La sorveglianza integrata morbillo-rosolia e la sorveglianza della rosolia congenita e in gravidanza in vista dell'obiettivo di eliminazione

Roma 26 giugno 2015

Laboratori regionali per morbillo/rosolia: una rete accreditata è possibile

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WHO European Measles & Rubella Laboratory Network (Labnet)

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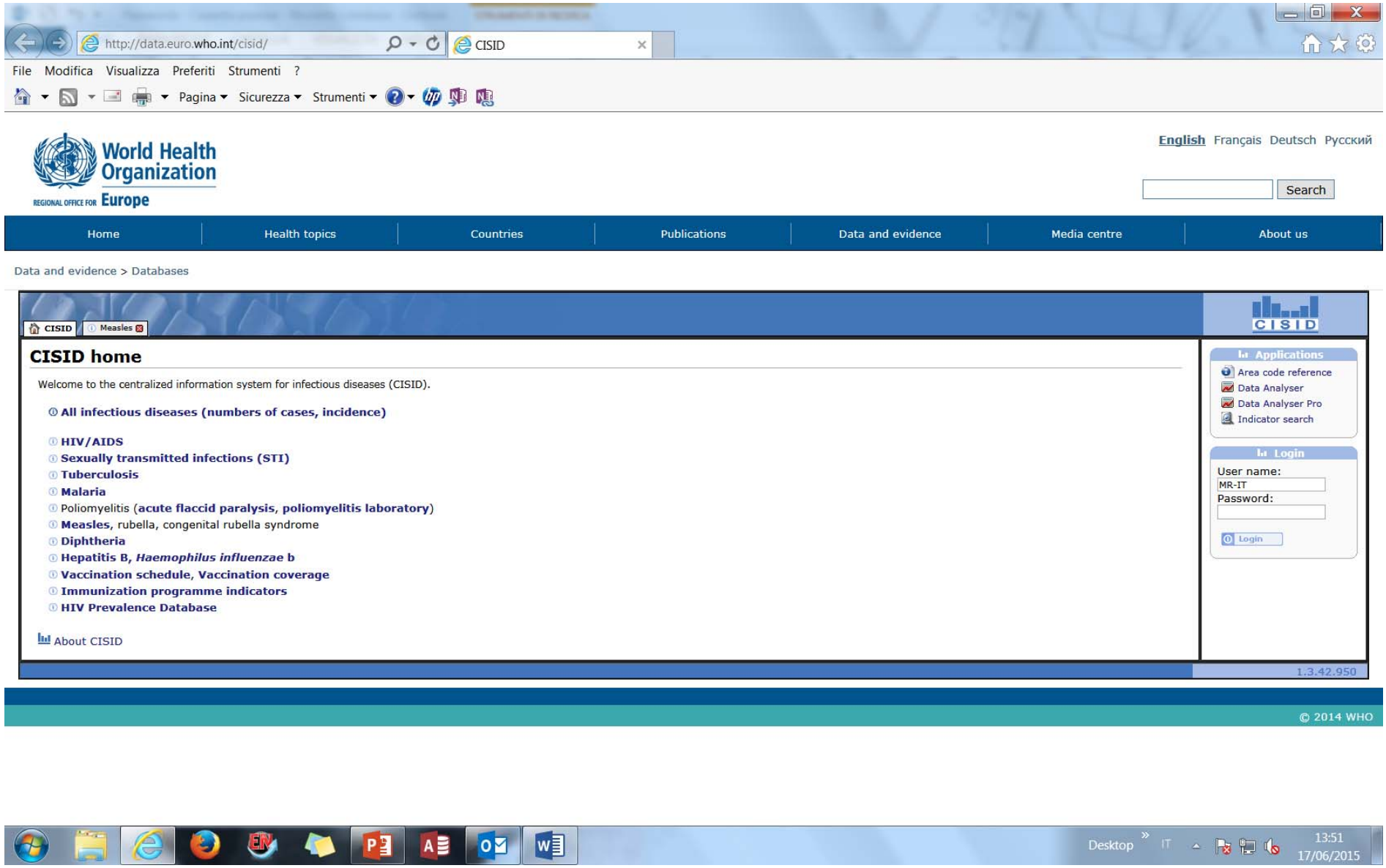
Measles and Rubella Laboratory Network

High-quality laboratory investigation is critical to understanding the impact of a country's vaccination programme on the prevalence and spread of disease. Suspected cases of measles and rubella may well be caused by other pathogens that have similar clinical symptoms. Even a penicillin allergic rash can be mistaken for a measles or rubella infection. The only way to confirm whether or not a case is actually measles or rubella is to test a suitable clinical specimen taken from the patient within a week after the onset of rash for the presence of IgM antibodies or viral RNA.

In order to facilitate high-quality laboratory investigation, WHO/Europe coordinates a Measles-Rubella Laboratory Network (LabNet). Established in 2002 and comprising a total of 71 laboratories, the LabNet consists of National Reference Laboratories (NL) supervised by Regional Reference Laboratories (RRL). Of the 53 Member States in the Region, 49 have nominated a national measles-rubella reference lab. Three regional reference laboratories in Luxembourg, Berlin and Moscow, in addition to the global specialized laboratory in London, each supervise a sub-region. Some Member States have nominated one or several WHO-recognized sub-national laboratories (Kyrgyzstan 1 SNL, Russian Federation 10 SNL, Ukraine 2 SNL, Turkey 7 SNL).

WHO/Europe supervises an annual accreditation review, with the aim of ensuring high quality laboratory investigation for measles and rubella in the Region. This programme assesses the performance of the participating laboratories based on the number of IgM tests conducted, the timeliness and completeness of reporting laboratory data, including virus detection and genotyping, the score in proficiency testing and confirmatory testing, the implementation of quality control measures and the score from the on-site review, conducted annually by the Regional Laboratory Coordinator or his delegate.

As the Region works to achieve measles and rubella elimination, it is extremely important to identify hot-spots of virus circulation, understand routes of transmission, establish the source of importation and monitor the progress of elimination. In all of these areas, molecular epidemiology has become a crucial tool, and this is another important component of the work undertaken by the LabNet. Genotype information is now available in the WHO database for more than 13 000 measles viruses and 1 300 rubella viruses. Of these, more than 10 000 measles viruses have also been uploaded to the WHO genotype analysis database.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Measles
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All infectious diseases (numbers of cases, incidence)
HIV/AIDS
Sexually transmitted infections (STI)
Tuberculosis
Malaria
Poliomyelitis (acute flaccid paralysis, poliomyelitis laboratory)
Measles, rubella, congenital rubella syndrome
Diphtheria
Hepatitis B, Haemophilus influenzae b
Vaccination schedule, Vaccination coverage
Immunization programme indicators
HIV Prevalence Database
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Area code reference
Data Analyser
Data Analyser Pro
Indicator search
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MR-IT
Password:
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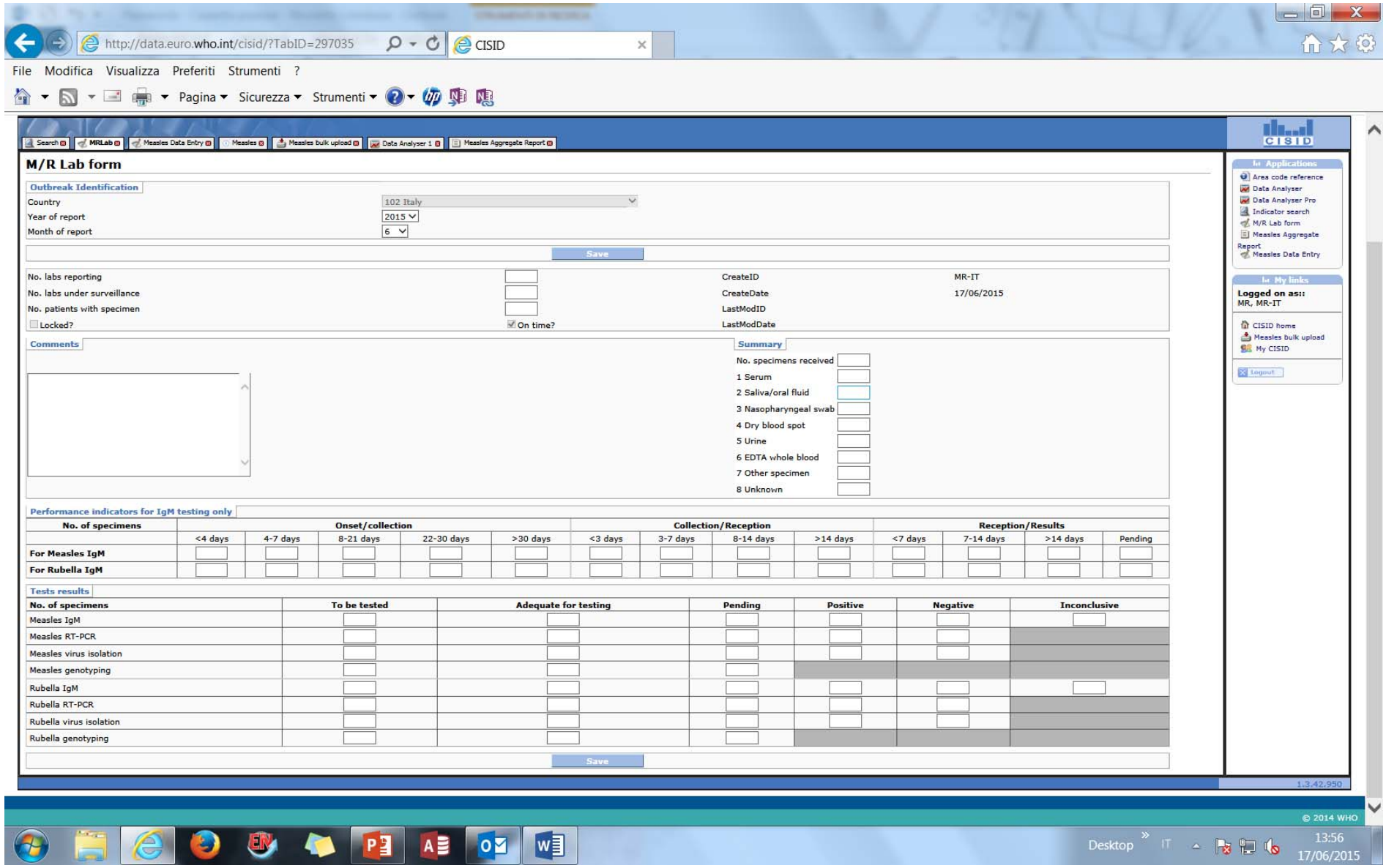
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CISID
M/R Lab form
Outbreak Identification
Country 102 Italy
Year of report 2015
Month of report 6
Save
No. labs reporting
No. labs under surveillance
No. patients with specimen
Locked?
On time?
CreateID MR-IT
CreateDate 17/06/2015
LastModID
LastModDate
Comments
Summary
No. specimens received
1 Serum
2 Saliva/oral fluid
3 Nasopharyngeal swab
4 Dry blood spot
5 Urine
6 EDTA whole blood
7 Other specimen
8 Unknown
Performance indicators for IgM testing only
No. of specimens
Onset/collection
<4 days
4-7 days
8-21 days
22-30 days
>30 days
Collection/Reception
<3 days
3-7 days
8-14 days
>14 days
Reception/Results
<7 days
7-14 days
>14 days
Pending
For Measles IgM
For Rubella IgM
Tests results
No. of specimens
To be tested
Adequate for testing
Pending
Positive
Negative
Inconclusive
Measles IgM
Measles RT-PCR
Measles virus isolation
Measles genotyping
Rubella IgM
Rubella RT-PCR
Rubella virus isolation
Rubella genotyping
Save
Applications
Area code reference
Data Analyser
Data Analyser Pro
Indicator search
M/R Lab form
Measles Aggregate Report
Measles Data Entry
My links
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MR, MR-IT
CISID home
Measles bulk upload
My CISID
Logout
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WHO RACOMANDATIONS

A marzo 2015 il Ministero della Salute ha ospitato una delegazione di funzionari dell'OMS e di componenti della Commissione Regionale Europea di Verifica (CRV) dell'eliminazione del morbillo e della rosolia, in visita in Italia per valutare lo stato di avanzamento del processo di eliminazione nel nostro paese.

La delegazione, pur riconoscendo i progressi fatti in Italia verso l'obiettivo di eliminazione di queste malattie, ha fornito alcune raccomandazioni sia politiche che tecniche per il miglioramento della performance del Paese in detto ambito.

In particolare per quanto riguarda il laboratorio, e stata sottolineatoa la necessità di istituire un network nazionale di laboratori, coerenti con gli standard OMS, per la diagnosi dei casi, con particolare riguardo alla rosolia in gravidanza e congenita che presentano maggiori difficoltà di diagnosi ed interpretazione dei risultati.

Questionario WHO

L'ANNUAL REPORT PER L'ACCREDITAMENTO DEL LABORATORIO NAZIONALE DI RIFERIMENTO

World Health Organization

Measles and Rubella Laboratory
Check-list for Annual WHO Accreditation

Date of Review: / / **On-site / by correspondence*** Accreditation for calendar year:

Laboratory:

Institute:

Address:

Country

Phone: Email: Website:

Head of Institute: Head of Department:

Head of Laboratory:

Head Mea/Rub Lab: Chief Technician:

Name of Laboratory used for Virus Isolation/Detection:

Name of Laboratory used for Virus Sequencing:

(Laboratories that act as a reference laboratory for sub-national laboratories should complete annex I to the checklist)

Introduction

Accreditation of Measles Rubella Laboratory is reviewed annually (if possible) by the WHO Regional Office and based on laboratory performance during the immediately preceding 12 months. Accreditation is given for the forthcoming 12 months.

There are eight criteria for accreditation:

1. **Measles and rubella IgM test results are reported by the laboratory on at least 80% of measles and rubella IgM specimens within 4 or 7 days of receipt (according to the recommended regional reporting timeliness):**
   To allow an appropriate response to measles and rubella cases, test results should be reported to the EPI programme in a timely manner.

2. **IgM tests are performed on at least 50 specimens annually.**
   To maintain skills in performing serological assays, Virus laboratories should maintain appropriate reagents and assay kits to have capacity to test continually through the year. To maintain expertise it is required that laboratories test a minimum of 50 specimens for EIA IgM or IgG detection annually, spread across the year. Where surveillance specimens are insufficient to meet this indicator then the lab may use non-surveillance specimens for completing the minimum requirement.

3. **The accuracy of measles and rubella IgM detection is at least 90%.**
   Accuracy is determined by the agreement in test results on sera submitted by the (sub) National Laboratory to the supervisory laboratory (National or Regional Reference Laboratory (RRL) during the 12-month review period. The percentage of specimens sent for validation is dependent on the quality of the laboratory and could range from 10-100% with the lower proportion for a fully accredited laboratory and 100% for a laboratory that has failed accreditation. Specimens for validation should be representative of all results (positive, negative and equivocal) and outbreaks, and should be sent to the supervisory laboratory at regular intervals.

4. **Internal quality control (QC) procedures are implemented.**
   Appropriate QC procedures are in place and followed, including; appropriate serological and PCR controls (such as in-house positive controls and assay controls), micro-pipettor calibration and temperature recording of incubators and refrigerators/freezers. QC data sheets and summaries of corrective action are retained and available for review.

5. **The score on the most recent WHO approved serological proficiency test is at least 90%.**
   Proficiency test (PT) results to be reported within 14 days of panel receipt to receive full credit.

6. **The score on the most recent WHO measles/rubella molecular proficiency test panel is at least 90%.**
   Molecular QA/QC panel results to be reported within 2 months of panel receipt to receive full credit. This applies only to laboratories routinely performing molecular testing.

7. **Results from virus isolation/detection and genotyping (if performed) are completed within 2 months of receipt of specimen AND data reported to WHO monthly, for ≥80% of the specimens appropriate for genetic analysis.**
   Genotype information can assist national control programmes to determine transmission pathways and needs to be provided in a timely manner. Genetic data on appropriate specimens collected from separate chains of infection should be supplied to the national programme as soon as they become available, and to WHO through the MeaNS and RubeNS databases. Laboratories are also encouraged to submit sequence data to GenBank, once sequencing is completed, either directly or through MeaNS or RubeNS. **(Note: Virus isolation/detection and genotyping performance will be assessed only on specimens meeting the recommended collection and testing strategy)**

8. **The score from the on-site review of laboratory operating procedures and practices is at least 80%.** For Laboratories with consistently high performance indicators, the Regional Laboratory Coordinator may waive the on-site review upon satisfactory completion of the annual checklist by the laboratory (see below).

National Laboratories that serve Sub-national Laboratories

Countries that have established sub-national laboratories for measles and rubella surveillance should endeavour to monitor the quality and performance of these laboratories. National laboratories should consider establishing a confirmatory testing and proficiency testing programme, monitor timeliness of reporting and ensure the performance of IgM assays, in a similar process to that used for determining the quality and performance of the National and Regional measles/rubella LabNet. WHO is willing to provide technical advice to National Laboratories planning to establish a sub-national laboratory monitoring programme. **A separate checklist is available for those laboratories supporting sub-national laboratories.**

World Health Organization

Measles and Rubella National Laboratory
Check-list for Annual WHO Accreditation

Annex I to Part II of the Measles and Rubella National Laboratory check-list for annual WHO accreditation. For National Laboratories acting as reference laboratory.

Part II: Performance in Previous 12 Months

Dates from: __/__/____ (*dd mm yyyy*) To __/__/____ (*dd mm yyyy*)

1.	Confirmatory results on subnational laboratories' referred specimens	%
1.1	Number of specimens for confirmatory IgM testing from subnational laboratories received:	
1.2	Number of confirmatory results reported within 14 days:	

subnational laboratory submitting specimens for confirmation	Date specimens received at NRL	Number of specimens received	Number of specimens tested	Concordance	Date reported to subnational lab
				%	
				%	
				%	
				%	

La rete di laboratori sub-nazionali accreditata possibile

NETWORK DEI LABORATORI SUB-NAZIONALI ACCREDITATI
RUOLO DEL LABORATORIO NAZIONALE

1. Individuare ed attivare i nuovi laboratori, fornendo il necessario supporto tecnico/scientifico per la conferma della diagnosi e/o per la genotipizzazione.
2. Preparare le Linee Guida ed organizzare corsi di formazione e addestramento tecnico, finalizzati a tutti gli aspetti della sorveglianza di laboratorio e all'adeguamento agli standard richiesti dall'OMS anche per i laboratori già presenti.
3. Monitorare il mantenimento degli standard richiesti dall'OMS nell'esecuzione dei test di diagnosi sierologica e molecolare di tutti i laboratori nella conferma e caratterizzazione virale dei casi di morbillo e rosolia, attraverso il retesting di campioni già esaminati dai laboratori regionali (conditio sine qua non richiesta da OMS), l'invio di qestionari riguardanti i vari aspetti delle attività dei laboratori, l'analisi dei risultati ottenuti e d eventualmente la visita in loco

NETWORK DEI LABORATORI SUB-NAZIONALI ACCREDITATI

1. In tutte le Regioni sono già disponibili risorse tecniche e istituzionali per supportare la sorveglianza proposta. Il NRL OMS-LabNet ha le competenze necessarie per garantire la conferma di laboratorio dei casi e la tipizzazione dei ceppi di morbillo e rosolia. Inoltre, il laboratorio nazionale continuerà a garantire la sorveglianza di laboratorio nelle more della costituzione del network e del raggiungimento degli standard richiesti dall'OMS.
2. Il processo di adeguamento agli standard OMS degli Laboratori Regionali già esistenti e la realizzazione dei nuovi secondo gli stessi standard, richiederà nuovi investimenti.

3.2 Performance of measles and rubella surveillance in 2014

Please provide results for surveillance performance indicators as rate or percentage. Please also show both *numerator* and *denominator* used for calculation of performance indicators, **AS DEFINED IN ATTACHMENT ANNEX 1.** All cells to be completed with numeric values, except for cells in the column "Remarks".

Standard indicators

Measles	Rate or percentage	Numerator	Denominator	Remarks
Rate of laboratory investigations	12,4	174	1398	The rate is 81.9% If considering data from laboratories with no information available on proficiency, EQA, or accreditation status.

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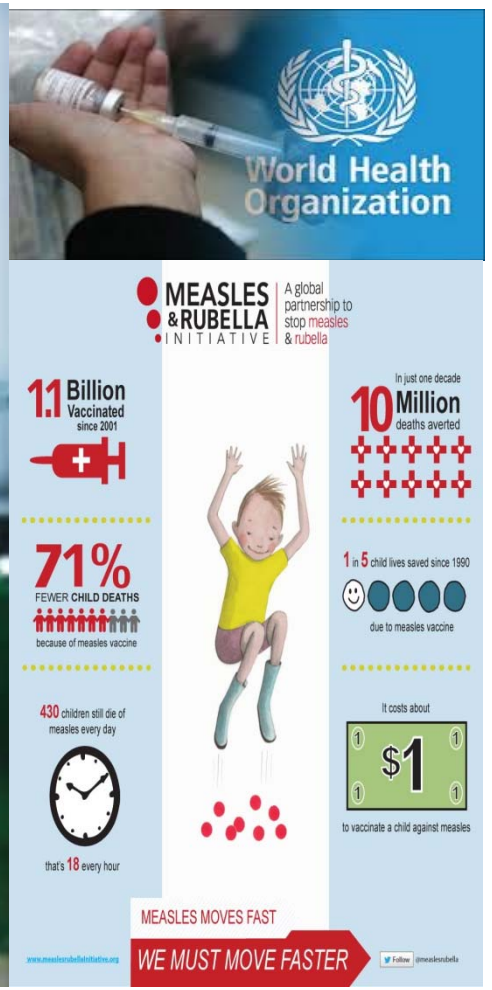

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