



ワクチンの定期接種 欧州の視点

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厚生科学審議会 予防接種・ワクチン分科会
研究開発及び生産流通部会
2017年5月29日

**「ワクチンは、医学と公衆衛生における
最も偉大な功績の1つである」**

Ref: MMWR 1999; 48(12):243-248

NITAG : 定義

National Immunization Technical Advisory Group 予防接種諮問機関

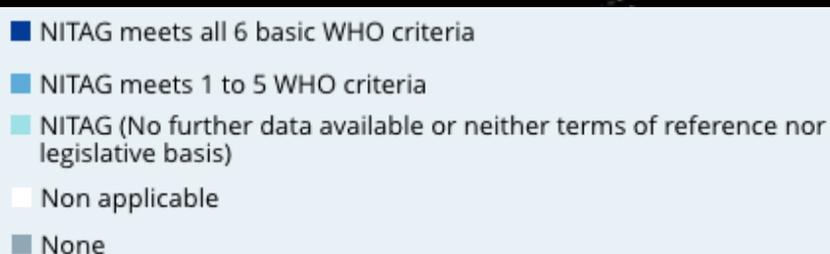
「多分野の専門家で構成された国の公式な専門諮問機関であり、国民の予防接種に関する政策について、独立した立場からのエビデンスに基づく助言を保健当局に対して行う」

NITAG Background Paper
SAGE April 2017



WHO グローバル ワクチン アクションプラン 「2020年までにすべての国にNITAGを」

2015年の状況
世界人口の88%を占める116 (60%) の
加盟国がNITAGありと報告



NITAG Background Paper, SAGE April 2017
<http://www.nitag-resource.org>

NITAG :

WHOによる6つの基本的な基準 (2010年)

- 正式な法律上ないし行政上の基盤
- 正式な文書による付託事項
- 常任委員は少なくとも5つの異なる領域の専門家から構成
- 少なくとも年に1回以上の会合
- 議題および背景資料の配信
- 利益相反の公表義務



NITAG：構成

- 常任専門委員
 - 予防接種およびワクチンの多くの側面をカバーする広い範囲の専門領域を代表（免疫学、臨床医学、疫学、医療経済学、臨床研究など）
 - 各個人の立場で参加
 - 信頼できる、かつ、利益相反の該当がないこと
 - 最終的な勧告内容の決定
- 非常任委員
 - 行政機関において重要な役職を持つ
（例：規制当局、検定機関、定期接種化に関わる機関）
 - それぞれの役職としての立場で参加
- リエゾン委員
 - 専門団体や主要な連携機関を代表（例：WHO）
- 小委員会

構成内容は、各国での要件やリソースに応じて調整される。

Duclos P, Vaccine 28S (2010) A18–A25



NITAG :

エビデンスに基づく意思決定

エビデンスの質の評価（例：GRADEに照らして）

- 疾病負荷と臨床における疾病管理
- ワクチン候補物質の特性
 - 安全性、有効性、効果
 - コールドチェーン、接種スケジュールなど
- 経済学的な側面
 - 直接医療費と社会としてのコスト、集団免疫
- より広い公衆衛生および政策的な検討
 - 既存の予防接種計画への組み入れ
 - パンデミックの可能性、民族移動、・・・
 - 他の公衆衛生上の取り組みとの優先順位付け
 - 総合的なリスク・ベネフィット

意思決定の内容は、各国の状況や優先事項に応じて調整される



NITAG: コミュニケーション

行政と産業が結託しているのではないかという
疑いがメディアで定期的に報じられている

- 利害関係の宣言と、その公表が必要
- ワクチン製造業者との関わりには十分な枠組みが必要
（例：英 Horizon Scanning、独 Jour Fixe）
- 会議および議事録の公開
- 構造化され透明性のある、ステークホルダー（医療従事者、メディア、一般市民）とのコミュニケーション



欧州のNITAG: 事例



JCVI
1963年設立



Health Council
1902年設立



CTV
1985年設立

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Committee on Vaccinations

予防接種委員会

In order to be able to give advice to the Minister of Health, Welfare and Sport on the full spectrum of vaccination care, there is the Committee on Vaccinations. The criteria that must be met, have been formulated in the advisory report [*The individual, collective and public importance of vaccination*](#), published in 2013. This permanent committee succeeds the Committee on the National Immunisation Programme. For this broad advisory task, the Health Council of the Netherlands cooperates with the National Health Care Institute.

予防接種委員会は、予防接種に関する全般的な事項について保健・福祉・スポーツ大臣に助言をするために設置されている。満たすべき基準は、2013年に発行された勧告「個人・集団および公衆における予防接種の重要性」にまとめられている。この委員会は国立予防接種プログラム委員会の後継であり、広い助言活動についてHealth Council of the NetherlandsとNational Health Care Instituteが協力している。この活動はPreventionフォーカスエリアの一環である。



Que recherchez-vous ? Chercher

LE HCSP

AVIS ET RAPPORTS

LA REVUE ADSP

LE POINT SUR

accueil / CTV Comité technique des vaccinations

CTV Comité technique des vaccinations

予防接種技術委員会

Partager 2 19

▼ Présentation ▼ Membres ▼ Déclarations publiques d'intérêt

Présentation

Le comité des vaccinations a pour missions :

1. D'assurer la veille scientifique sur les évolutions et les perspectives en matière de vaccins ;
2. D'élaborer la stratégie vaccinale en fonction des données épidémiologiques et d'études bénéfice-risque individuel et collectif et d'études médico-économiques relatives aux mesures envisagées ;
3. De proposer des adaptations en matière de recommandations et d'obligations vaccinales pour la mise à jour du calendrier vaccinal.

Membres

Déclarations publiques d'intérêt 利害関係の宣言

Déclarations publiques d'intérêt du CTV (4635 ko)

Abiteboul Dominique.pdf	Autran Brigitte.pdf	Beytout Jean.pdf	Billette de Villemeur Agathe.pdf	De Wazières Benoât.pdf	Dervaux Benoât.pdf	Dufour VÇronique.pdf
Floret Daniel.pdf	Gilbert Serge.pdf	Grimprel Emmanuel.pdf	Hanslik Thomas.pdf	Launay Odile.pdf	May Thierry.pdf	Monnier-Curat Anne-Marie.pdf
Nicand élisabeth.pdf	Partouche Henri.pdf	Salmon-Ceron Dominique.pdf	Sclafer JÇrime.pdf	Taha Muhamed-Kheir.pdf	Torny Didier.pdf	





Joint Committee on Vaccination and Immunisation

予防接種合同委員会 (JCVI)は英国の保健当局に対して予防接種に関する勧告を行っている

The Joint Committee on Vaccination and Immunisation (JCVI) advises UK health departments on immunisation.

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Membership 委員

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- Dr Peter Baxter (Sheffield Childrens NHS Foundation Trust)
- Alison Lawrence (lay member)
- Professor Anthony Scott (London School of Hygiene & Tropical Medicine)
- Professor Adam Finn (University of Bristol)
- Dr Fiona van der Klis (National Institute for Public Health and the Environment, Netherlands)





JCVIのプロセス

プロセスには、入手可能な以下のエビデンスの評価が含まれる

- 公表文献
- 公表されていないデータ
- WHOなどの国際機関による勧告
- 専門家とのやりとり
- **受託された** 臨床研究
- **受託された** 疫学的解析
- **受託された** オペレーショナル解析
- **受託された** 態度調査
- **受託された** 予防接種施策のインパクトと費用対効果のカスタムメイドの数学モデル
- ワクチン開発におけるホライゾン・スキャニング
- 関係団体に対するエビデンスの要求

一定の条件が満たされた場合、推奨内容は義務となる

51年前 1966年の英国のワクチンスケジュール



Vaccine/Age	Visit 1 1-6 months	Visit 2 1-6 months	Visit 3 1-6 months	Visit 4 7-10 months	Visit 5 7-10 months	Visit 6 15-18 months	Visit 4 18-21 months	School entry	8-12 years
Diphtheria, Tetanus, Pertussis	DTwP 1	DTwP 2	DTwP 3				DTwP 4	DT	DT
Polio				Polio 1	Polio 2	Polio 3		Polio 4	
Smallpox		Smallpox 1 at 4-5 months							Smallpox 2
BCG									BCG (>12 years)

2017年の英国のワクチンスケジュール



ワクチン・年齢	Maternal	2 months	3 months	4 months	12 m	3-5 years	5-11 years	13-18 y	
DTP-IPV -Hib-HBV	DTaP	DTaP-IPV-Hib- HBV	DTaP-IPV-Hib- HBV	DTaP-IPV-Hib- HBV	Hib-MenC	dTaP-IPV		dT-IPV	Elderly
髄膜炎菌C			MenC					MenACWY	TIV
ロタウイルス		Rv	Rv						Pneumoc occal
MMR					MMR	MMR			Shingles
肺炎球菌		PCV13		PCV13	PCV13				
子宮頸がん (HPV)								HPVx2	
髄膜炎菌B		MenB		MenB	MenB				
インフルエンザ	TIV					LAIV (from 2 years)	LAIV		

予防接種計画に便益があることを示すにはサーベイランスが不可欠

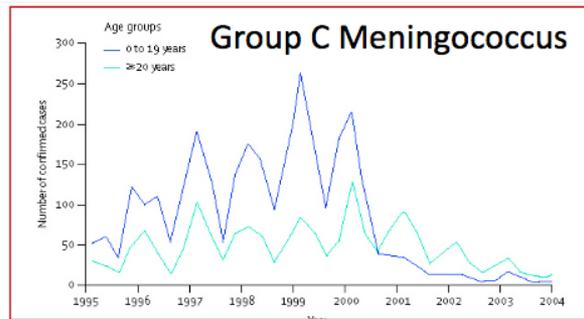
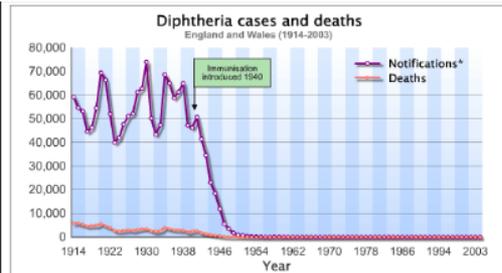


Figure: Cases of laboratory-confirmed meningococcal serogroup C disease by age group and quarter, 1995-2004

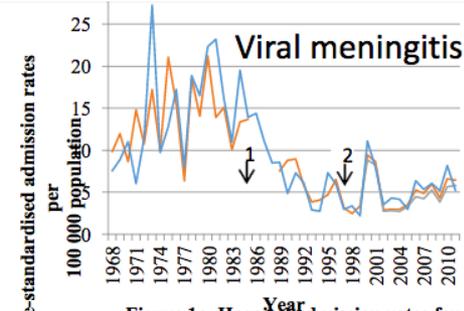


Figure 1a. Hospital admission rates for viral meningitis in children younger than 15 years

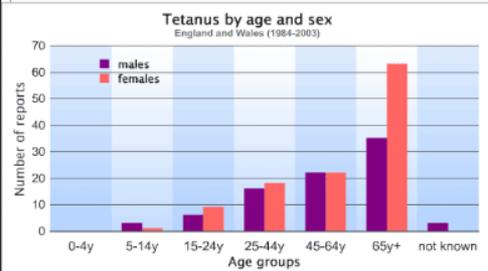
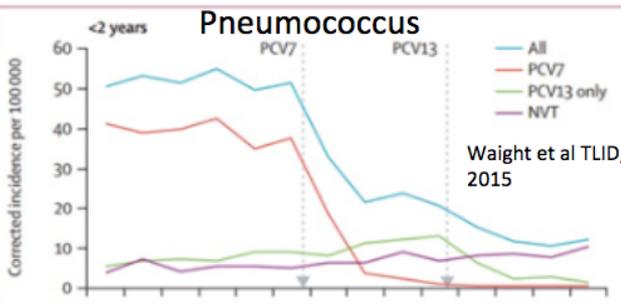
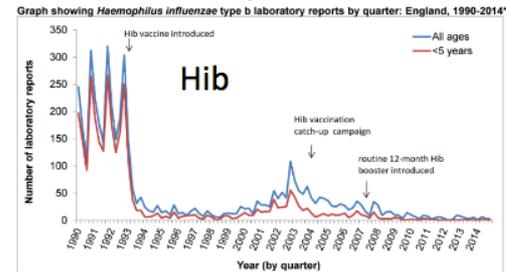


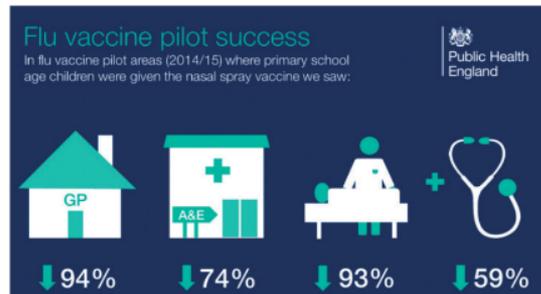
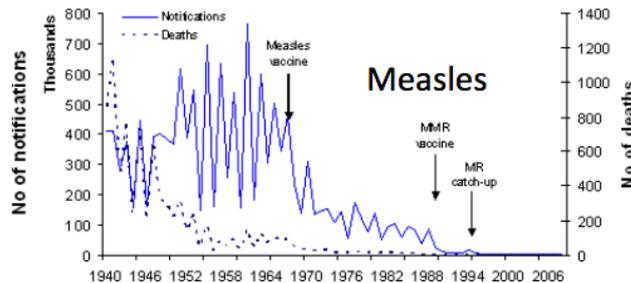
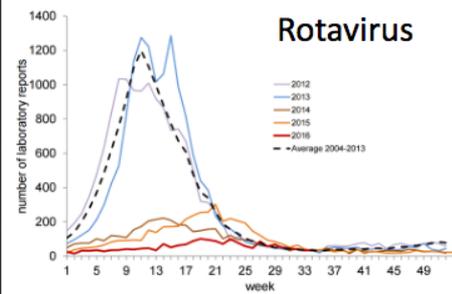
Figure 2. Weekly rotavirus laboratory reports compared to weekly mean reports (2004-2013), England and Wales



Waight et al TLID, 2015



*Provisional data
Source: Routine laboratory data combined with reference laboratory data





JCVIにおける課題

- 財政上の制約がある状況において、ワクチンの効果と疫学の変化を監視する強力なシステムの維持
- 費用対効果分析、国民の意識、健康上のベネフィットのバランス
- 医療経済学により決定が左右されすぎると、柔軟性に欠ける場合あり
- 国民の予防接種に対する信頼 – JCVIの重要な役割

NITAG：キーマッセージ

- WHOの目標：2020年までに全ての国にNITAGを設置
- エビデンスに基づく意思決定（例：GRADE）
- NITAGの役割は諮問機関として勧告を行うことであり、実施、調整ないし規制を行う機関として機能するものではない
- NITAG専門委員における利益相反のポリシー
- 医療従事者と一般大衆（メディア）からの信頼を維持するために透明性とコミュニケーションが必須





ありがとうございました





Vaccines NIP System The EU Perspective

H Bogaerts MD FFPM



MHLW Council
29 May 2017

**“Vaccines are one of
the greatest achievements of
biomedical science and
public health”**

Ref: MMWR 1999; 48(12):243-248

NITAG: Definition

National Immunization Technical Advisory Group

“Formally constituted national technical advisory bodies of multidisciplinary groups of national experts responsible for providing independent, evidence-informed advice to health authorities on all policy-related issues for all vaccines across all populations.”

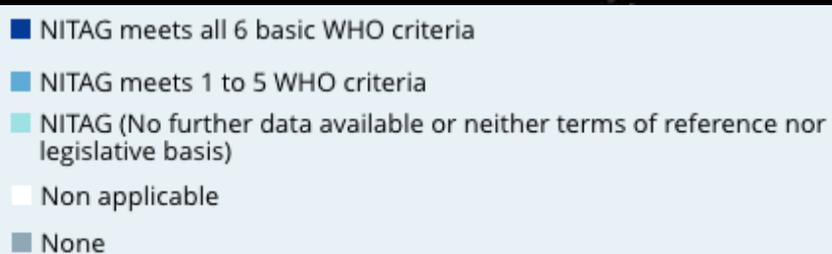
**NITAG Background Paper
SAGE April 2017**

www.who.int/immunization/sage/meetings/2017/april/1_NITAGs_background_document_SAGE_April_2017.pdf?ua=1



WHO Global Vaccine Action Plan: “NITAGs in all countries by 2020”

Status 2015
116 (60%) Member States
accounting for 88% of the global population
reported the existence of a NITAG



NITAG Background Paper, SAGE April 2017
<http://www.nitag-resource.org>

NITAG:

6 basic criteria WHO, 2010

- Formal legislative or administrative basis
- Formal written terms of reference
- At least five different areas of expertise represented among core members
- At least one meeting per year
- Circulation of the agenda and background documents
- mandatory disclosure of any conflict of interest



NITAG: Composition

- Core expert members
 - Represent a broad range of expertise covering many aspects of immunization and vaccines (immunology, clinical medicine, epidemiology, HE, Clinical research ...)
 - Serve in their personal capacity
 - Credible and free of relevant conflicts of interest
 - Decide on the final set of recommendations
- *Ex officio* members
 - hold key government positions (e.g. Regulatory, Nat control lab, NIP)
 - Serve because of their position held
- Liaison members
 - represent professional societies, key technical partners (e.g. WHO)
- Sub-committees

Each country will adjust the composition based on its own needs and resources.



NITAG:

Evidence based decision making

Evaluation of the quality of the evidence - e.g. according to GRADE

- Disease burden and clinical disease management
- Vaccine candidate characteristics
 - Safety, efficacy, impact
 - cold chain, schedule,...
- Economic aspects
 - Direct and Societal costs, herd effects
- Broader public health and political considerations
 - Integration in current vaccination programme
 - Pandemic potential, population migration, ...
 - Prioritization Vs other Public Health measures
 - Overall Risk/ Benefit

Each country will adjust decision making based on its own local situation and priorities.



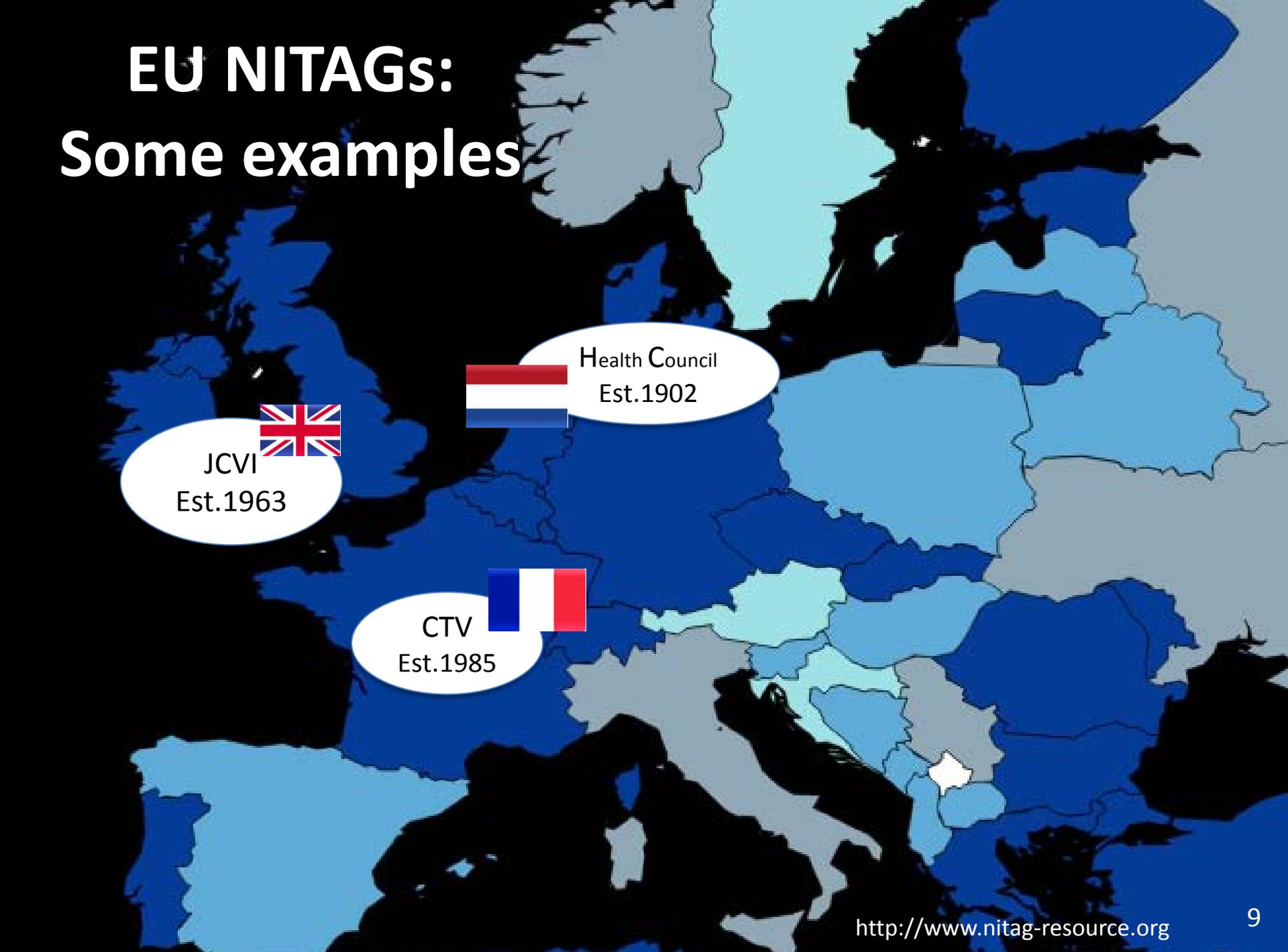
NITAG: Communication

Potential allegations of collusion between governments and industry, are regularly reported in the media.

- Declaration of interests and their disclosure needed.
- Interactions with vaccine manufacturers should be highly structured (e.g. Horizon Scanning -UK, Jour Fixe-GE)
- Meetings/Minutes to be made public
- Structured and transparent communication with relevant stakeholders (HCP, Media, Public)



EU NITAGs: Some examples



JCVI
Est.1963



Health Council
Est.1902



CTV
Est.1985



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Committee on Vaccinations

In order to be able to give advice to the Minister of Health, Welfare and Sport on the full spectrum of vaccination care, there is the Committee on Vaccinations. The criteria that must be met, have been formulated in the advisory report [The individual, collective and public importance of vaccination](#), published in 2013. This permanent committee succeeds the Committee on the National Immunisation Programme. For this broad advisory task, the Health Council of the Netherlands cooperates with the National Health Care Institute.

This activity is a permanent part of [Prevention](#) focus area.



Que recherchez-vous ?

LE HCSP

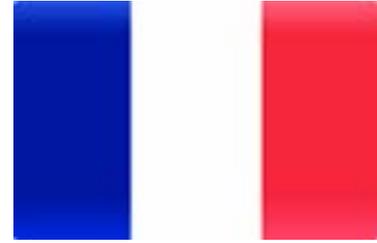
AVIS ET RAPPORTS

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CTV Comité technique des vaccinations



Partager   2   19

▼ Présentation ▼ Membres ▼ Déclarations publiques d'intérêt

Présentation

Le comité des vaccinations a pour missions :

1. D'assurer la veille scientifique sur les évolutions et les perspectives en matière de vaccins ;
2. D'élaborer la stratégie vaccinale en fonction des données épidémiologiques et d'études bénéfice-risque individuel et collectif et d'études médico-économiques relatives aux mesures envisagées ;
3. De proposer des adaptations en matière de recommandations et d'obligations vaccinales pour la mise à jour du calendrier vaccinal.

Membres

Déclarations publiques d'intérêt

Déclarations publiques d'intérêt du CTV  (4635 ko)

 Abiteboul Dominique.pdf	 Autran Brigitte.pdf	 Beytout Jean.pdf	 Billette de Villemeur Agathe.pdf	 De Wazières Benoât.pdf	 Dervaux Benoât.pdf	 Dufour VÇronique.pdf
 Floret Daniel.pdf	 Gilberg Serge.pdf	 Grimprel Emmanuel.pdf	 Hanslik Thomas.pdf	 Launay Odile.pdf	 May Thierry.pdf	 Monnier-Curat Anne-Marie.pdf
 Nicand élisabeth.pdf	 Partouche Henri.pdf	 Salmon-Ceron Dominique.pdf	 Sclafer JÇrime.pdf	 Taha Muhamed-Kheir.pdf	 Torny Didier.pdf	





Joint Committee on Vaccination and Immunisation

The Joint Committee on Vaccination and Immunisation (JCVI) advises UK health departments on immunisation.

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JCVI process:

- The process involves appraisal of the available evidence:
 - published literature
 - unpublished data
 - advice from international bodies including WHO
 - correspondence with key experts;
 - **commissioned** clinical research
 - **commissioned** epidemiological analyses
 - **commissioned** operational analyses
 - **commissioned** attitudinal research
 - **commissioned bespoke mathematical modelling studies of the impact and cost effectiveness of immunisations strategies;**
 - horizon scanning of vaccine developments
 - calls for evidence from interested parties

Recommendations are binding if certain criteria are met.

51 years ago

Vaccines in the UK programme 1966



Vaccine/Age	Visit 1 1-6 months	Visit 2 1-6 months	Visit 3 1-6 months	Visit 4 7-10 months	Visit 5 7-10 months	Visit 6 15-18 months	Visit 4 18-21 months	School entry	8-12 years
Diphtheria, Tetanus, Pertussis	DTwP 1	DTwP 2	DTwP 3				DTwP 4	DT	DT
Polio				Polio 1	Polio 2	Polio 3		Polio 4	
Smallpox		Smallpox 1 at 4-5 months							Smallpox 2
BCG									BCG (>12 years)



UK Schedule in 2017

Vaccine/Age	Maternal	2 months	3 months	4 months	12 m	3-5 years	5-11 years	13-18 y
Diphtheria, Tetanus, Pertussis, Polio, Hib, HBV	DTaP	DTaP-IPV-Hib-HBV	DTaP-IPV-Hib-HBV	DTaP-IPV-Hib-HBV	Hib-MenC	dTaP-IPV		dT-IPV
Meningococcal C			MenC					MenACWY
Rotavirus		Rv	Rv					
Measles, Mumps, Rubella					MMR	MMR		
Pneumococcal		PCV13		PCV13	PCV13			
Cervical cancer (HPV)								HPVx2
Meningococcal B		MenB		MenB	MenB			
Influenza	TIV					LAIV (from 2 years)	LAIV	

- Elderly
- TIV
- Pneumococcal
- Shingles



Surveillance critical to demonstrate programme benefit

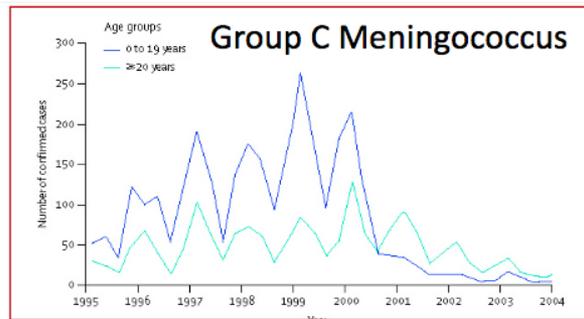
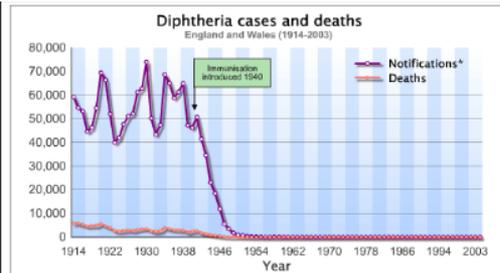


Figure 1. Cases of laboratory-confirmed meningococcal serogroup C disease by age group and quarter, 1995-2004

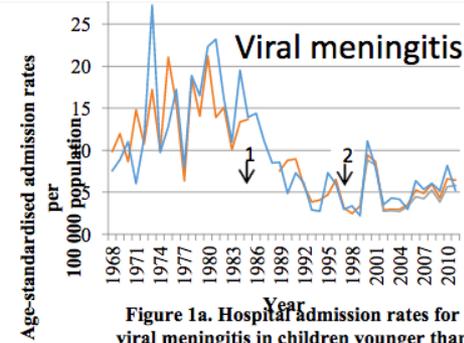
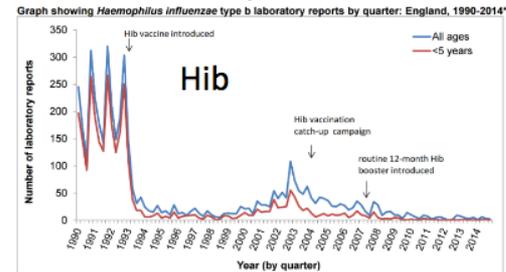
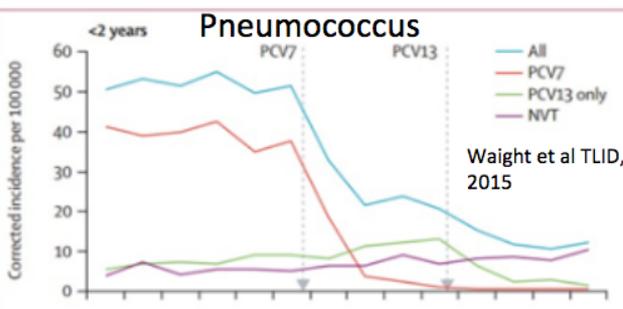
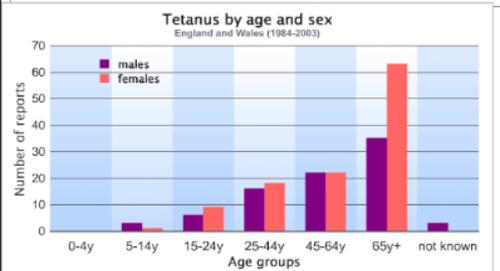
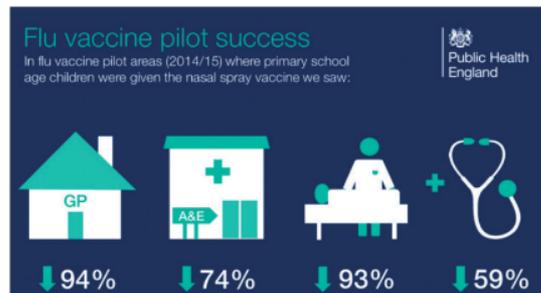
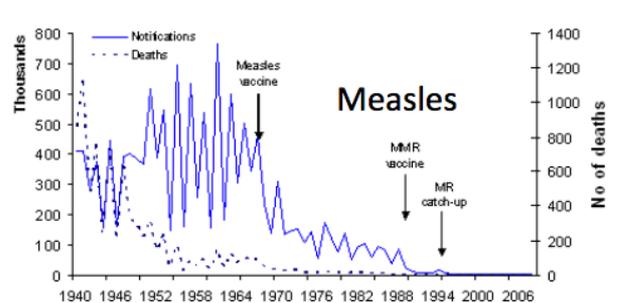
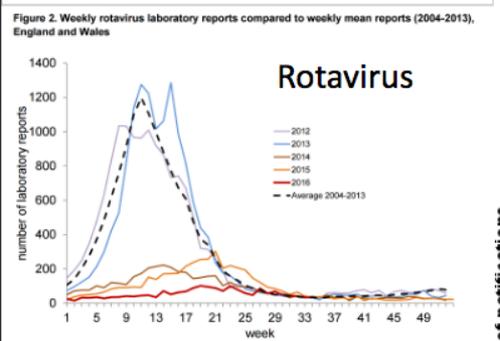


Figure 1a. Hospital admission rates for viral meningitis in children younger than 15 years



*Provisional data
Source: Routine laboratory data combined with reference laboratory data



Some challenges for JCVI



- Maintaining strong systems to monitor vaccine impact and changing epidemiology when finances are constrained
- Balance between cost-effectiveness analysis, public perception and health benefit
- Health economic drivers of decisions could reduce flexibility
- Public confidence in immunisation – **important role of JCVI**

NITAG: Key Messages

- WHO objective: NITAGs in all countries by 2020
- Evidence based decision making (e.g. GRADE)
- NITAGs have a consultative role by making recommendations and should not serve as an implementing, coordinating or regulatory body.
- Conflict of interest policy for Expert NITAG members
- Transparency and communication are essential to maintain trust among HCPs and the Public (Media)





ありがとうございました

