



*SS Virologia Molecolare, SC Microbiologia e Virologia
Fondazione IRCCS Policlinico San Matteo, Pavia, Italy*

Diagnosis and management of fetal rubella infection

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ESCMID Postgraduate Education Course
Infectious Diseases in Pregnant Women, Fetuses and Newborns
Bertinoro, Italy
25-29 September 2016

Congenital rubella syndrome (CRS)

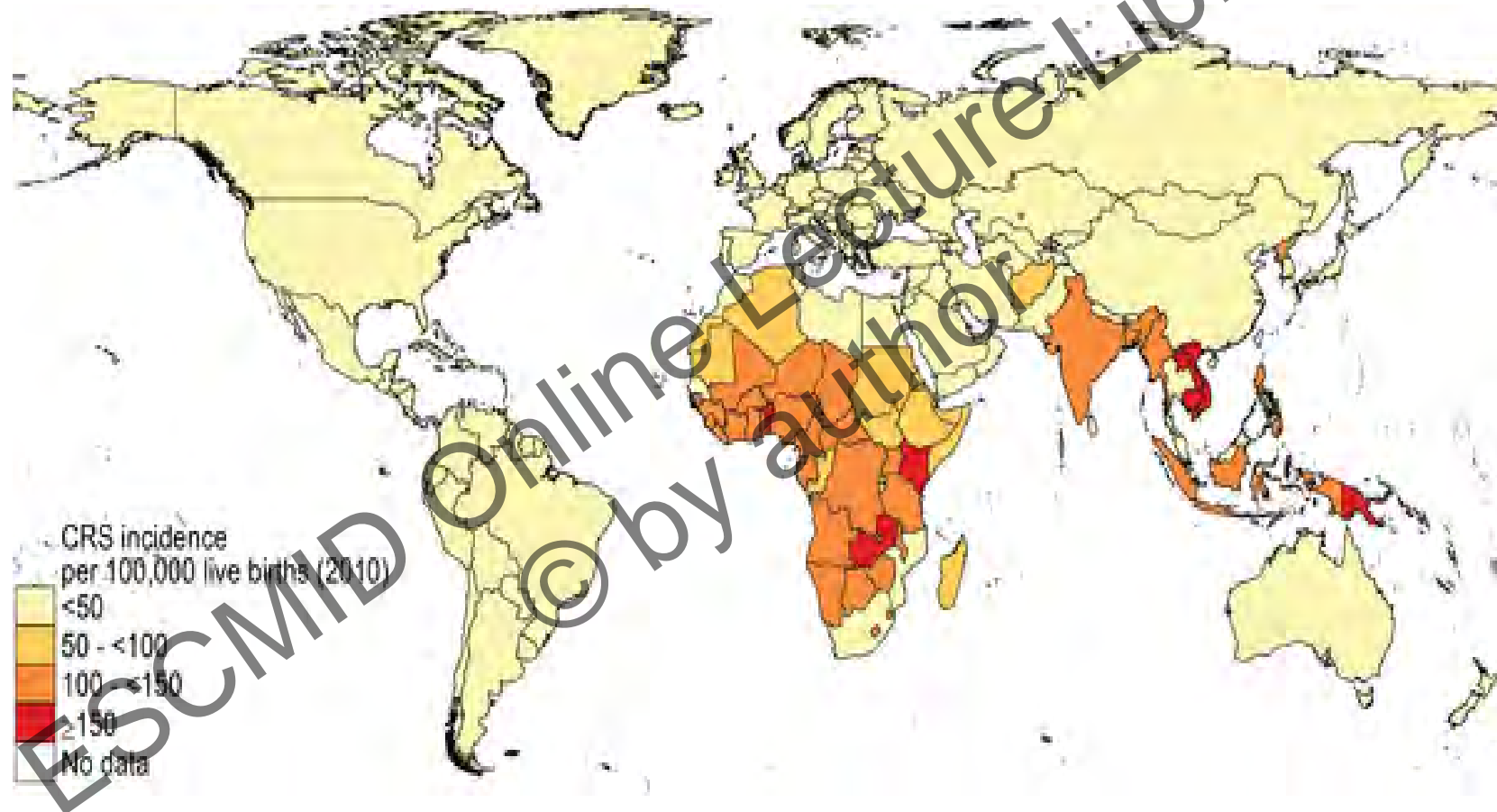
Background

- 1962-1965** worldwide pandemic of rubella
- 1964-1965** 11, 000 fetal deaths and 20,000 infants born with CRS, in the United States
- 1969** first rubella vaccine licensed in the United States
- 2015** rubella and CRS elimination in the Americas

WHO aims to eliminate rubella (incidence of <1 case per 1,000,000 live births)
to reduce congenital rubella cases (<1 case per 100,000 live births)

Today >100,000 infants born with CRS/year worldwide

Estimates of the median incidence of CRS per 100,000 live births by country in 2010



Vynnycky E, Adams EJ, Cutts FT, Reef SE, Navar AM, et al. (2016) Using Seroprevalence and Immunisation Coverage Data to Estimate the Global Burden of Congenital Rubella Syndrome, 1996-2010: A Systematic Review. PLoS ONE 11(3): e0149160. doi:10.1371/journal.pone.0149160
<http://journals.plos.org/plosone/article?id=info:doi/10.1371/journal.pone.0149160>

SURVEILLANCE REPORT

Rubella monitoring

1 July 2015-30 June 2016



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- The 28 EU/EEA countries reported a total of **1,708 cases**
- In **24/28** countries the rubella notification rate was **<1 case per million population** (elimination target)
 - Among these 24, **14/24** countries reported **zero cases**, **10/25** reported **0.01-0.99 cases**

Poland: **1,553 cases (91%) → 40.9 cases per million**

Ireland : **6 cases → 1.3 cases per million**

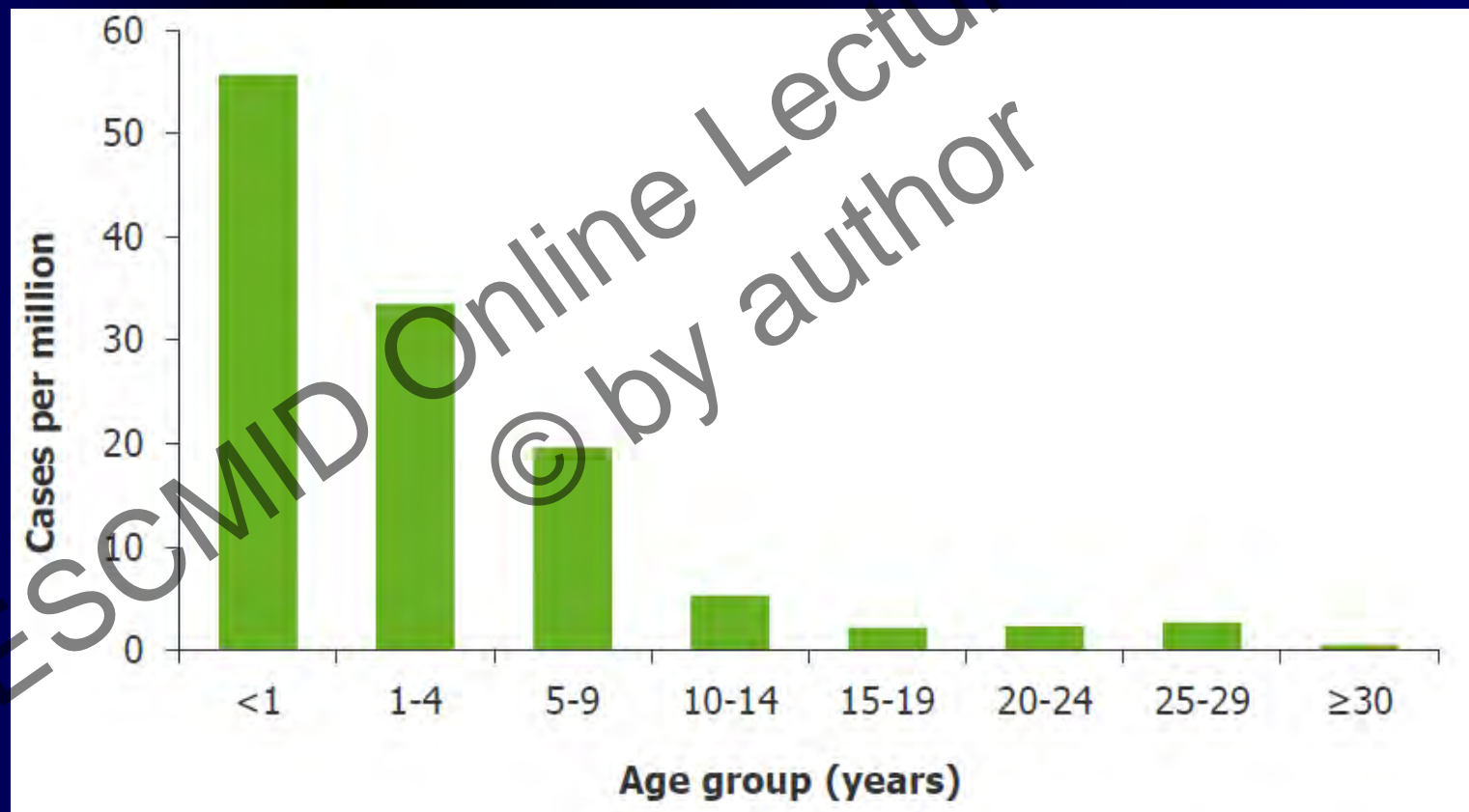
Germany : **91 cases → 1.1 cases per million**

Portugal: **11 cases → 1.1 cases per million**

Rubella notification rate (cases per million) by age groups

1 January–31 December 2015

EU/EEA countries (n=2, 193 with known age)



SURVEILLANCE REPORT

Rubella monitoring

1 July 2015-30 June 2016

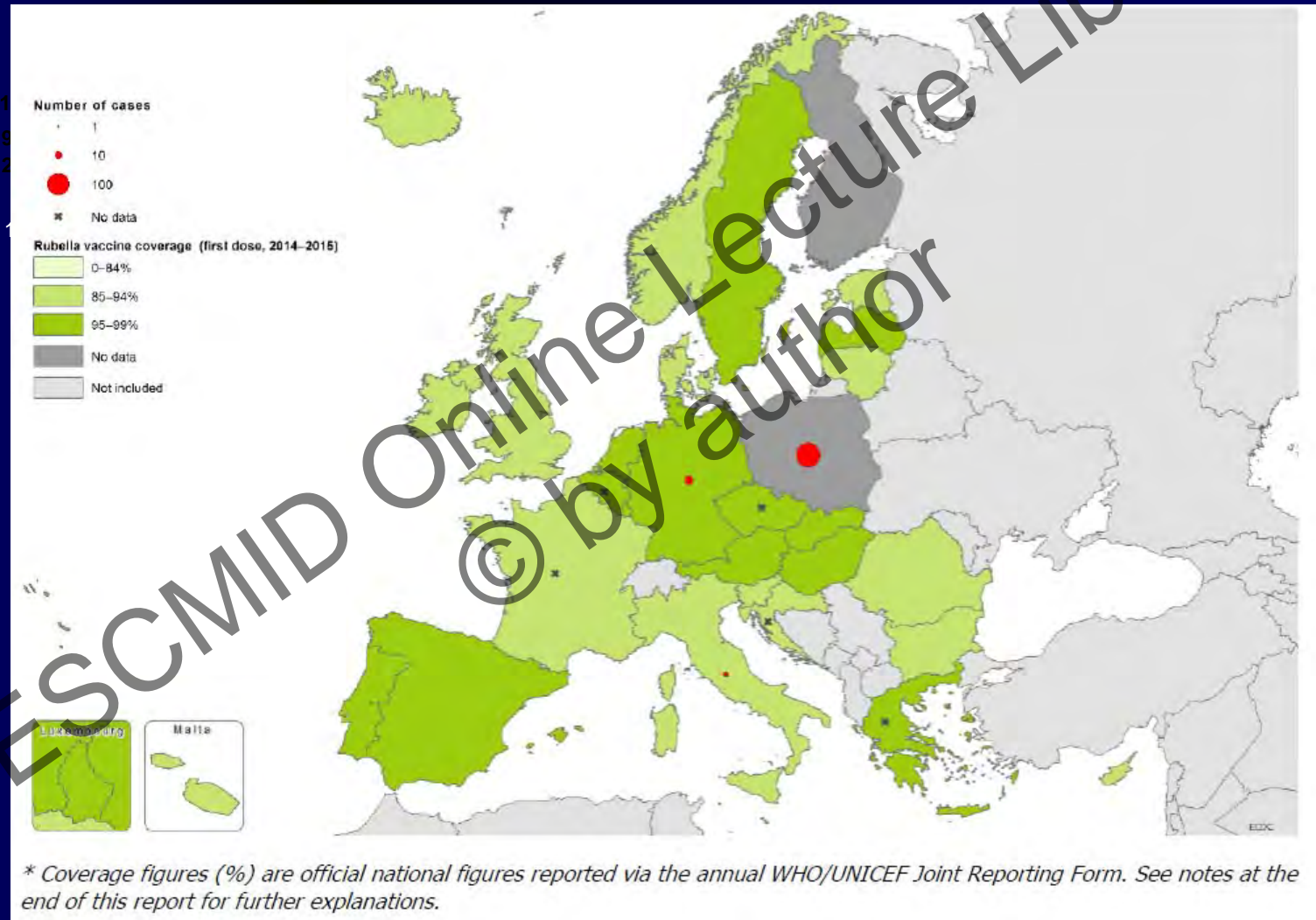


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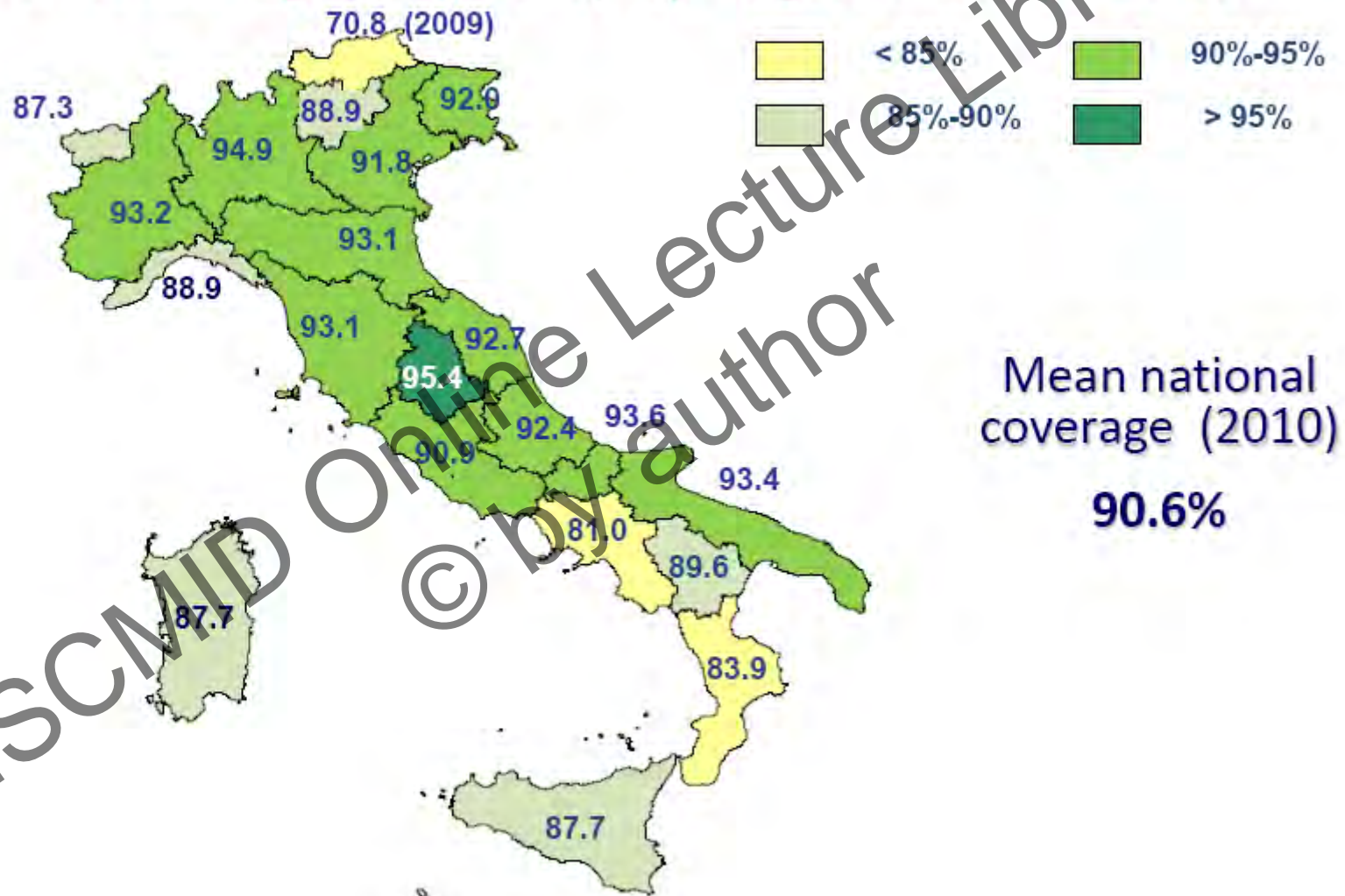
April 2016

End of rubella susceptibility screening in pregnancy in England because the WHO considers rubella in the UK eliminated.

Number of rubella cases by country, June 2016 (n=144), and rubella vaccine coverage (first dose, 2014–2015, WHO*), EU/EEA countries



First dose MMR-MMRV vaccination coverage in children aged 2 years, by region. Italy 2010

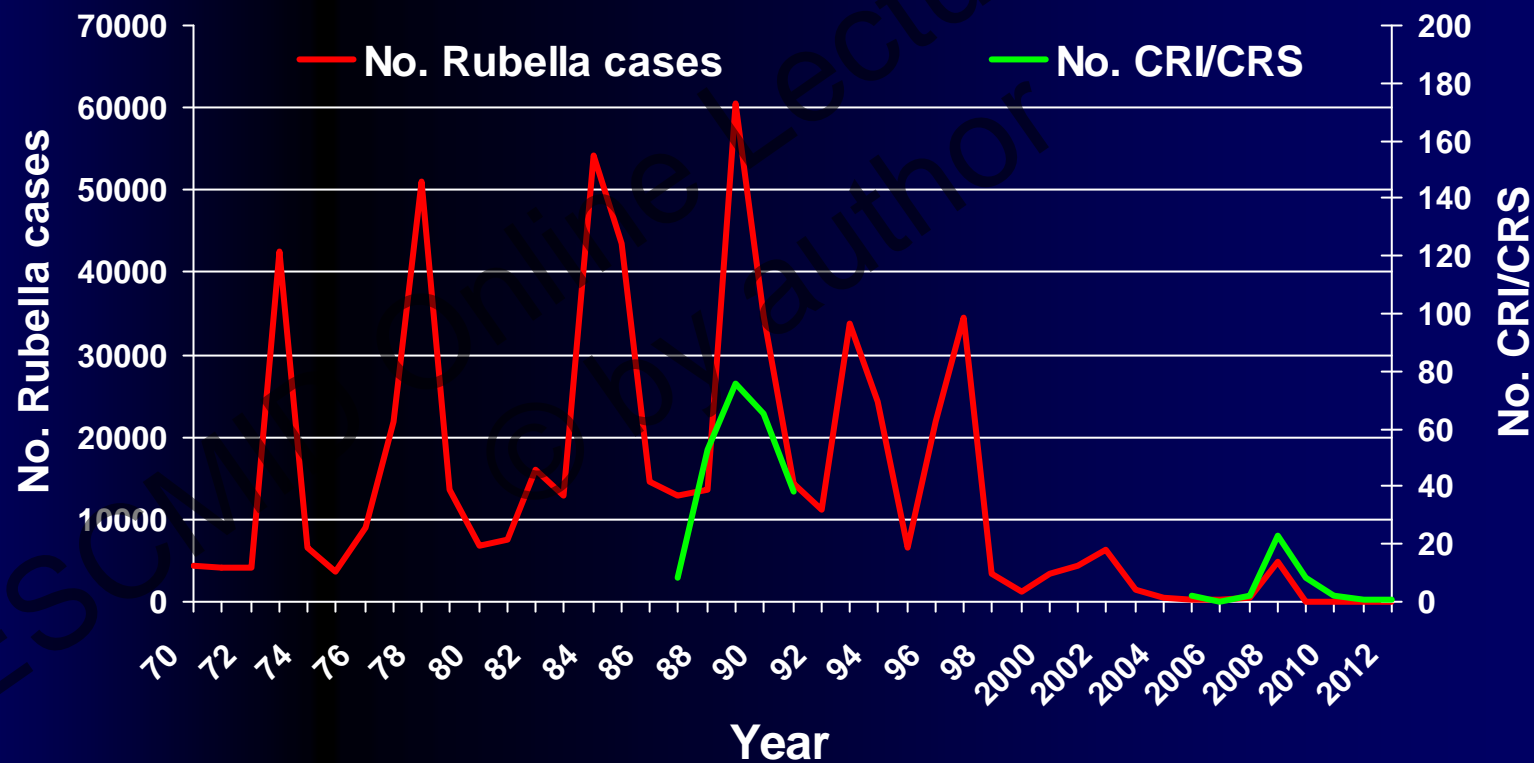


Source: Italian Ministry of Health

Rubella vaccination in Italy

- 1972 monovalent rubella vaccine:
vaccination of adolescent females
- early 1990s combined measles-mumps-rubella (MMR) vaccine
- 1999 national immunization programme:
universal vaccination with 1 dose of MMR (12-15 mos)
- 2003 first national measles and congenital rubella elimination plan:
universal vaccination with 2 doses of MMR (12-15 mos; 5-6 yrs)
offered to all susceptible adolescent and adults

Rubella in Italy, 1970-2012



Source: www.iss.it , WHO

CRI, congenital rubella infection; CRS, congenital rubella syndrome

SURVEILLANCE AND OUTBREAK REPORTS

Congenital rubella still a public health problem in Italy: analysis of national surveillance data from 2005 to 2013

C Giambi (cristina.giambi@iss.it)¹, A Filia¹, M C Rota¹, M Del Manso¹, S Declich¹, G Nacca¹, E Rizzuto², A Bella¹, regional contact points for rubella³

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2. Communicable Diseases Unit, Directorate General of Health Prevention, Ministry of Health, Rome, Italy
3. The contact points are listed at the end of the article.

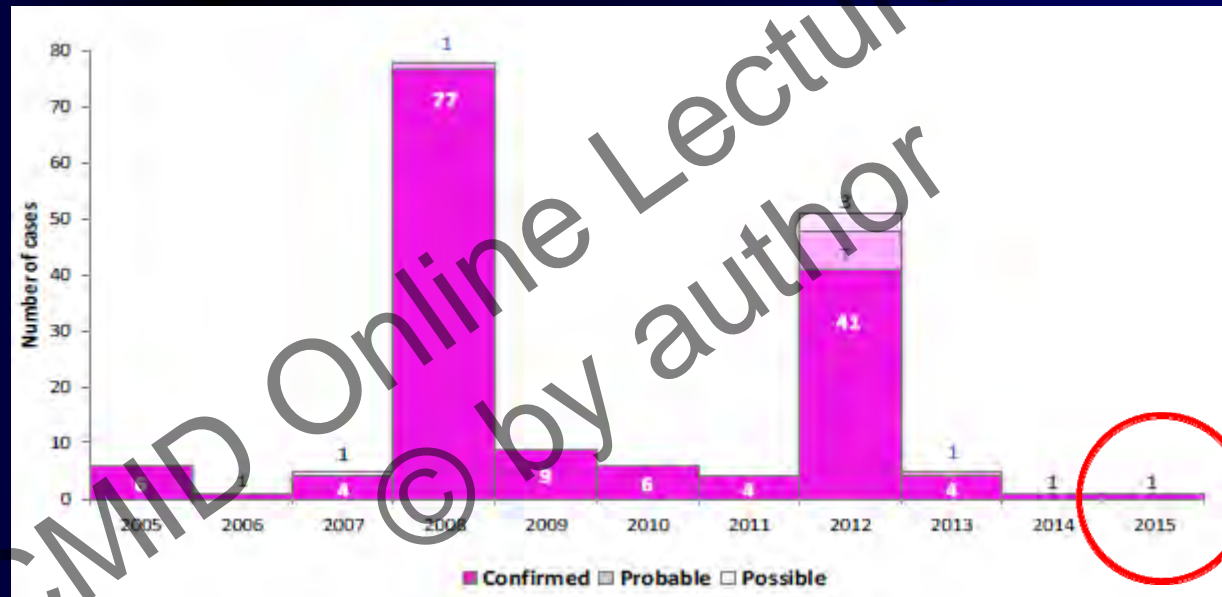
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Giambi C, Filia A, Rota MC, Del Manso M, Declich S, Nacca G, Rizzuto E, Bella A, regional contact points for rubella. Congenital rubella still a public health problem in Italy: analysis of national surveillance data from 2005 to 2013. *Euro Surveill.* 2015;20(16):pii=21103. Available online: <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=21103>

Article submitted on 17 November 2014 / published on 23 April 2015

Rubella in pregnancy by year and classification in Italy 2005-2015

(N=167 → 154 confirmed, 9 probable and 4 possible cases)



- 32 voluntary terminations
- 1 stillbirth
- 1 spontaneous abortion

Characteristics of women with rubella infection in pregnancy

- Median age: 27 years
 - 14% (23/161) foreign country
 - 42% (46/110) acquired rubella in the I trimester of pregnancy
 - for 38 women (23%) it is unknown if the infection was transmitted to the newborn
 - 29% (38/129) performed the rubella antibody screening before pregnancy
- Missed opportunity of vaccination**
- 45% (70/155) had previous pregnancies

2008 Rubella Outbreak. Characteristics of 22 pregnant women referred to San Matteo Hospital (Pavia)

| Pt# | Age in years | Place of origin | Parity | GA at onset | Prenatal Diagnosis | Outcome |
|-----|--------------|-----------------|--------|-------------|--------------------|------------------|
| 1 | 25 | Montemesola, TA | na | | | TOP |
| 2 | 37 | Torino | na | | | Term, uninfected |
| 3 | 18 | Bolzano | na | | | Term uninfected |
| 4 | 23 | Tropea, VV | 1 | | | CRI (twins) |
| 5 | 36 | Firenze | 0 | | | TOP |
| 6 | 33 | Milano | 0 | 15 | | TOP |
| 7 | 36 | Salina, ME | 2 | 15 | | CRI |
| 8 | 36 | Verbania | 0 | 11 | | TOP |
| 9 | 33 | Taranto | na | 9 | | TOP |
| 10 | 36 | Firenze | na | 10 | | m. CRI |
| 11 | 39 | Milano | na | 15 | CRI | |
| 12 | 33 | Milano | na | 11 | nd | |
| 13 | 35 | Cologno, MI | 2 | 19 | nd | |
| 14 | 21 | Piacenza | na | 10 | nd | |
| 15 | 32 | Isernia | na | 16 | Absence of CRI | Term, uninfected |
| 16 | 26 | Varese | 0 | 4 | nd | TOP |
| 17 | 35 | Messina | 1 | 18 | Absence of CRI | Term, uninfected |
| 18 | 35 | Monza | na | 11 | CRI | |
| 19 | na | Messina | na | 27 | nd | m. CRI |
| 20 | 28 | Varzi, PV | na | -2 | nd | uninfected |
| 21 | 20 | Brescia | na | 2 | Absence of CRI | Term, uninfected |
| 22 | na | Bergamo | na | 4 | nd | Term, CRS |

4 Voluntary termination (VT)

6 fetuses with CRI (VT)

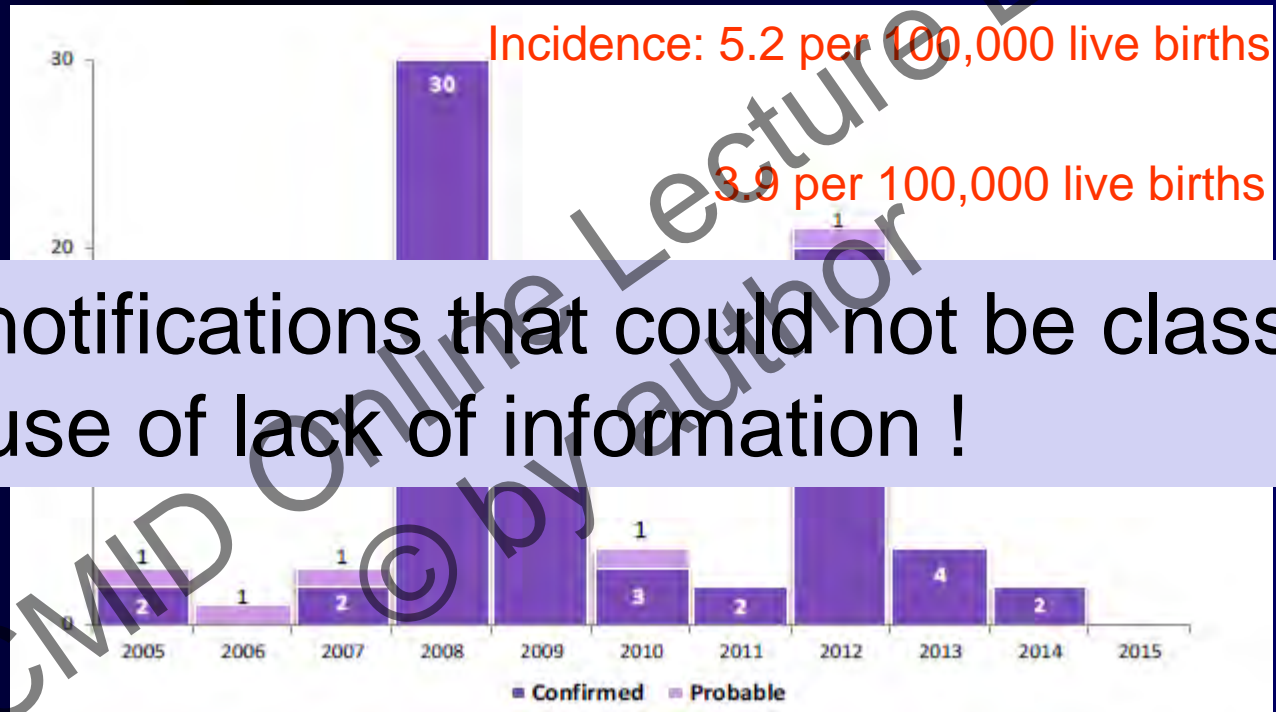
7 newborns with CRI/CRS

6 newborns without CRI

1 newborn lost

Congenital rubella infections by year and classification in Italy 2005-2015

(N=84 → 76 confirmed and 8 probable cases*)



+ **64** notifications that could not be classified because of lack of information !

Clinical information available in 78/84 cases

At least one clinical manifestation was reported for **62** cases:

- Congenital heart disease (43 children)
- Hearingloss (29)
- Cataract (13)
- Meningoencephalitis (11)
- Microcephaly (11)

Rubella in pregnancy by year and classification in Italy 2005-2015

(N=167 → 154 confirmed, 9 probable and 4 possible cases)



CC, F, 26-year-old, (9 week gestation)

Signs/symptoms:

- fever $<38^{\circ}\text{C}$
- macular rash
- no lymphadenopathy

History:

- no vaccination
- no prenatal screening
- allergy (strawberry)

CC, F, 26-year-old, (9 week gestation)

+1*

rubella-specific antibodies IgG and IgM: **negative**

rubella RNA (real time PCR) on pharyngeal swab, blood, urine: **positive**

+8

rubella-specific antibodies IgG and IgM: **positive**

low IgG avidity index

* Days from onset of infection

Risk of fetal transmission and outcome

(307 newborns from mothers with rubella 1976-1989, UK)

| Weeks' gestation (WG) | Risk of congenital infection | Symptomatic newborns /infected newborns (%) |
|-----------------------|------------------------------|---|
| 1-12 | 13/16 (81%) | 11/13 (85%) |
| 13-16 | 29/54 (54%) | 9/26 (35%) |
| 17-22 | 33/92 (36%) | 0 |
| 23-30 | 19/63 (30%) | 0 |
| 31-36 | 15/25 (60%) | 0 |
| >36 | 8/8 (100) | 0 |

Prenatal diagnosis

Indication

Rubella during the I trimester

Rubella during the II trimester (<18WG)

Reinfection during I trimester ?

Vaccination in pregnancy ?

Prenatal diagnosis

When?

- 20-21 weeks' gestation
- 6-8 weeks after maternal infection

Prenatal diagnosis of congenital rubella infection

Samples and techniques

- amniotic fluid
 - viral RNA
 - virus isolation
- fetal blood
 - IgM
 - viral RNA
 - virus isolation

Performing molecular tests in multiple replicates

2008 Rubella Epidemic. Prenatal Diagnosis in 12 women with rubella infection

| Pt # | Week of gestation at | | Samples | Rubella virus diagnostic techniques | | Outcome |
|------|----------------------|------------------------|---------------------------------------|-------------------------------------|----------|----------------------|
| | Onset | Prenatal diagnosis | | rt-PCR | IgM | |
| 1 | 13 | 20 | AF | Positive | | TOP |
| 2 | 16 | 16 | AF | Negative | | Absence of infection |
| 3 | 14 | 20 | AF Fetal blood | Negative Negative | Negative | Absence of infection |
| 4 | 14 | 20 (twin pregnancy) | AF twin A Fetal blood AF twin B | Positive Positive Positive | Positive | CRI |
| 5 | 13 | 21 | AF Fetal blood | Positive Positive | Positive | TOP |
| 6 | 15 | 21 (twin pregnancy) | AF twin A Fetal blood AF twin B | Positive Positive Positive | Negative | TOP |
| 7 | 15 | 21 | AF Fetal blood | Positive Positive | Positive | CRI |
| 11 | 15 | 21 | AF Fetal blood | Negative Positive | Positive | TOP |
| 15 | 16 | 24 | AF | Negative | | Absence of infection |
| 17 | 18 | 23 | AF | Negative | | Absence of infection |
| 18 | 11 | 20 | AF Fetal blood | Positive Positive | | TOP |
| 21 | 2 | 20 | AF Fetal blood | Negative Negative | Negative | Absence of infection |

AF, amniotic fluid; ND, not done; TOP, termination of pregnancy; CRI, Congenital Rubella Infection

Diagnosis of congenital rubella infection at birth

INDICATION

- suspected or confirmed maternal rubella during pregnancy
- confirmation of prenatal diagnosis results
- signs at birth

Some Common Manifestations of Congenital Rubella

| Permanent | Transient |
|--|--|
| <ul style="list-style-type: none">• Cataract | <ul style="list-style-type: none">• Low birth weight |
| <ul style="list-style-type: none">• Retinopathy | <ul style="list-style-type: none">• Hepatosplenomegaly |
| <ul style="list-style-type: none">• Sensorineural deafness | <ul style="list-style-type: none">• Meningoencephalitis |
| <ul style="list-style-type: none">• Heart defects | <ul style="list-style-type: none">• Thrombocytopenic purpura |
| <ul style="list-style-type: none">• Microphthalmia | <ul style="list-style-type: none">• Bone lesions |
| <ul style="list-style-type: none">• Microcephaly | |

Diagnosis of congenital rubella infection in newborn

- Serology

IgM

IgG 'persistence' (> 6 mos)

- Virology

detection of viral RNA/isolation

- blood
- urine
- nasal/throath swab
- cerebrospinal fluid

CC, F, 26-years-old, 1 p (9 week gestation)

+1*

rubella-specific antibodies IgG and IgM: **negative**

rubella RNA (real time PCR) on pharyngeal swab, blood, urine: **positive**

+8

rubella-specific antibodies IgG and IgM seroconversion
low IgG avidity index

+13

Voluntary termination (11 week gestation)

*Days from onset of infection

Even one case is one too many!

PREVENTION

ESCMID Online Lecture Library
© b...hor

Pre conceptional rubella susceptibility screening

IgG

```
graph TD; IgG((IgG)) --> Presence[Presence]; IgG --> Absence[Absence]; Presence --> Immunity[Immunity= protection]; Immunity --> Stop[STOP! No further testing]; Absence --> Vaccination[Vaccination !!];
```

Presence

Absence

Immunity= protection

Vaccination !!

STOP!

No further testing

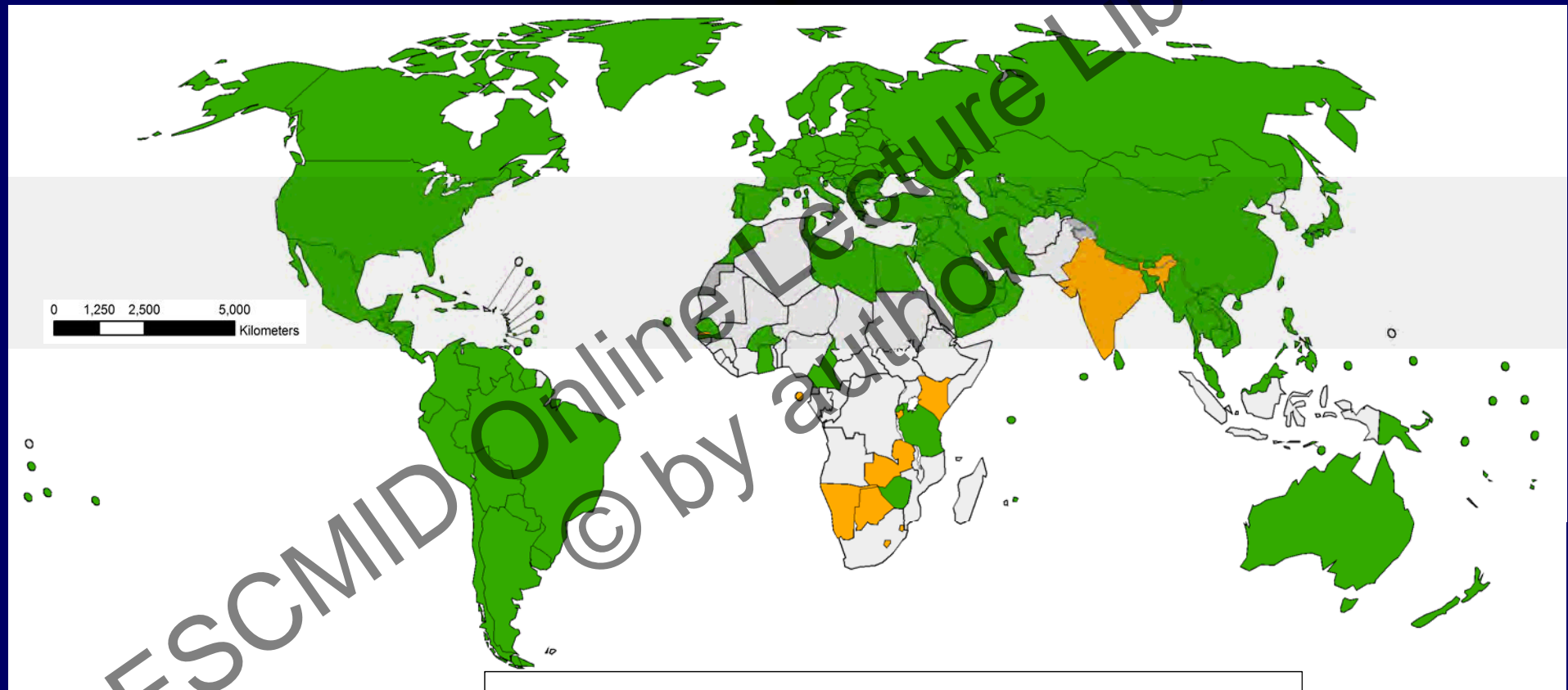
Rubella vaccine and immunization strategies





Update on vaccine characteristics

Live attenuated vaccine

- HPV 77
- Cendehill
- **RA 27/3** (1a strain)
- **BRD-2** (China)
- **TO-336, Takahashi, Matsuura** (Japan)

Countries with Rubella vaccine in the national immunization programme; and planned introductions in 2016-2017



| | | |
|---|---|--------------------------|
|  | Introduced to date | (149 countries or 76.8%) |
|  | Planned introductions in 2016 | (10 countries or 5.2%) |
|  | Not WHO Member State or Not Introduced/No Plans | (35 countries or 18%) |
|  | Not applicable | |

Data source: WHO/IVB Database, as of 27 June 2016
Map production Immunization Vaccines and Biologicals (IVB),
World Health Organization

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement. ©WHO 2016. All rights reserved.



Potential risks of administering vaccine to seronegative women of childbearing age

➤ Mild side-effects

- ✓ low grade fever
- ✓ lymphadenopathy
- ✓ rash
- ✓ acute transient arthritis

➤ Other potential risks

- ✓ chronic arthritis: NO
- ✓ autism (MMR): NO
- ✓ CRS (if vaccine administered during pregnancy): NO

Early report

Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

A J Wakefield, S H Murch, A Anthony, J Linnell, D M Casson, M Malik, M Berelowitz, A P Dhillon, M A Thomson, P Harvey, A Valentine, S E Davies, J A Walker-Smith

Summary

Background We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

Methods 12 children (mean age 6 years [range 3–10], 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhoea and abdominal pain. Children underwent gastroenterological, neurological, and developmental assessment and review of developmental records. Ileocolonoscopy and biopsy sampling, magnetic-resonance imaging (MRI), electroencephalography (EEG), and lumbar puncture were done under sedation. Barium follow-through radiography was done where possible. Biochemical, haematological, and immunological profiles were examined.

Findings Onset of behavioural symptoms was associated, by the parents, with measles, mumps, and rubella vaccination in eight of the 12 children, with measles infection in one child, and otitis media in another. All 12 children had intestinal abnormalities, ranging from lymphoid nodular hyperplasia to aphthoid ulceration. Histology showed patchy chronic inflammation in the colon in 11 children and reactive ileal lymphoid hyperplasia in seven, but no granulomas. Behavioural disorders included autism (nine), disintegrative psychosis (one), and possible postviral or vaccinal encephalitis (two). There were no focal neurological abnormalities and MRI and EEG tests were normal. Abnormal laboratory results were significantly raised urinary methylmalonic acid compared with age-matched controls ($p=0.003$), low haemoglobin in four children, and a low serum IgA in four children.

Interpretation We identified associated gastrointestinal disease and developmental regression in a group of previously normal children, which was generally associated in time with possible environmental triggers.

Lancet 1998; 351: 637–41
See Commentary page 611

Inflammatory Bowel Disease Study Group, University Departments of Medicine and Histopathology (A J Wakefield FRCS, A Anthony MB, J Linnell MD, A P Dhillon MRCPs, S E Davies MRCPs) and **The University Departments of Paediatric Gastroenterology** (S H Murch MB, D M Casson MRCP, M Malik MRCP, M A Thomson FRCS, J A Walker-Smith FRCS), **Child and Adolescent Psychiatry** (M Berelowitz FRCS), **Neurology** (P Harvey FRCS), and **Radiology** (A Valentine FRCS), **Royal Free Hospital and School of Medicine, London NW3 2QG, UK**
Correspondence to: Dr A J Wakefield

Introduction

We saw several children who, after a period of apparent normality, lost acquired skills, including communication. They all had gastrointestinal symptoms, including abdominal pain, diarrhoea, and bloating and, in some cases, food intolerance. We describe the clinical findings, and gastrointestinal features of these children.

Patients and methods

12 children, consecutively referred to the department of paediatric gastroenterology with a history of a pervasive developmental disorder with loss of acquired skills and intestinal symptoms (diarrhoea, abdominal pain, bloating and food intolerance), were investigated. All children were admitted to the ward for 1 week, accompanied by their parents.

Clinical investigations

We took histories, including details of immunisations and exposure to infectious diseases, and assessed the children. In 11 cases the history was obtained by the senior clinician (JW-S). Neurological and psychiatric assessments were done by consultant staff (PH, MB) with HMS-4 criteria. Developmental histories included a review of prospective developmental records from parents, health visitors, and general practitioners. Four children did not undergo psychiatric assessment in hospital; all had been assessed professionally elsewhere, so these assessments were used as the basis for their behavioural diagnosis.

After bowel preparation, ileocolonoscopy was performed by SHM or MAT under sedation with midazolam and pethidine. Paired frozen and formalin-fixed mucosal biopsy samples were taken from the terminal ileum; ascending, transverse, descending, and sigmoid colons, and from the rectum. The procedure was recorded by video or still images, and were compared with images of the previous seven consecutive paediatric colonoscopies (four normal colonoscopies and three on children with ulcerative colitis), in which the physician reported normal appearances in the terminal ileum. Barium follow-through radiography was possible in some cases.

Also under sedation, cerebral magnetic-resonance imaging (MRI), electroencephalography (EEG) including visual, brain stem auditory, and sensory evoked potentials (where compliance made these possible), and lumbar puncture were done.

Laboratory investigations

Thyroid function, serum long-chain fatty acids, and cerebrospinal-fluid lactate were measured to exclude known causes of childhood neurodegenerative disease. Urinary methylmalonic acid was measured in random urine samples from eight of the 12 children and 14 age-matched and sex-matched normal controls, by a modification of a technique described previously.² Chromatograms were scanned digitally on computer, to analyse the methylmalonic-acid zones from cases and controls. Urinary methylmalonic-acid concentrations in patients and controls were compared by a two-sample *t* test. Urinary creatinine was estimated by routine spectrophotometric assay.

Children were screened for antiendomyxial antibodies and boys were screened for fragile-X if this had not been done

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Correspondence to: Dr A J Wakefield

Autism (MMR): NO

Potential risks of administering vaccine during pregnancy

Rubella vaccine contraindicated during pregnancy



Avoid pregnancy for 1 month after immunization

But

No reported CRS in case of inadvertent maternal immunization

Summary of data on accidental vaccination before pregnancy and during early pregnancy

| Country | Live births to women receiving rubella immunization | | |
|--------------------|---|----------------------------------|-------------------------------------|
| | Within 3 months before conception or during pregnancy | Laboratory Evidence of Infection | Abnormalities compatible with CRS ¶ |
| USA | 324 + | 6/222 (2.7%) | 0/324 |
| Germany (West BRD) | 280 + | 3/69 (4.3%) | 0/279 |
| Sweden | 5 + | NK | 0/5 |
| U.K. | 71 + | 4/52 (7.7%) | 0/71 |
| Brazil | 1647 * | 67/1647 (4.1%) | 0/1647 |
| Ecuador | 43 * | 2/43 (5%) | 0/43 |
| El Salvador | 59 * | 1/59 (1.6%) | 0/59 |
| Paraguay | 119 * | 0/119 | 0/119 |
| Iran | 117 ¥ | | 0/117 |
| Costa Rica | 93 * | 0/93 (0%) | 0/93 |
| Mexico | 175€ | 0/174 | 0/174 |
| Total | 2933# | 83/2478 (3.3 %) | 0/2931 |

¶Confirmed susceptibles; actual number much higher.

MMR vaccine in seronegative women who have recently given birth

Rosolia in gravidanza, via al piano vaccini

L'impegno del San Matteo sulle donne in età fertile per minimizzare i rischi di cecità e danni nel feto

PAVIA

Una donna incinta arriva al pronto soccorso con uno sfogo sulla pelle e la febbre. E dagli esami risulta che non ha fatto la rosolia. È da questo caso reale che è nato l'impegno straordinario del San Matteo sui vaccini per tutelare i soggetti a rischio. Due i progetti: potenziare la copertura della vaccinazione antinfluenzale tra il personale dell'ospedale e proteggere le donne in età fertile dalla rosolia, pericolosissima per la salute del nascituro.

«Con il calo dei vaccinati a livello nazionale cresce il rischio per la salute pubblica – spiega la dottoressa Alba Muzzi, della direzione medica di presidio del

San Matteo, specialista in malattie infettive ed in igiene e medicina preventiva – soprattutto delle fasce più vulnerabili che vengono esposte a maggiori rischi. Anche perché, più malati ci sono, più si riduce l'efficacia dell'immunità vaccinale». L'infettivologa cerca di combattere i pregiudizi sui vaccini: «La vaccinazione non provoca una alterazione del sistema immunitario, al contrario stimola le naturali difese del corpo a reagire prontamente. Una corretta alimentazione e il giusto stile di vita non bastano a tenere lontane patologie infettive e malattie esantematiche».

A partire da questa settimana in collaborazione con l'Asl il San Matteo offre alle donne in età



fertile la possibilità vaccinarsi contro la rosolia: «Il virus, se contratto in gravidanza, può provocare al nascituro gravi malformazioni che vanno da un danno neurologico permanente alla cecità, passando per difficoltà di apprendimento – spiega –



LA DOTTORESSA MUZZI

Lotta all'influenza in ospedale, chiediamo al personale di immunizzarsi per tutelare i pazienti già debilitati

Per prevenire tutto questo al termine della gravidanza le donne che dovessero essere sprovviste di copertura dalla rosolia potranno fare il vaccino direttamente nel reparto di ginecologia e ostetricia diretto dal dottor Arsenio Spinillo». Da metà ottobre parti-

ranno anche le vaccinazioni antinfluenzali dentro il San Matteo: «Abbiamo una copertura del 100% tra i sanitari più giovani e tra virologi, infettivologi e operatori delle aree a rischio, dalla cardiologia all'unità coronarica – spiega la dottoressa – sono quelli che conoscono il virus e gli effetti devastanti che l'influenza potrebbe avere su un soggetto ricoverato per altra patologia. Si tratta vdi tutelare l'utenza e di non ammalarsi proprio quando c'è un epidemia in corso e il ruolo dell'ospedale è fondamentale. In altri reparti però la copertura è intorno al 30%: per questo anche quest'anno organizzeremo le vaccinazioni itineranti in ospedale». (a.gh.)

N= 22 women vaccinated

Rubella susceptibility screening in pregnancy

IgG and IgM

Limits:

Gestational age

IgM interpretation

“false” IgG seroconversion

Take home messages

Rubella serostatus → **before**/after pregnancy

Pre-conceptual

post partum

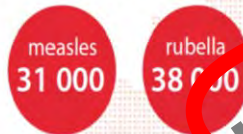
post-abortion

→ **vaccination!!!**

Prenatal diagnosis → **reference centers**

Free Europe from MEASLES AND RUBELLA

Approximate number of cases in
the WHO European Region in 2013



! Elimination in Europe is
critical for eliminating
these diseases worldwide

What can
health care workers do?

Recommend vaccination

Patients follow their health care providers' advice. Those who strongly recommend vaccination can overcome negative patient attitudes and double the rate of acceptance among hesitant patients.



Use every opportunity to vaccinate

9 out of 10 children needing a dose of measles-containing vaccine will not be vaccinated when they visit a medical facility for another reason.



www.euro.who.int/measles



International pediatric association
asociación internacional de pediatría
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THANK YOU VERY MUCH!