving health

A Multi-User Approach

2012

http://www.nap.edu/catalog.php?record_id=13382

2013

<http://www.nap.edu/catalog/13531/ranking-vaccines-a-prioritization-software-tool-phase-ii-prototype-of>

2014

http://www.nap.edu/catalog.php?record_id=18763

A Multi-Criteria Approach

Health Considerations	<ul style="list-style-type: none"> • Premature Deaths Averted per Year • Incident Cases Prevented per Year • QALYs Gained or DALYs Averted
Economic Considerations	<ul style="list-style-type: none"> • Net Direct Costs (Savings) of Vaccine Use per Year • Workforce Productivity Gained per Year • One-Time Costs • Cost-Effectiveness (\$/QALY or \$/DALY)
Demographic Considerations	<ul style="list-style-type: none"> • Benefits Infants and Children • Benefits Women • Benefits Socioeconomically Disadvantaged • Benefits Military Personnel • Benefits Other Priority Population
Public Concerns	<ul style="list-style-type: none"> • Availability of Alternative Public Health Measures • Potential Complications Due to Vaccines • Disease Raises Fear and Stigma in the Public • Serious Pandemic Potential
Scientific and Business Considerations	<ul style="list-style-type: none"> • Likelihood of Financial Profitability for the Manufacturer • Demonstrates New Production Platforms • Existing or Adaptable Manufacturing Techniques • Potential Litigation Barriers Beyond Usual • Interests from NGOs and Philanthropic Organizations
Programmatic Considerations	<ul style="list-style-type: none"> • Potential to Improve Delivery Methods • Fits into Existing Immunization Schedules • Reduces Challenges Relating to Cold-Chain Requirements
Intangible Values	<ul style="list-style-type: none"> • Eradication or Elimination of the Disease • Vaccine Raises Public Health Awareness
Policy Considerations	<ul style="list-style-type: none"> • Interest for National Security, Preparedness, and Response • Advances Nation's Foreign Policy Goals
User-Defined Attributes	<ul style="list-style-type: none"> • Up to Seven Attributes

A compliant version of the table can be found on Page 34

Use Case Scenarios



Public Health
Agency of Canada



SERUM INSTITUTE
OF INDIA LTD.



Key New Features in SMART Vaccines 1.1

www.nap.edu/smartvaccines

Expanded Set of Nations

SMART Vaccines

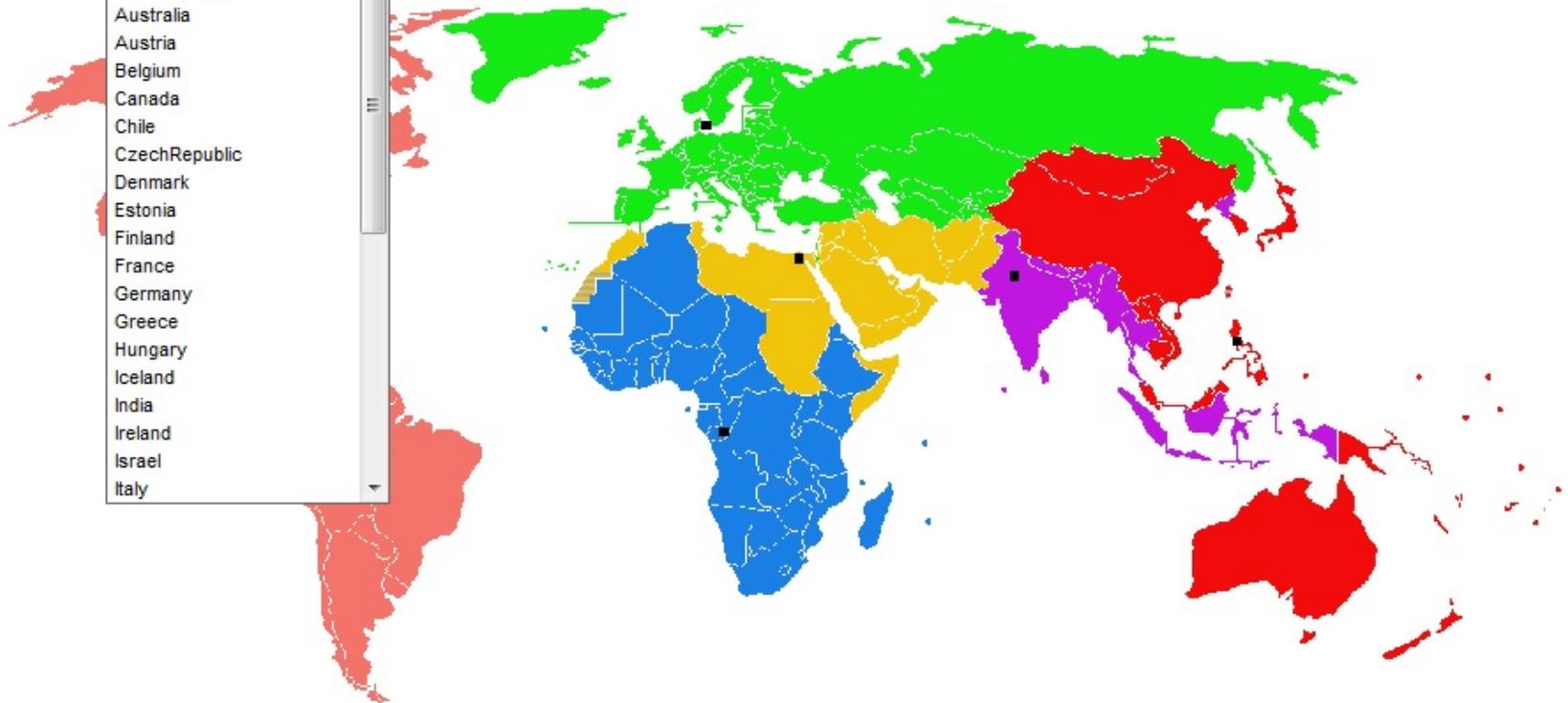
Specify: Population Disease Vaccine
Evaluate: Attributes Weights Priorities

Select the country or region and sub-population. NOTE: SMART Scores are calculated for the total population.

Population:

select

- select
- UnitedStates
- Australia
- Austria
- Belgium
- Canada
- Chile
- CzechRepublic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- India
- Ireland
- Israel
- Italy



SMART Scores

SMART Vaccines

- Specify: Population Disease Vaccine
- Evaluate: Attributes Weights Priorities

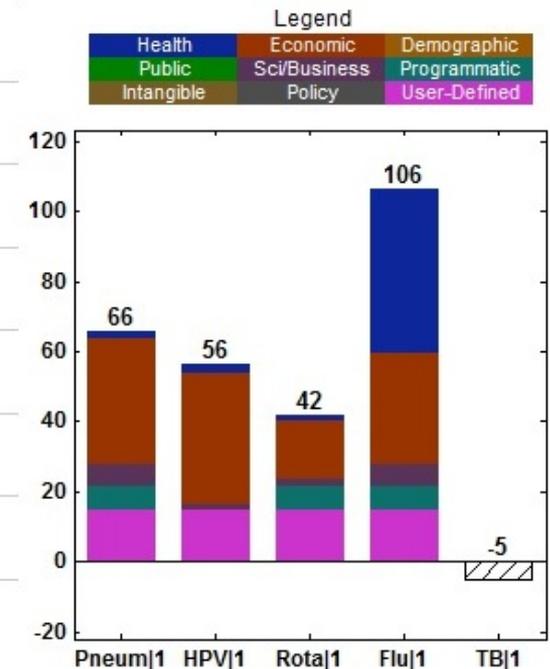
Select vaccine candidates to compare. Set attributes and scores. View SMART Score calculated for total population.
NOTE: Orange highlighted scores have been altered in Analysis; Vaccine Profile.

United States Vaccine Candidates: Values (Scores)

Attributes Selected	Pneumo vac...	HPV vaccine1	Rota vaccin...	Flu vaccine1	TB vaccine1
Incident Cases Prevented per Year	6562 (0)	2340 (0)	222928 (4)	6119401 (122)	6580 (0)
Quality adjusted life-years (QALYs) Gained	7725 (8)	13416 (13)	2965 (3)	136271 (136)	7035 (7)
Cost-Effectiveness (\$/QALY)	-1030 (101)	-3264 (103)	54194 (46)	10836 (89)	118126 (-18)
Demonstrates New Production Platforms	yes (100)	yes (100)	yes (100)	yes (100)	no (0)
Existing or Adaptable Manufacturing Techniques	yes (100)	no (0)	no (0)	yes (100)	no (0)
Potential to Improve Delivery Methods	yes (100)	no (0)	yes (100)	yes (100)	no (0)
Impact on Public Education	fav... (100)	fav... (100)	fav... (100)	fav... (100)	ad... (0)

NOTE: Hatched bars contain negative scores.

SMART Score



- Analysis
- Assessment
 - Weights
 - Vaccine Profile
 - Print

Transparent Results

SMART Vaccines

Specify: ● Population ● Disease ● Vaccine
 Evaluate: ● Attributes ● Weights ● Priorities

Output

Attribute	Weight	Pneumo vaccine1		HPV vaccine1		Rota vaccine1	
		Value	Score	Value	Score	Value	Score
Incident Cases Prevented per Year	15%	6562	0	2340	0	222928	4
Quality adjusted life-years (QALYs) Gained	14%	7725	8	13416	13	2965	3
Cost-Effectiveness (\$/QALY)	17%	-1030	101	-3264	103	54194	46
Demonstrates New Production Platforms	2%	yes	100	yes	100	yes	100
Existing or Adaptable Manufacturing Techniq...	17%	yes	100	no	0	no	0
Potential to Improve Delivery Methods	30%	yes	100	no	0	yes	100
Impact on Public Education	5%	favora...	100	favora...	100	favora...	100

Input

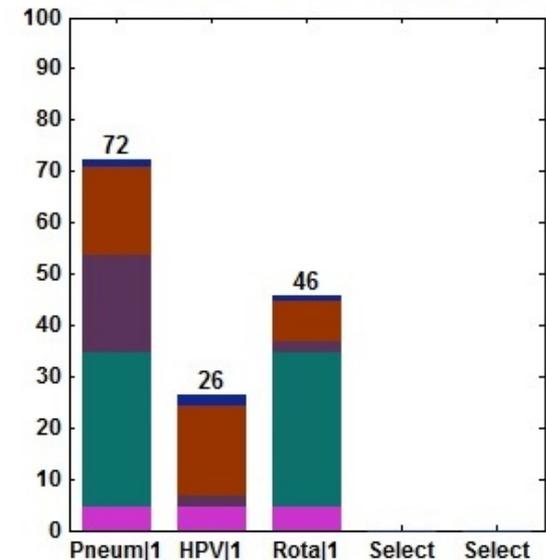
Vaccine Characteristics	Pneumo vaccine1	HPV vaccine1	Rota vaccine1
Coverage	35%	33%	67%
Effectiveness	41%	90%	74%
Length of Immunity (years)	Life	Life	Life
Doses Required per Person (number)	3	3	3
Cost per Dose (\$)	\$10	\$10	\$8
Cost to Administer per Dose (\$)	\$10	\$10	\$10
R&D and Licensure Costs (\$ Millions)	< \$100	> \$1 billion	< \$100
Likelihood of Licensure within 10 Years (%)	100%	100%	100%

Print

09-Sep-2014 13:55:59

SMART Score

Legend



Analysis

○ Assessment ○ Weights
 ○ Vaccine Profile ● Print

**Product Profile
Design Using
SMART Vaccines 1.1**

Characteristics of PS23

SMART Vaccines

Specify: ● Population ● Disease ● Vaccine
 Evaluate: ● Attributes ● Weights ● Priorities

Specify vaccine characteristics.

Continue

Population: SouthAfrica

Select Disease: Pneumo

Vaccine Name: PS23

Subpopulation: female

Product Profile:

Age Groups (years)	Population (n)	Target	Coverage (percentage)	Effectiveness (percentage)
Infants < 1	504851	<input type="checkbox"/>	--	0
Children 1 to < 20	9593485	<input checked="" type="checkbox"/>	65	65
Adults 20 to < 65	13928527	<input checked="" type="checkbox"/>	75	70
Elderly >= 65	1377384	<input checked="" type="checkbox"/>	65	55

herd immunity

Save

Delete

Vaccine Characteristic	Value
Length of Immunity (years)	10
Doses Required per Person (number)	1
Cost per Dose (\$)	25
Cost to Administer per Dose (\$)	20
R&D and Licensure Costs (\$)	\$500 million - \$1 billion

or lifetime immunity

Characteristics of PS30

SMART Vaccines

- Specify: ● Population ● Disease ● Vaccine
 Evaluate: ● Attributes ● Weights ● Priorities

Specify vaccine characteristics.

Continue

Population: SouthAfrica

Select Disease: Pneumo

Vaccine Name: PS30

Subpopulation: female

Product Profile:

Age Groups (years)	Population (n)	Target	Coverage (percentage)	Effectiveness (percentage)
Infants < 1	504851	<input type="checkbox"/>	--	0
Children 1 to < 20	9593485	<input checked="" type="checkbox"/>	65	85
Adults 20 to < 65	13928527	<input checked="" type="checkbox"/>	75	80
Elderly >= 65	1377384	<input checked="" type="checkbox"/>	65	70

herd immunity

Save

Delete

Vaccine Characteristic	Value
Length of Immunity (years)	10
Doses Required per Person (number)	1
Cost per Dose (\$)	40
Cost to Administer per Dose (\$)	20
R&D and Licensure Costs (\$)	> \$1 billion

or lifetime immunity

Characteristics of PC

SMART Vaccines

Specify: Population Disease Vaccine
 Evaluate: Attributes Weights Priorities

Specify vaccine characteristics.

Continue

Population: SouthAfrica

Select Disease: Pneumo

Vaccine Name: PC

Subpopulation: female

Product Profile:

Age Groups (years)	Population (n)	Target	Coverage (percentage)	Effectiveness (percentage)
Infants < 1	504851	<input checked="" type="checkbox"/>	70	70
Children 1 to < 20	9593485	<input checked="" type="checkbox"/>	65	75
Adults 20 to < 65	13928527	<input checked="" type="checkbox"/>	75	80
Elderly >= 65	1377384	<input checked="" type="checkbox"/>	70	65

herd immunity

Save

Delete

Vaccine Characteristic	Value
Length of Immunity (years)	10
Doses Required per Person (number)	3
Cost per Dose (\$)	30
Cost to Administer per Dose (\$)	20
R&D and Licensure Costs (\$)	\$100 - \$500 million

or lifetime immunity

Attributes and Weights

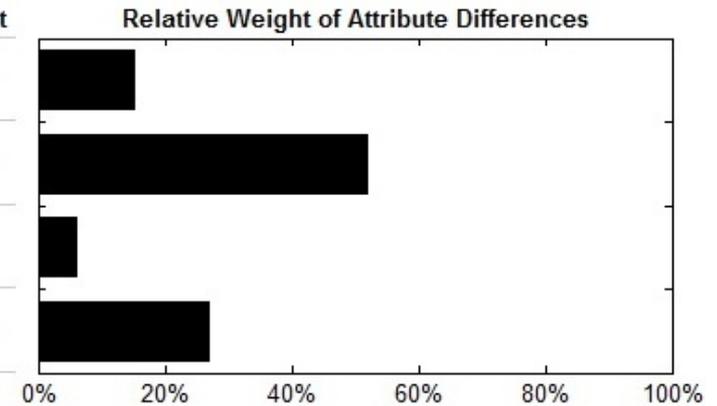
SMART Vaccines

Specify: Population Disease Vaccine
 Evaluate: Attributes Weights Priorities

Rank attributes in order of importance (1 = MOST IMPORTANT) and fine tune weights.

Continue

Attributes Selected	Least Favorable	Most Favorable	Rank	Modify	Weight
Premature Deaths Averted per Year	0	5000	3	<input type="text"/>	15%
Quality adjusted life-years (QALYs) Gained	0	100000	1	<input type="text"/>	52%
Net Direct Costs (Savings) of Vaccine Use per Year (Millions)	50	0	4	<input type="text"/>	6%
Cost-Effectiveness (\$/QALY)	10000	0	2	<input type="text"/>	27%



Initial SMART Scores

SMART Vaccines

Specify: ● Population ● Disease ● Vaccine
 Evaluate: ● Attributes ● Weights ● Priorities

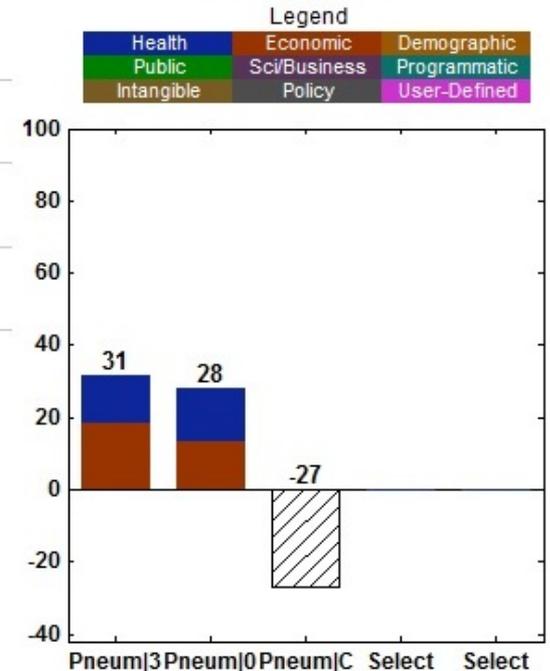
Select vaccine candidates to compare. Set attributes and scores. View SMART Score calculated for total population.
 NOTE: Orange highlighted scores have been altered in Analysis; Vaccine Profile.

SouthAfrica Vaccine Candidates: Values (Scores)

Attributes Selected	Pneumo PS23	Pneumo PS30	Pneumo PC	Select	Select
Premature Deaths Averted per Year	1265 (25)	1444 (29)	1460 (29)		
Quality adjusted life-years (QALYs) Gained	16702 (17)	18930 (19)	19354 (19)		
Net Direct Costs (Savings) of Vaccine Use per Year (Millions)	20 (60)	39 (22)	204 (-309)		
Cost-Effectiveness (\$/QALY)	4417 (56)	5412 (46)	18437 (-84)		

NOTE: Hatched bars contain negative scores.

SMART Score



Analysis

- Assessment
- Weights
- Vaccine Profile
- Print

Coverage Adjustment

SMART Vaccines

Specify: ● Population ● Disease ● Vaccine
 Evaluate: ● Attributes ● Weights ● Priorities

Examine vaccine profile effects on attributes and SMART Score.

SouthAfrica Vaccine

Vaccine: Pneumo|PC

Likelihood of Licensure within 10 Years: 0% 100% **100%**

Coverage (%): 0% 100% **80%**

Effectiveness (%): 0% 100% **77%**

Length of Immunity (Years): 1Yr Life **10Yrs**

Doses per Person: 1 5 **3**

Cost per Dose: \$1 \$1,000 **\$30**

Cost to Administer per Dose: \$1 \$1,000 **\$20**

R&D and Licensure Costs (\$100 Millions): <\$1 >\$10 **\$5-10**

Update

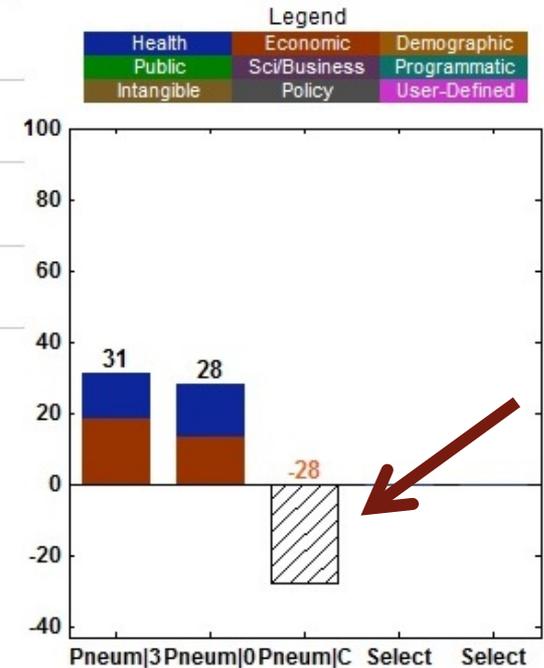
Vaccine updated

Coverage and effectiveness changes uniformly redistributed to vaccine target population sub-groups.

Attributes	Values (Scores)
Premature Deaths Averted per Year	1645 (33)
Quality adjusted life-years (QALYs) Gained	21805 (22)
Net Direct Costs (Savings) of Vaccine Use per Year (Millions)	230 (-361)
Cost-Effectiveness (\$/QALY)	18412 (-84)

NOTE: Hatched bars contain negative scores.

SMART Score



Analysis

● Assessment ● Weights
 ● Vaccine Profile ● Print

Effectiveness Adjustment

SMART Vaccines

Specify: ● Population ● Disease ● Vaccine
 Evaluate: ● Attributes ● Weights ● Priorities

Examine vaccine profile effects on attributes and SMART Score.

SouthAfrica Vaccine

Vaccine: Pneumo|PC

Likelihood of Licensure within 10 Years: 0% 100% **100%**

Coverage (%): 0% 100% **71%**

Effectiveness (%): 0% 100% **80%**

Length of Immunity (Years): 1Yr Life **10Yrs**

Doses per Person: 1 5 **3**

Cost per Dose: \$1 \$1,000 **\$30**

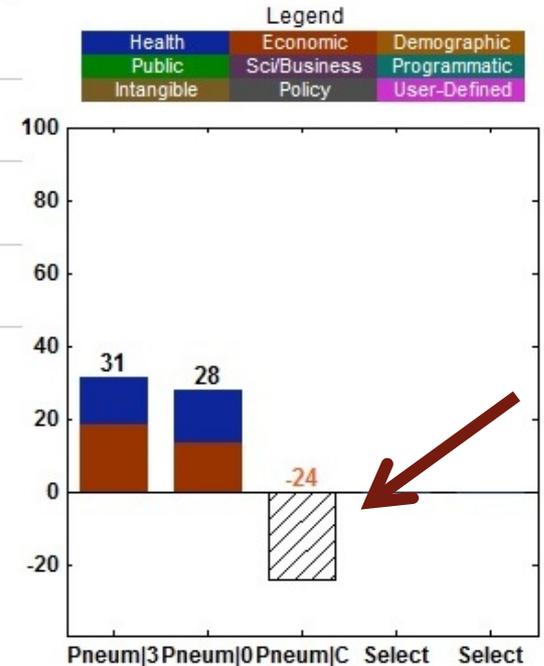
Cost to Administer per Dose: \$1 \$1,000 **\$20**

R&D and Licensure Costs (\$100 Millions): <\$1 >\$10 **\$5-10**

Attributes	Values (Scores)
Premature Deaths Averted per Year	1502 (30)
Quality adjusted life-years (QALYs) Gained	19902 (20)
Net Direct Costs (Savings) of Vaccine Use per Year (Millions)	202 (-305)
Cost-Effectiveness (\$/QALY)	17652 (-77)

NOTE: Hatched bars contain negative scores.

SMART Score



Update

Vaccine updated

Coverage and effectiveness changes uniformly redistributed to vaccine target population sub-groups.

Analysis

- Assessment
- Weights
- Vaccine Profile
- Print

Immunity Adjustment

SMART Vaccines

Specify: ● Population ● Disease ● Vaccine
 Evaluate: ● Attributes ● Weights ● Priorities

Examine vaccine profile effects on attributes and SMART Score.

SouthAfrica Vaccine

Vaccine: Pneumo|PC

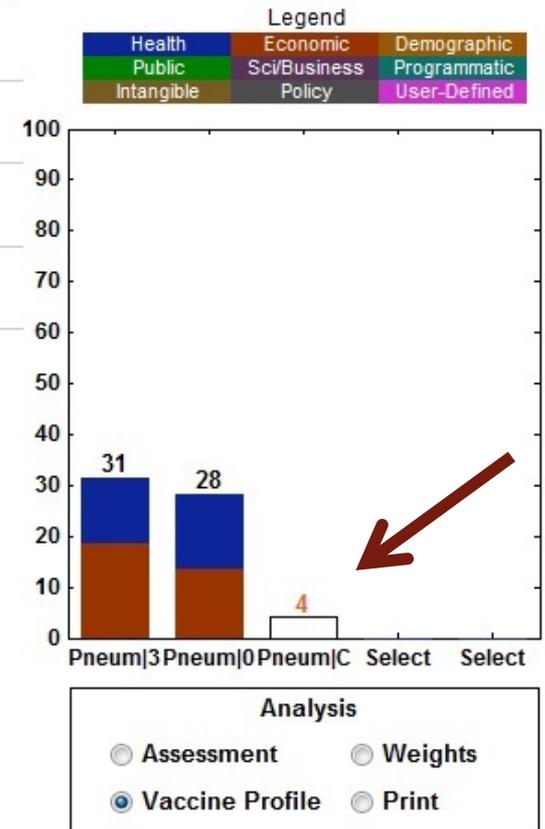
Likelihood of Licensure within 10 Years	0% <input type="range"/> 100%	100%
Coverage (%)	0% <input type="range"/> 100%	71%
Effectiveness (%)	0% <input type="range"/> 100%	77%
Length of Immunity (Years)	1Yr <input type="range"/> Life	15Yrs
Doses per Person	1 <input type="range"/> 5	3
Cost per Dose	\$1 <input type="range"/> \$1,000	\$30
Cost to Administer per Dose	\$1 <input type="range"/> \$1,000	\$20
R&D and Licensure Costs (\$100 Millions)	<\$1 <input type="range"/> >\$10	\$5-10

Update Vaccine updated

Attributes	Values (Scores)
Premature Deaths Averted per Year	1460 (29)
Quality adjusted life-years (QALYs) Gained	19354 (19)
Net Direct Costs (Savings) of Vaccine Use per Year (Millions)	113 (-125)
Cost-Effectiveness (\$/QALY)	11142 (-11)

NOTE: Hatched bars contain negative scores.

SMART Score



Product Profile Change

SMART Vaccines

Specify: ● Population ● Disease ● Vaccine
 Evaluate: ● Attributes ● Weights ● Priorities

Examine vaccine profile effects on attributes and SMART Score.

SouthAfrica Vaccine

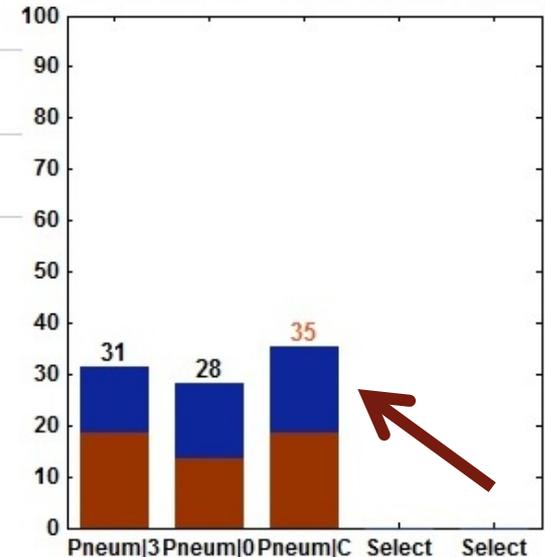
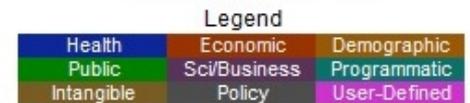
Vaccine: Pneumo|PC

Likelihood of Licensure within 10 Years	0% <input type="range"/> 100%	100%
Coverage (%)	0% <input type="range"/> 100%	80%
Effectiveness (%)	0% <input type="range"/> 100%	80%
Length of Immunity (Years)	1Yr <input type="range"/> Life	15Yrs
Doses per Person	1 <input type="range"/> 5	2
Cost per Dose	\$1 <input type="range"/> \$1,000	\$20
Cost to Administer per Dose	\$1 <input type="range"/> \$1,000	\$20
R&D and Licensure Costs (\$100 Millions)	<\$1 <input type="range"/> >\$10	\$5-10

Vaccine updated

Attributes	Values (Scores)
Premature Deaths Averted per Year	1693 (34)
Quality adjusted life-years (QALYs) Gained	22423 (22)
Net Direct Costs (Savings) of Vaccine Use per Year (Millions)	28 (44)
Cost-Effectiveness (\$/QALY)	4050 (60)

SMART Score



Analysis

Assessment Weights
 Vaccine Profile Print

Beyond Cost-Effectiveness

SMART Vaccines

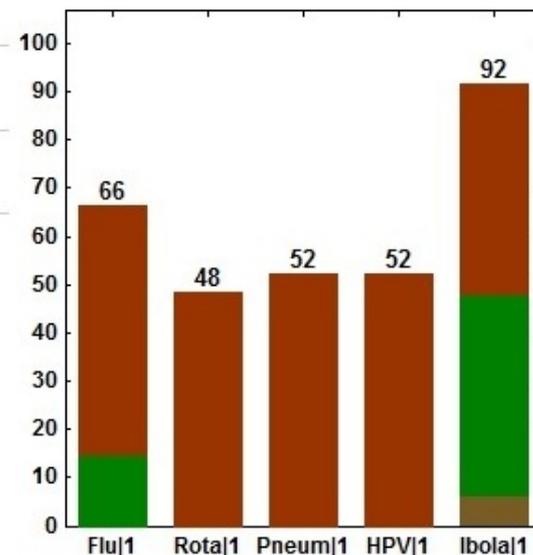
Specify: Population Disease Vaccine
 Evaluate: Attributes Weights Priorities

Select vaccine candidates to compare. Set attributes and scores. View SMART Score calculated for total population.
 NOTE: Orange highlighted scores have been altered in Analysis; Vaccine Profile.

United States Vaccine Candidates: Values (Scores)

Attributes Selected	Flu vaccine1	Rota vaccin...	Pneumo vac...	HPV vaccine1	Ibola vaccin...
Cost-Effectiveness (\$/QALY)	10836 (99)	54194 (93)	-1030 (100)	-3264 (100)	125799 (84)
Disease Raises Fear and Stigma in the Public	no (0)	no (0)	no (0)	no (0)	yes (100)
Serious Pandemic Potential	yes (100)	no (0)	no (0)	no (0)	yes (100)
Eradication or Elimination of the Disease	no (0)	no (0)	no (0)	no (0)	yes (100)

SMART Score



Analysis

Assessment Weights
 Vaccine Profile Print

Demonstrated Benefits of SMART Vaccines

- 1. Transparency.**
- 2. Discussion Facilitation.**
- 3. Decision Convergence.**

Guiding Principle

SMART Vaccines will have the greatest potential and value if it is programmed as a **dynamic, continuously evolving software application and made freely available in an **open-source environment** to all decision makers and developers around the world.***

* *Ranking Vaccines: A Prioritization Software Tool* (Phase II, 2013).

Increasing Awareness

The committee places a strong emphasis on the importance of additional outreach and communication efforts to achieve the best use of SMART Vaccines.

IOM Dissemination Efforts



EMORY
UNIVERSITY

Berkeley
UNIVERSITY OF CALIFORNIA



W
UNIVERSITY of
WASHINGTON



Institut Pasteur



LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE



World Health
Organization



The Vaccine Alliance



EUROPEAN CENTRE FOR
DISEASE PREVENTION
AND CONTROL

dcvmn

Developing Countries Vaccine
Manufacturers Network

Going Forward

A transition strategy to a permanent home for SMART Vaccines is necessary for the ongoing use, enhancement, and the survival of the software as a tool for strategic planning.

Transition Process

The National Vaccine Program Office and the Fogarty International Center of the National Institutes of Health will be best served if they promptly create a process to facilitate the transition of SMART Vaccines to a permanent home.

Permanent Host

The ultimate future applications and benefits of SMART Vaccines depend on the **strengths of the organization or consortium** that becomes the permanent host.

Partnership Model

The committee believes not only that the best hosting organization will have a **significant international presence and reputation**, but also will best serve the user community if it is—or partners with—a **research-intensive institution of higher education.**

Community Development

The committee urges that a community of users, developers, and decision makers be created, fostered, and supported (most likely by the host of SMART Vaccines) to facilitate further use of the tool, data development and curation, and to guide additional software improvements and enhancements.

Data Requirements

The **data requirements** that may seem to loom large in the eyes of potential users are **not created by the software** itself—it merely brings them to the forefront. One cannot make intelligent, data-informed decisions about vaccine priorities without these data.

Web-based Platform

The committee believes that a fully Web-based version is an essential next step in the development of SMART Vaccines.

Critical R&D Priorities

- 1. Software enhancements.**
- 2. Integrated database system development.**
- 3. Community of users, developers, and decision makers.**
- 4. Group consensus process.**

Leading Change

As a multi-stakeholder decision support system, the software has the potential to change the practices of many parties in the vaccine enterprise—suppliers, users, and supporters of vaccine deployment, both domestically and internationally.

A Sense of Urgency

The economic challenges and profound changes seen in today's health care system should create a sense of urgency to improve disease prevention strategies using tools such as SMART Vaccines.

Health Considerations	<ul style="list-style-type: none"> • Premature Deaths Averted per Year • Incident Cases Prevented per Year • QALYs Gained or DALYs Averted
Economic Considerations	<ul style="list-style-type: none"> • Net Direct Costs (Savings) of Vaccine Use per Year • Workforce Productivity Gained per Year • One-Time Costs • Cost-Effectiveness (\$/QALY or \$/DALY)
Demographic Considerations	<ul style="list-style-type: none"> • Benefits Infants and Children • Benefits Women • Benefits Socioeconomically Disadvantaged • Benefits Military Personnel • Benefits Other Priority Population
Public concerns	<ul style="list-style-type: none"> • Availability of Alternative Public Health Measures • Potential Complications Due to Vaccines • Disease Raises Fear and Stigma in the Public • Serious Pandemic Potential
Scientific and Business Considerations	<ul style="list-style-type: none"> • Likelihood of Financial Profitability for the Manufacturer • Demonstrates New Production Platforms • Existing or Adaptable Manufacturing Techniques • Potential Litigation Barriers Beyond Usual • Interests from NGOs and Philanthropic Organizations
Programmatic Considerations	<ul style="list-style-type: none"> • Potential to Improve Delivery Methods • Fits into Existing Immunization Schedules • Reduces Challenges Relating to Cold-Chain Requirements
Intangible Values	<ul style="list-style-type: none"> • Eradication or Elimination of the Disease • Vaccine Raises Public Health Awareness
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User-Defined Attributes	<ul style="list-style-type: none"> • Up to Seven Attributes