



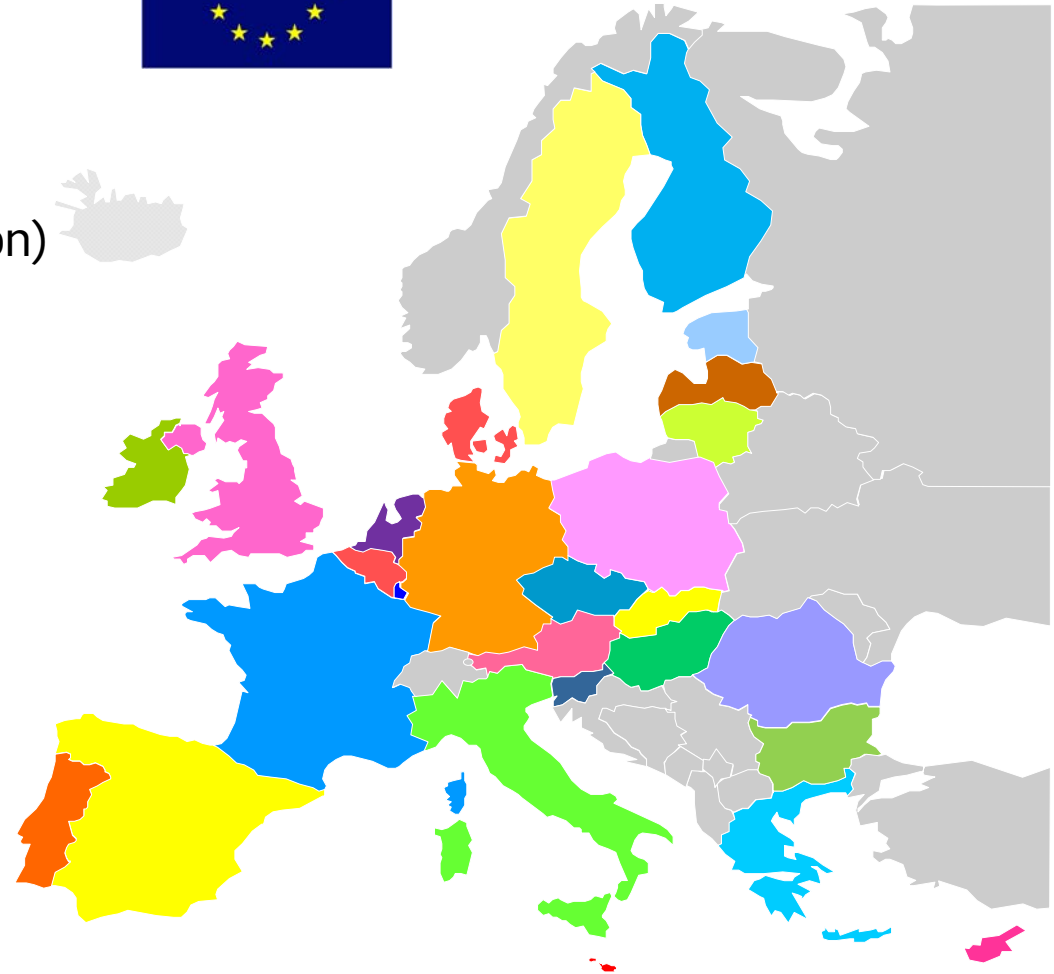
# The threat of multidrug-resistant microorganisms and how to deal with it in Europe

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Antimicrobial resistance and Healthcare-associated infections (ARHAI)  
European Centre for Disease Prevention and Control

Lyon, 8 June 2011

# What is the European Union?

- 27 Member States
- 23 official languages
- > 500 million inhabitants  
(per country: 416,333 – 81.7 million)
- €25,100 GDP/capita  
(per country : 10,400 – 69,300)
- A patchwork of cultures!

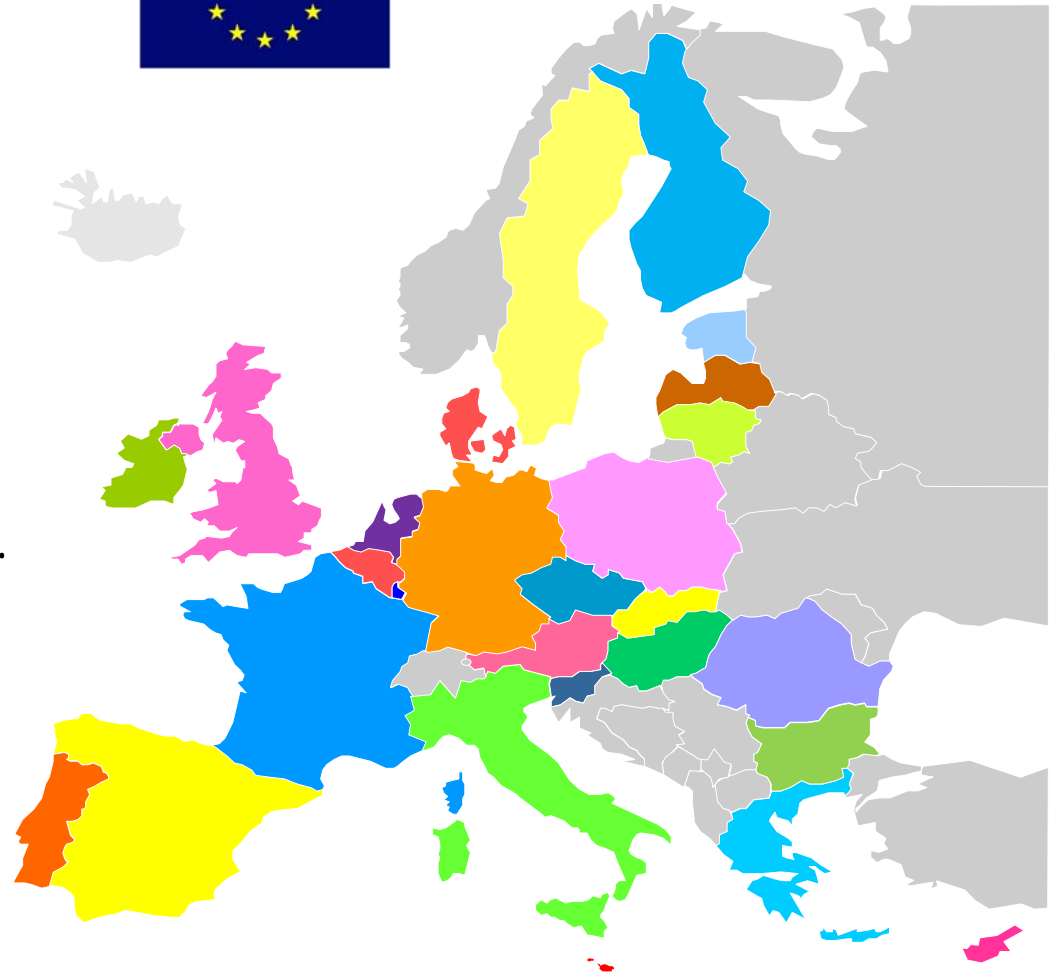


1 € = 1.36 US\$

# Healthcare resources in the EU



- %GDP for healthcare:  
approx. 6 to 11%
- Physicians:  
27 to 200 per 100,000 inh.
- Nurses:  
327 to 1550 per 100,000 inh.
- Ratio nurses/physicians:  
1.6 to 36



Source: Eurostat and WHO Health For All online database (WHO Euro, latest available year).

# What does “Antimicrobial Resistance” represent?



Several, inter-related compartments of healthcare, i.e. patients in primary care, hospitals, nursing homes and long-term care facilities, food animals, food, environment)

Many types of infection, i.e. respiratory tract, urinary tract, skin and soft tissue, bloodstream, surgical site, related to medical devices, etc.)

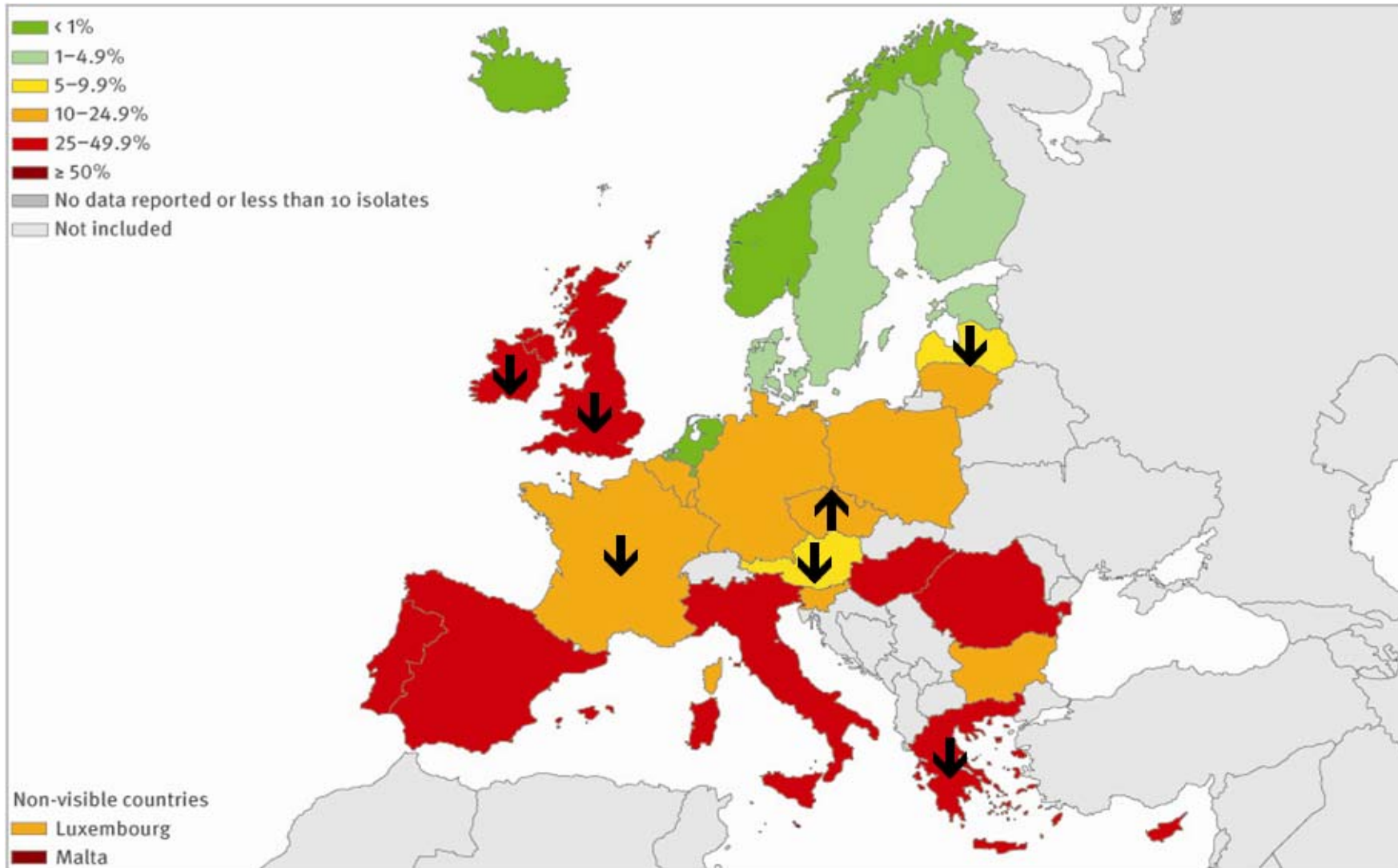
Many bacteria/microorganisms

Many antimicrobials and mechanisms of resistance

**Patients with infections caused by resistant bacteria!**



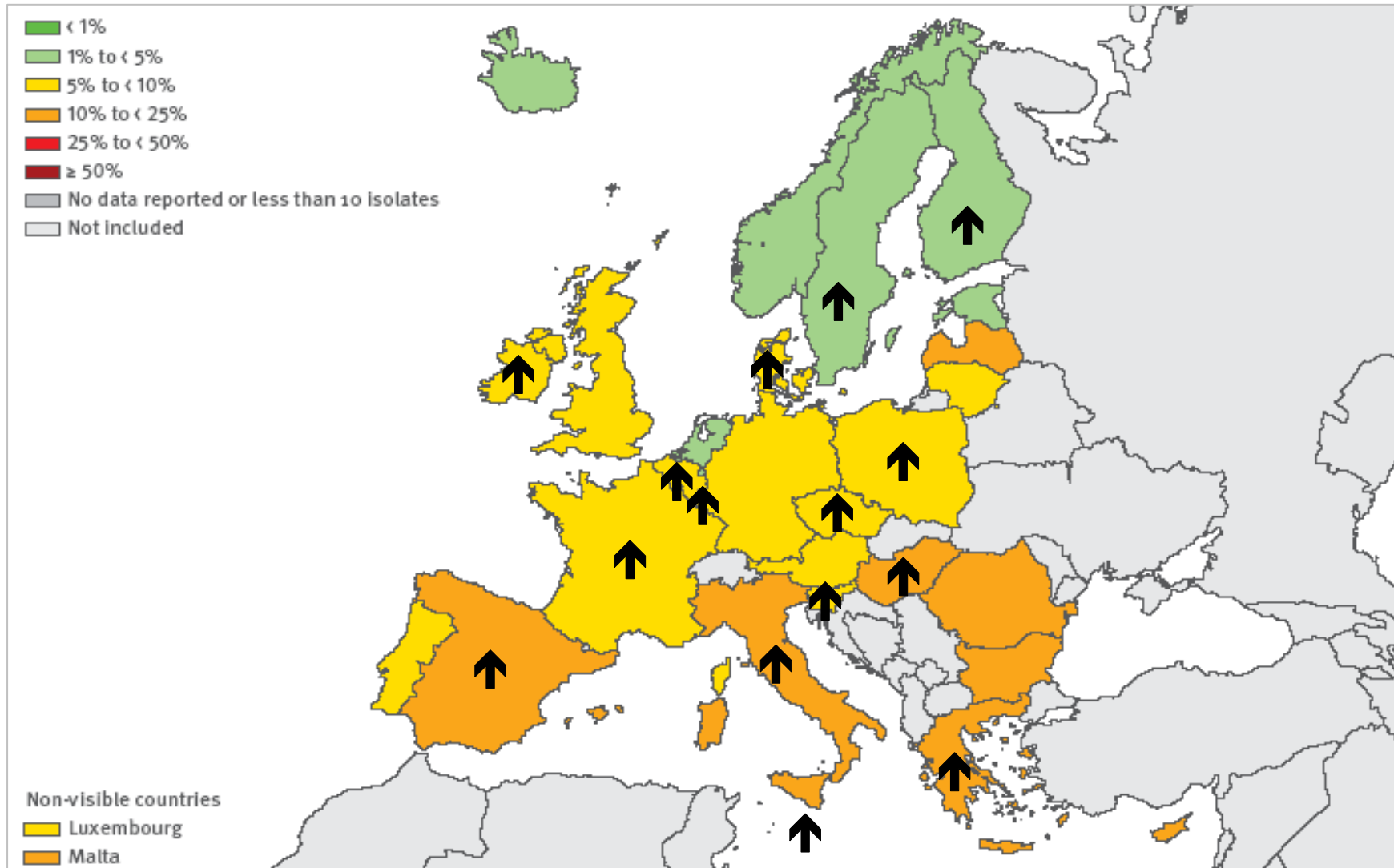
# *Staphylococcus aureus*: proportion of invasive isolates resistant to meticillin (MRSA), 2009



Source: EARS-Net, 2010.

The symbols ↑ and ↓ indicate a significant increasing or decreasing trend for the period 2006-2009, respectively. These trends were calculated on laboratories that consistently reported during 2006-2009.

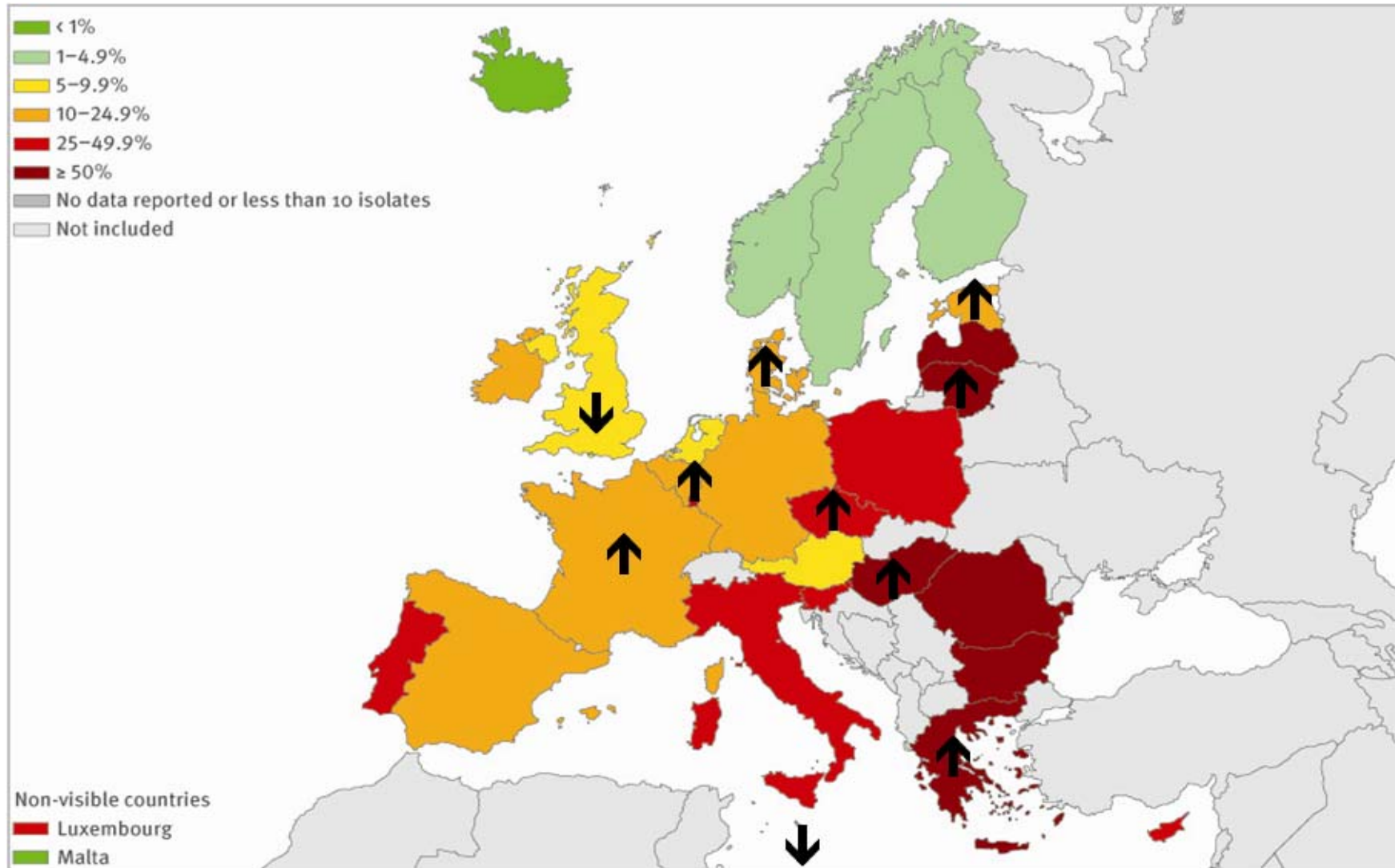
# *Escherichia coli*: Proportion of invasive isolates resistant to third-generation cephalosporins, 2009



Source: EARS-Net, 2010.

The symbols ↑ and ↓ indicate a significant increasing or decreasing trend for the period 2006-2009, respectively. These trends were calculated on laboratories that consistently reported during 2006-2009.

# *Klebsiella pneumoniae*: proportion of invasive isolates resistant to third-generation cephalosporins, 2009



Source: EARS-Net, 2010. The symbols ↑ and ↓ indicate a significant increasing or decreasing trend for the period 2006-2009, respectively. These trends were calculated on laboratories that consistently reported during 2006-2009.

# Burden of multidrug-resistant (MDR) bacteria in the EU, Iceland and Norway



## Human burden

Infections (6 most frequent MDR bacteria, 4 main types of infection)

approx. 400,000 / year

Attributable deaths

approx. 25,000 / year

Extra hospital days

approx. 2.5 million / year

## Economic burden

Extra in-hospital costs

approx. € 900 million / year

Productivity losses

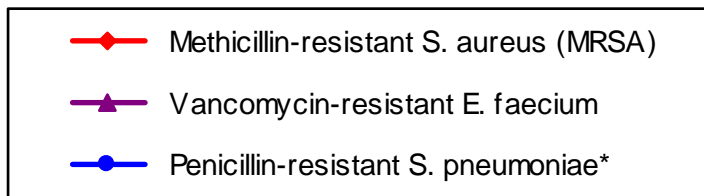
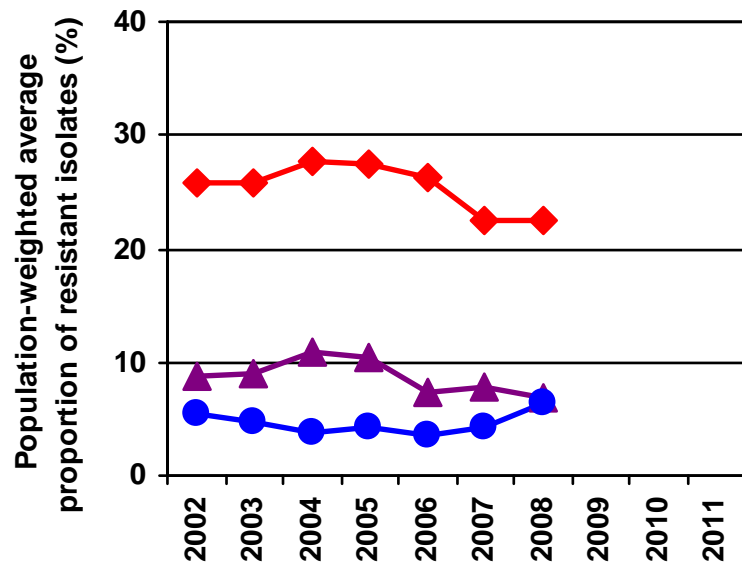
approx. € 600 million / year

Limitation: these are underestimates.

# Population-weighted, average %resistant isolates among bacteria from bloodstream infections, EU, Iceland and Norway, 2002-2008

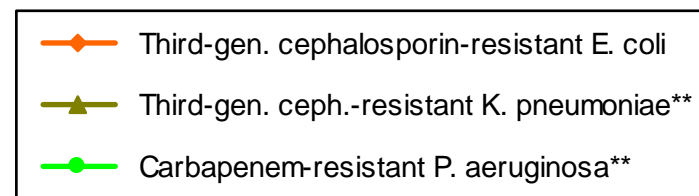
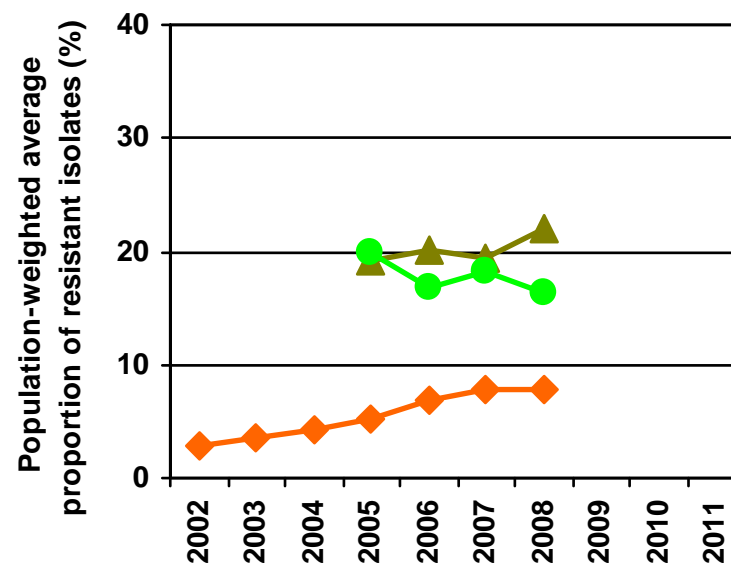


## Gram-positive bacteria



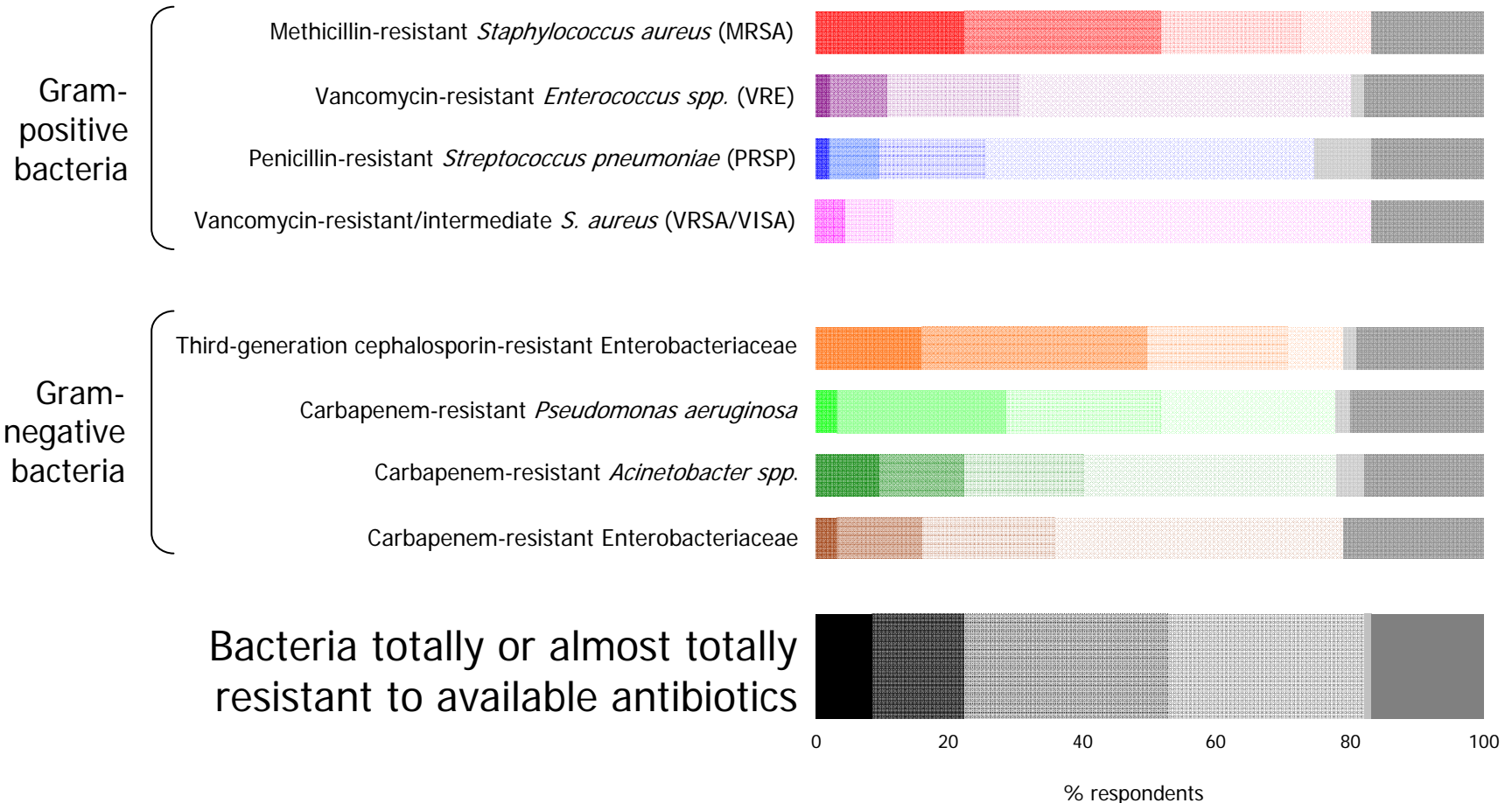
\*Excluding Greece, which did not report data.

## Gram-negative bacteria



\*\*Excluding Belgium and Slovakia, which did not report data.

# Survey of European intensive care specialists on experience with infections due to resistant bacteria, 2009

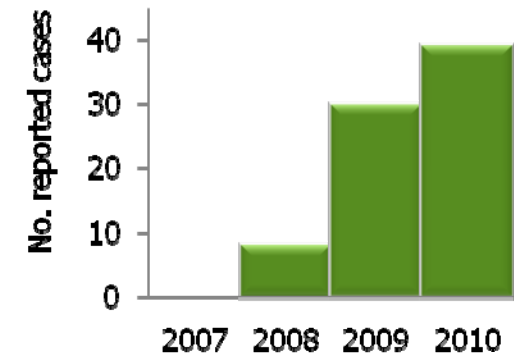


No. treated patients during past 6 months: ■ >10 patients ▒ 3-10 patients ▒ 1-2 patients ▒ 0 ▒ Do not know ▒ Missing

# New Delhi Metallo-beta-lactamase (NDM-1) producing *Enterobacteriaceae*: emergence in Europe

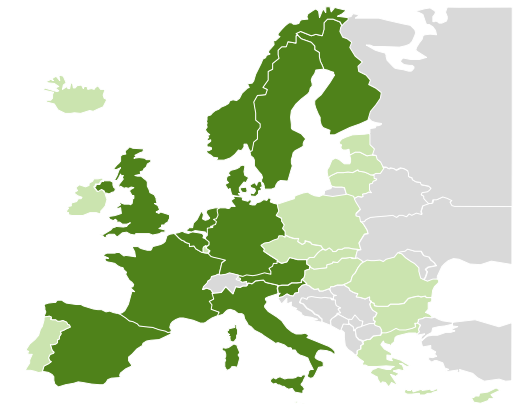


- 11 August 2010: article in *Lancet Infect Dis*
- 17 August 2010: "Epidemiological update" on ECDC website
- 27 August 2010: ECDC threat assessment on EWRS
- 20 September 2010: ECDC follow-up question to EU Member States, Iceland and Norway
- By 4 October 2010: a total of 77 cases were reported from 13 countries in 2008-2010
- Most cases with healthcare or travel to the Indian subcontinent.
- A smaller proportion of cases had received healthcare in different parts of the Balkans.



NDM-1-producing *Enterobacteriaceae* cases reported (as of 4 October 2010):

- Yes
- No
- Not covered by survey



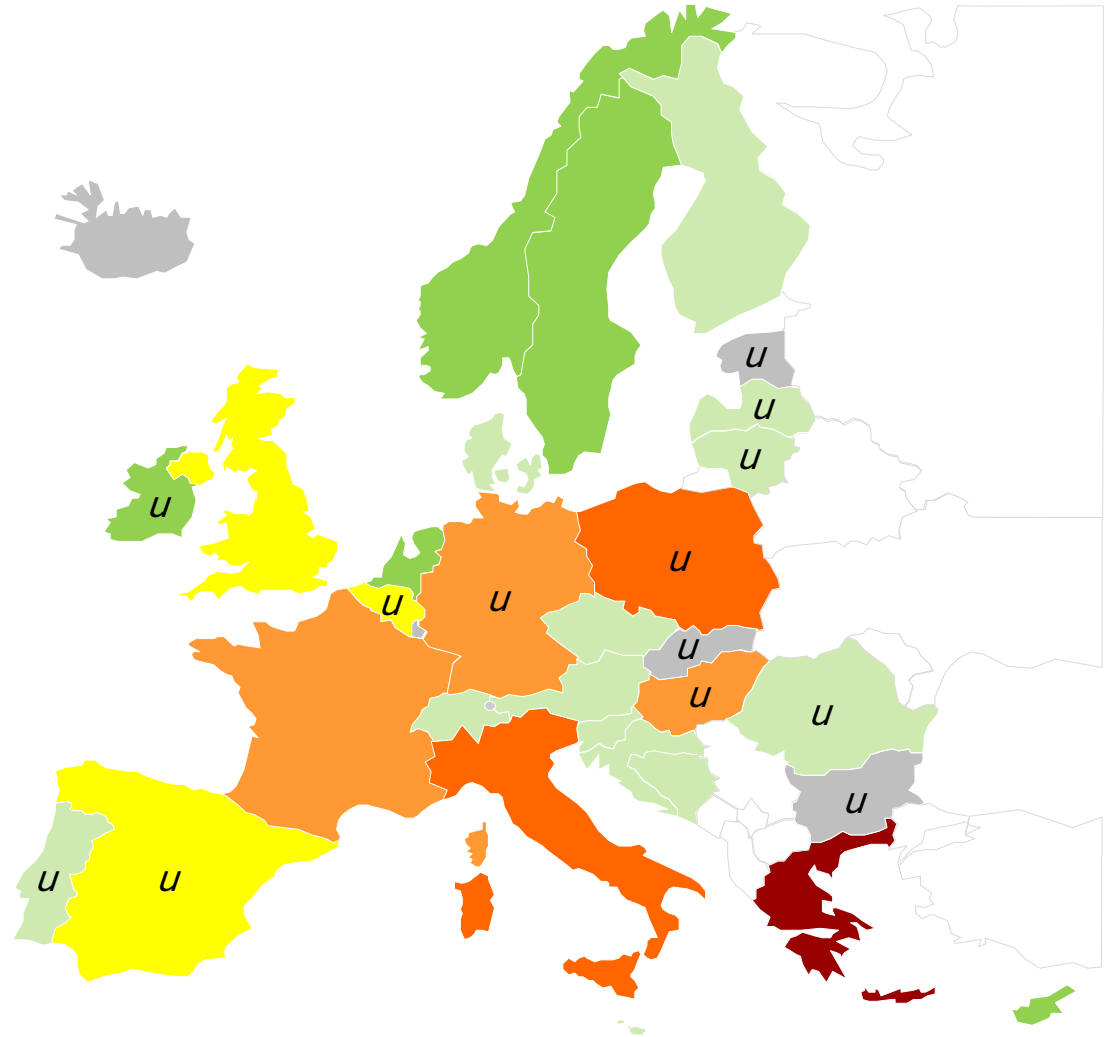
# Carbapenemase\* -producing *Enterobacteriaceae* (CPE) in Europe



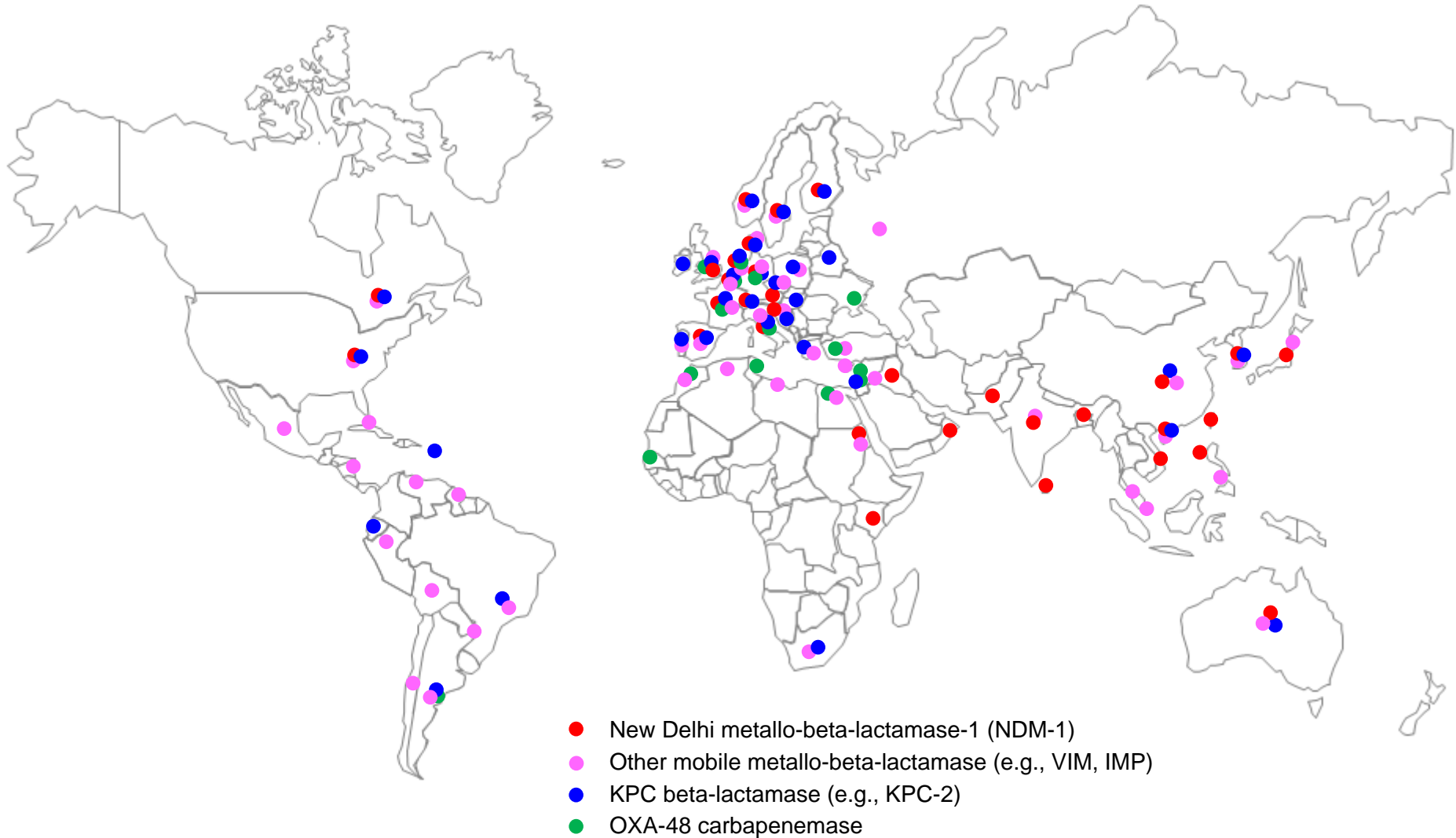
- Not reported
- Sporadic occurrence
- Single hospital outbreak
- Independent hospital outbreaks
- Regional spread
- Inter-regional spread
- Endemic
- Other countries

*u* Likely underdetection and/or underreporting of cases

\*All carbapenemases (not only NDM-1).



# Worldwide emergence and spread of carbapenemases (as of March 2011)



Adapted and updated from: Walsh T. *Int J Antimicrob Agents* 2010;36(Suppl 3): S8-S14.

# National guidance for detection and control of carbapenemase-producing *Enterobacteriaceae* (CPE): response in Europe (as of October 2010)



- National guidance for detection of CPE:  
 14 countries (table)
- National guidance for control of CPE:  
 11 countries (table)
- Four additional countries (Estonia, Finland, Ireland and Slovakia) indicated that such guidance was in development (for Finland: control guidelines)

Country	Carbapenemase-producing <i>Enterobacteriaceae</i> National guidance on:			
	Detection and surveillance methods	Referral to reference laboratory	Notification to health authorities	Infection control measures
Austria	√	√	√	
Belgium	√	√	√	√
Czech Republic	√	√	√	
Finland	√	√		
France	√	√	√	√
Germany	√	√		√
Greece	√	√	√	√
Netherlands	√	√	√	√
Norway	√	√		√
Poland	√	√	√	√
Portugal	√	√	√	√
Slovenia	√	√		√
Sweden	√	√	√	√
United Kingdom	√	√	√	√

# "EU law": Article 288 of the Treaty of the European Union



*"To exercise the Union's competences, the institutions shall adopt regulations, directives, decisions, recommendations and opinions."*

- *"A **regulation** shall have general application. It shall be binding in its entirety and directly applicable in all Member States.*
- *A **directive** shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.*
- *A **decision** shall be binding in its entirety upon those to whom it is addressed.*
- ***Recommendations** and **opinions** shall have no binding force."*



Photo: Stuart Chalmers, CC-BY

# Treaty of the European Union ("Lisbon Treaty"): Public Health - Article 168 (ex Article 152 TEC)



Competence on public health is shared between the European Union and Member States.

1. A high level of human health protection shall be ensured in... all Union policies and activities. Union action, which shall complement national policies,... Such action shall cover the fight against major health scourges...
2. ... The European Union may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation...



Photo: Stuart Chalmers, CC-BY

# Treaty of the European Union ("Lisbon Treaty"): Public Health - Article 168 (ex Article 152 TEC)



Competence on public health is shared between the European Union and Member States.

5. The European Parliament and the Council,... , may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges...
6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this article.
7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care...



Photo: Stuart Chalmers, CC-BY

# Main actions to prevent and control antimicrobial resistance

**Prudent use of antimicrobials**  
(only when needed, correct dose, dose intervals, duration)



**Infection control**  
(hand hygiene, screening, isolation)



**New antibiotics**  
(with a novel mechanism of action, research, development)



# Council Recommendation on the prudent use of antimicrobial agents, 2001





Photo: Stuart Chalmers, CC-BY



Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine (2002/77/EC)

# Council Recommendations and Conclusions, 2008-2009




  
**COUNCIL OF THE EUROPEAN UNION**


**Council Conclusions on Antimicrobial Resistance (AMR)**

*2876th EMPLOYMENT, SOCIAL POLICY, HEALTH AND CONSUMER AFFAIRS Council meeting*  
Luxembourg, 10 June 2008

The Council adopted the following conclusion:


The Council of the European Union

1. **RECALLS** that Article 152 of the Treaty establishing the European Community states that Community action in the field of public health is to complement national policies and be directed to ensure a high level of human health protection. This Community action shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.
2. **RECALLS** the Council Recommendation (2002/77/EC) on the prudent use of antimicrobial agents in human medicine<sup>1</sup>.
3. **NOTES** that the first Report<sup>2</sup> from the Commission on the basis of Member States' reports on the implementation of the Council Recommendation (2002/77/EC) on the prudent use of antimicrobial agents in human medicine<sup>3</sup> (see(2005) 1745)

<sup>1</sup> doc. 14751/01  
<sup>2</sup> doc. 5427/06 Report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2002/77/EC) on the prudent use of antimicrobial agents in human medicine

1  
EN

Council Conclusions on Antimicrobial Resistance (AMR) (10 June 2008)

3.7.2009  Official Journal of the European Union C 151/1

1  
(Resolutions, recommendations and opinions)

**RECOMMENDATIONS**  
**COUNCIL**

**COUNCIL RECOMMENDATION**  
of 9 June 2009  
on patient safety, including the prevention and control of healthcare associated infections  
(2009/C 151/01)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular the second subparagraph of Article 152(4) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament<sup>(1)</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>(2)</sup>,

Having regard to the opinion of the Committee of the Regions<sup>(3)</sup>,

Whereas:

- (1) Article 152 of the Treaty provides that Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and disease, and eliminating sources of danger to human health.
- (2) It is estimated that in Member States between 8% and 12% of patients admitted to hospital suffer from adverse events while receiving healthcare<sup>(4)</sup>.
- (3) The European Centre for Disease Prevention and Control (ECDC) has estimated that, on average, healthcare associated infections occur in one hospitalised patient in 30, that is to say 4,1 million patients a year in the EU.
- (4) Opinion of 27 April 2009 was published in the Official Journal.
- (5) Opinion of 23 March 2009 was published in the Official Journal.
- (6) Opinion of 22 April 2009 was published in the Official Journal.
- (7) National report 'Improving Patient Safety in the EU' prepared for the European Commission, published 2008 by the ECDC Co-operation.

EU and that 37 000 deaths are caused every year as a result of such infections.

Poor patient safety represents both a severe public health problem and a high economic burden on limited health resources. A large proportion of adverse events, both in the hospital sector and in primary care, are preventable with systemic factors appearing to account for a majority of them.



This recommendation builds upon and complements work on patient safety carried out by the World Health Organization (WHO) through its World Alliance for Patient Safety, the Council of Europe and the Organisation for Economic Co-operation and Development (OECD).

The Commission, through the seventh framework programme for research and development<sup>(5)</sup> supports research in health systems, in particular in the quality of healthcare provision under the Health Theme, including a focus on patient safety. The latter is also given particular attention under the Information and Communication Technology Theme.

The Commission, in its White Paper 'Together for Health: A Strategic Approach for the EU 2008-2017' of 23 October 2007, identifies patient safety as an area for action.

Decision No 19137/04(UEC) of the European Parliament and of the Council of 18 December 2004 concerning the seventh framework programme of the European Community for research, technological development and demonstration activities (2007-2013) (OJ L 312, 30.12.2004, p. 1).

Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01)


  
**COUNCIL OF THE EUROPEAN UNION**


**Council Conclusions on innovative incentives for effective antibiotics**

*2980th EMPLOYMENT, SOCIAL POLICY, HEALTH AND CONSUMER AFFAIRS Council meeting*  
Brussels, 1 December 2009

The Council adopted the following conclusions:

*Nota bene: In this document, the term "antibiotics" encompasses medicinal products produced either synthetically or naturally used to kill or inhibit the growth of bacteria as well as those with alternative mechanisms of action e.g. effect on bacterial virulence. In this context, alternative methods for prevention and control of infections should also be taken into account.*

1. **RECALLS** the Community Strategy against antimicrobial resistance (COM(2001) 0333),
2. **RECALLS** the Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine<sup>1</sup>,
3. **RECALLS** the Council Conclusions on antimicrobial resistance of 10 June 2008<sup>2</sup>,
4. **RECALLS** the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections<sup>3</sup>,
5. **RECALLS** the WHO report (2004) Priority Medicines for Europe and the World<sup>4</sup>

<sup>1</sup> OJ L 34, 5.2.2002, p. 13.  
<sup>2</sup> 9637/08.  
<sup>3</sup> OJ C 151, 3.7.2009, p. 1.  
<sup>4</sup> [http://whqlibdoc.who.int/hq/2004/WHO\\_EDM\\_PAR\\_2004.7.pdf](http://whqlibdoc.who.int/hq/2004/WHO_EDM_PAR_2004.7.pdf).

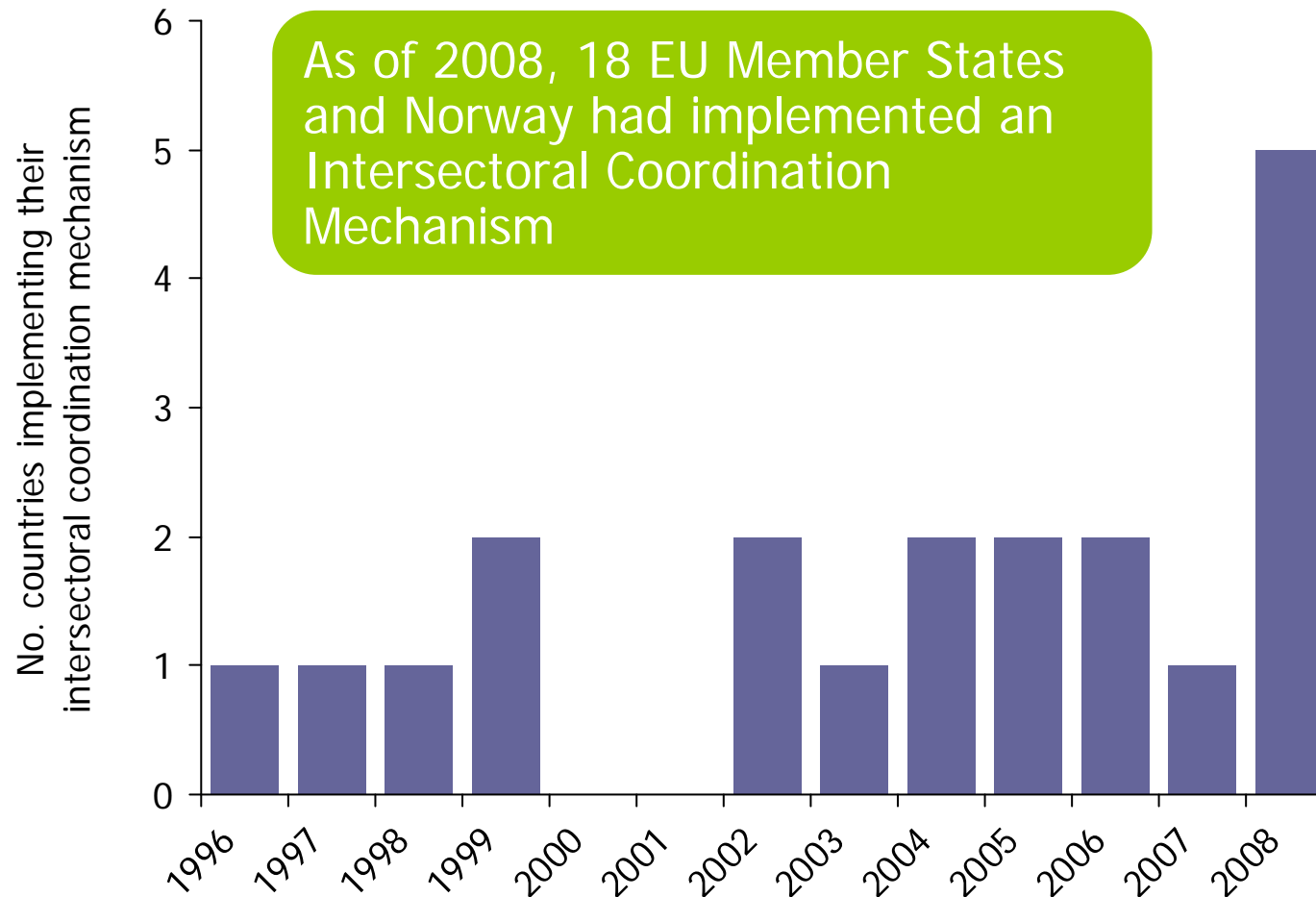
**P R E S S**

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[www.office@consilium.europa.eu](http://www.office@consilium.europa.eu) <http://www.consilium.europa.eu/fr/press>

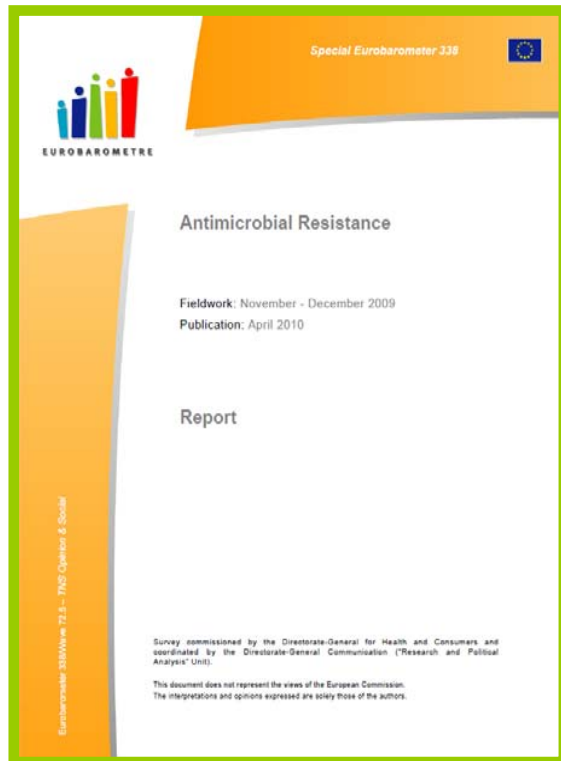
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Council Conclusions on innovative incentives for effective antibiotics (1 December 2009)

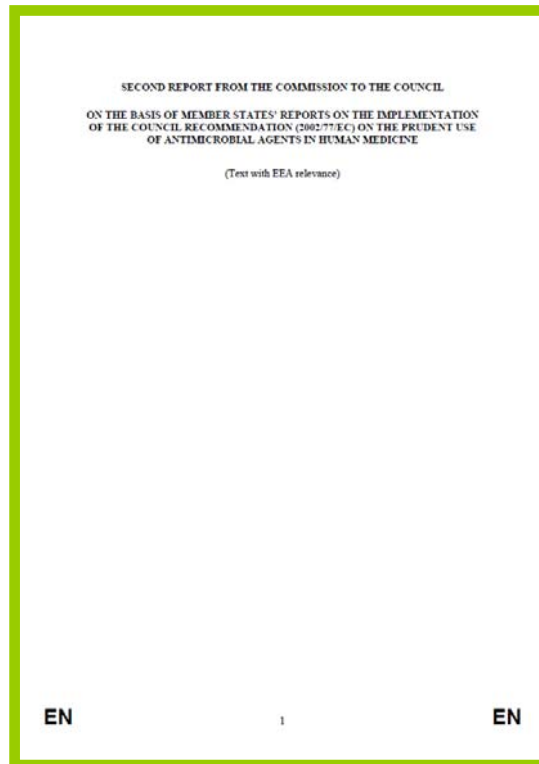
# Implementation of National Intersectoral Coordination Mechanisms on AMR



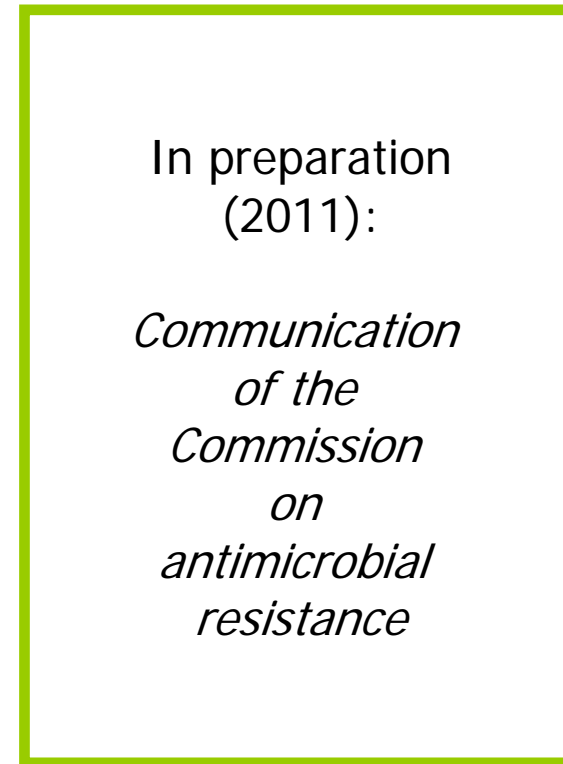
# Follow-up, 2010-2011



Special Eurobarometer 338  
"Antimicrobial resistance"



2nd report from the Commission to the Council  
on the basis of Member States' reports on the implementation  
of the Council Recommendation 2002/77/EC on the prudent  
use of antimicrobial agents in human medicine



# Role of European Agencies in the fight against antimicrobial resistance in Europe



## European Commission Directorate-General Health & Consumers (SANCO)

### ECDC

European Centre for Disease  
Prevention and Control  
(Stockholm, Sweden)

- *Support the Commission*
- *Perform surveillance*
- *Provide scientific opinions and risk assessments*
- *Communication*
- *Work jointly on cross-cutting issues such as antimicrobial resistance*

### EFSA

European Food Safety  
Authority  
(Parma, IT)

### EMA

European Medicines Agency  
(London, UK)

### EEA\*

European Environment Agency  
(Copenhagen, DK)

\*Under D-G Environment

# What is ECDC?



"An independent agency, named the European Centre for Disease Prevention and Control ...

... to identify, assess and communicate current and emerging health threats to human health from communicable diseases.

— ECDC Founding Regulation (851/2004)

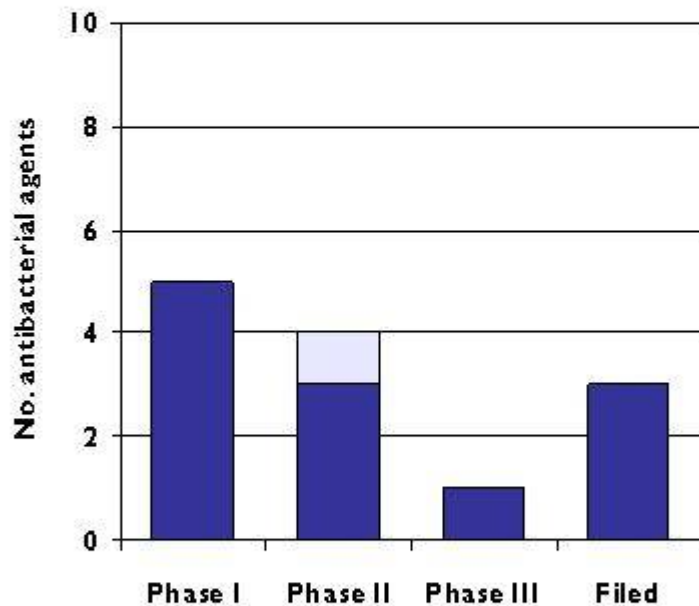
A European Union Agency which:

- is a member of the European Union (EU) family;
- covers EU 27, EEA/EFTA countries;
- reaches out to other countries beyond the EU 27 through Neighbourhood Policy and DG RELEX;
- supports and promotes global health security (role in International Health Regulations);
- financed through EU budget;
- based in Stockholm, Sweden



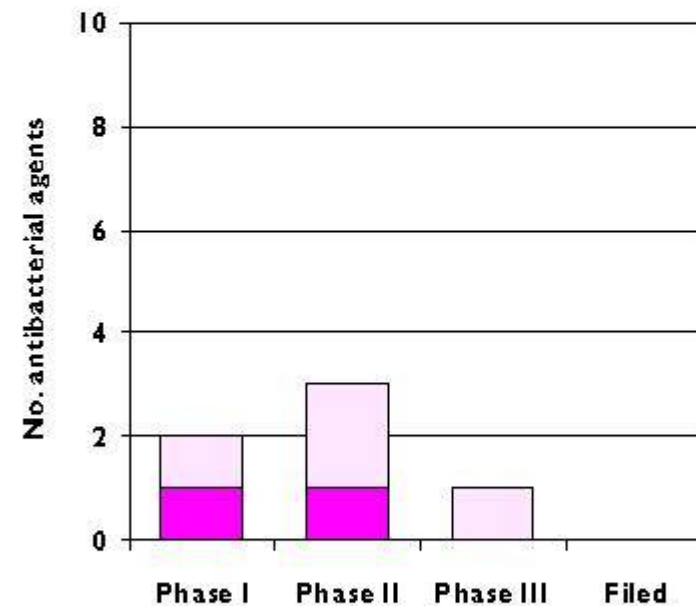
# 15 novel, systemically administered antibacterial agents in the pipeline

13 agents against Gram-positive bacteria



- Demonstrated *in vitro* activity based on actual data
- Assumed *in vitro* activity based on known class effects or mechanisms of action

6 agents against Gram-negative bacteria



- Demonstrated *in vitro* activity based on actual data
- Assumed *in vitro* activity based on known class properties or mechanisms of action

# Definitions for multidrug-resistant (MDR), extensively drug-resistant (XDR) and pandrug-resistant (PDR) bacteria: international expert proposal



ORIGINAL ARTICLE 16, 1111-1119 (2011) doi:10.1093/cid/cir111

## Multidrug-resistant, extensively drug-resistant and pandrug-resistant bacteria: an international expert proposal for interim standard definitions for acquired resistance

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**Abstract**

Many different definitions for multidrug-resistant (MDR), extensively drug-resistant (XDR) and pandrug-resistant (PDR) bacteria are being used in the medical literature to characterize the different patterns of resistance found in healthcare-associated, antimicrobial-resistant bacteria. A group of international experts came together through a joint initiative by the European Centre for Disease Prevention and Control (ECDC) and the Centers for Disease Control and Prevention (CDC), to create a standardized international terminology with which to describe acquired resistance profiles in *Staphylococcus aureus*, *Enterococcus* spp., *Enterobacteriaceae* (other than *Salmonella* and *Shigella*), *Pseudomonas aeruginosa* and *Acinetobacter* spp., all bacteria often responsible for healthcare-associated infections and prone to multidrug resistance. Epidemiologically significant antimicrobial categories were constructed for each bacterium. Lists of antimicrobial categories proposed for antimicrobial susceptibility testing were created using documents and breakpoints from the Clinical Laboratory Standards Institute (CLSI), the European Committee on Antimicrobial Susceptibility Testing (EUCAST) and the United States Food and Drug Administration (FDA). MDR was defined as acquired non-susceptibility to at least one agent in three or more antimicrobial categories, XDR was defined as non-susceptibility to at least one agent in all but two or fewer antimicrobial categories (i.e. bacterial isolates remain susceptible to only one or two categories) and PDR was defined as non-susceptibility to all agents in all antimicrobial categories. To ensure correct application of these definitions, bacterial isolates should be tested against all or nearly all of the antimicrobial agents within the antimicrobial categories and selective reporting and suppression of results should be avoided.

**Keywords:** Antimicrobial agents, definitions, extensively drug resistant, multidrug resistant, pandrug resistant

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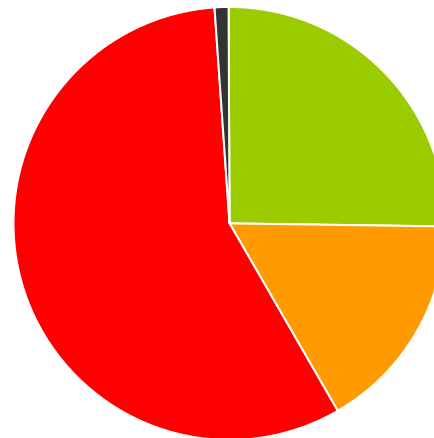
Isolate no.	Antimicrobial category								
	A	B	C	D	G	H	I		J
1	■	■	□	□	□	□	□	□	Not MDR
2	■	■	□	□	□	□	□	□	Not MDR
3	■	■	■	□	□	□	□	□	MDR
4	■	■	■	■	□	□	□	□	MDR
5	■	■	■	■	■	□	□	□	MDR
6	■	■	■	■	■	■	□	□	MDR
7	■	■	■	■	■	■	NT	NT	MDR, possible XDR
8	■	■	■	■	■	■	NT	NT	MDR, possible XDR
9	■	■	■	■	■	■	NT	NT	MDR, possible XDR, possible PDR
10	■	■	■	■	■	■	NT	NT	MDR, possible XDR, possible PDR
11	■	■	■	■	■	■	■	■	XDR
12	■	■	■	■	■	■	■	■	XDR
13	■	■	■	■	■	■	■	■	XDR
14	■	■	■	■	■	■	■	■	XDR
15	■	■	■	■	■	■	■	■	XDR
16	■	■	■	■	■	■	■	■	XDR
17	■	■	■	■	■	■	■	■	XDR
18	■	■	■	■	■	■	■	NT	XDR
19	■	■	■	■	■	■	■	NT	XDR
20	■	■	■	■	■	■	■	NT	XDR, possible PDR
21	■	■	■	■	■	■	■	NT	XDR, possible PDR
22	■	■	■	■	■	■	■	■	PDR

# Antibiotic use in European hospitals: point prevalence surveys



- Since 2006, web-based reporting system
- Information on therapy/prophylaxis and anatomic site
- 30% [range: 19-59%] patients were receiving antibiotics

- **60%**  
**peri-operative  
antibiotic  
prophylaxis  
courses  
> 1 day**



- 1 Dose
- 1 Day
- > 1 Day
- n.a.

- Part of **EU point prevalence survey**  
on healthcare-associated infections and antibiotic use  
(2010: pilot survey, 2011-2012: full scale)

# Guidance for prevention and control, 2006-2011



- ***Clostridium difficile***: background document Kuijper EJ, et al. Clin Microbiol Infect 2006 Oct;12 Suppl 6:2-18 guidance for prevention and control Vonberg RP, et al. Clin Microbiol Infect 2008 May;14 Suppl 5:2-20.
- **MRSA**: review of national guidelines, guidance for prevention and control of MRSA in hospitals, and in the community (2011)
- **Carbapenemase-producing *Enterobacteriaceae***: risk assessment & interim guidance for prevention and control (2011)
- **Systematic reviews and evidence-based guidance** (2010 onwards):
  - Peri-operative antibiotic prophylaxis
  - Organisation of hospital infection control programmes
  - ... of antimicrobial stewardship programmes

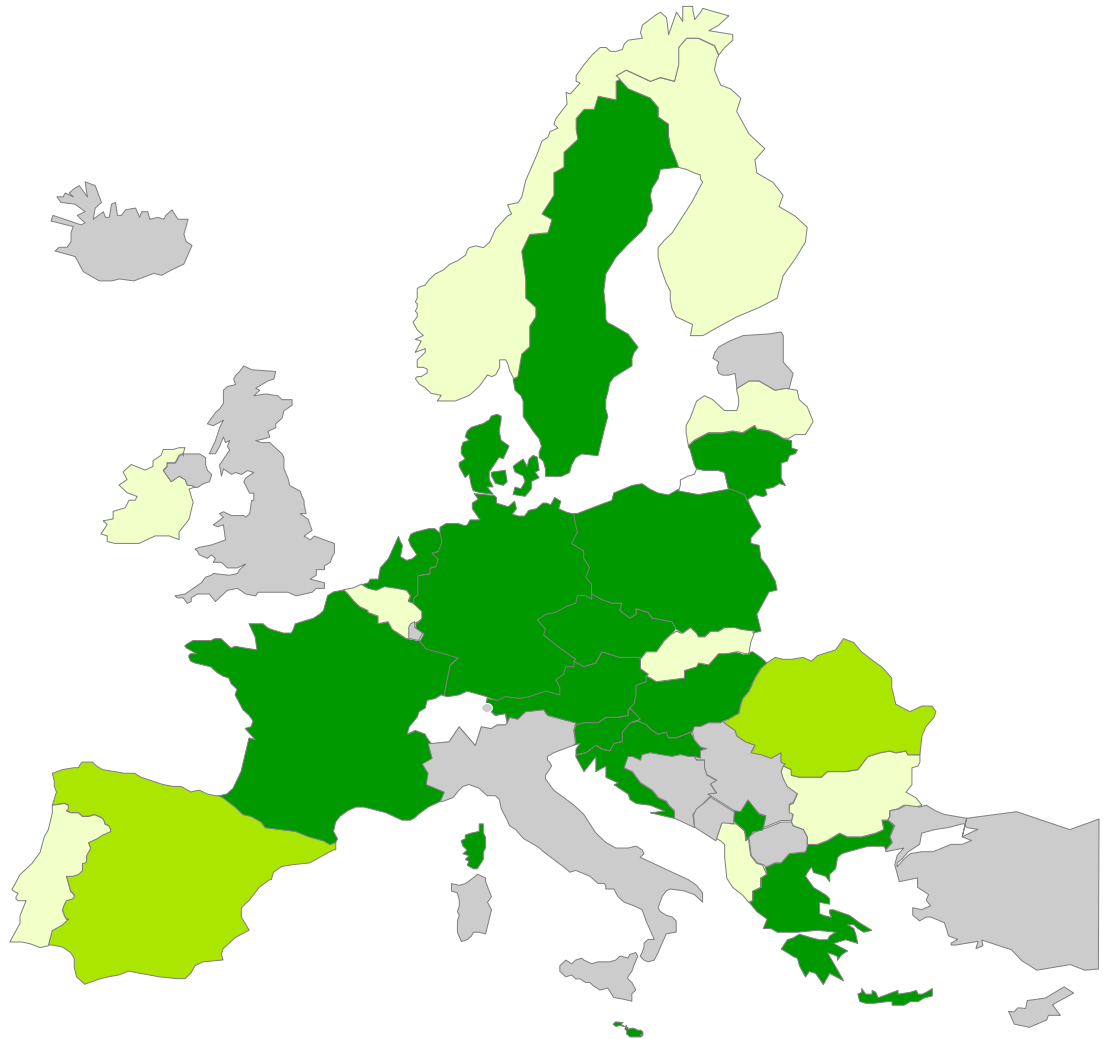


# Country visits to discuss antimicrobial resistance (AMR) issues, 2006-2011



Country visits to discuss AMR issues (as of June 2011)

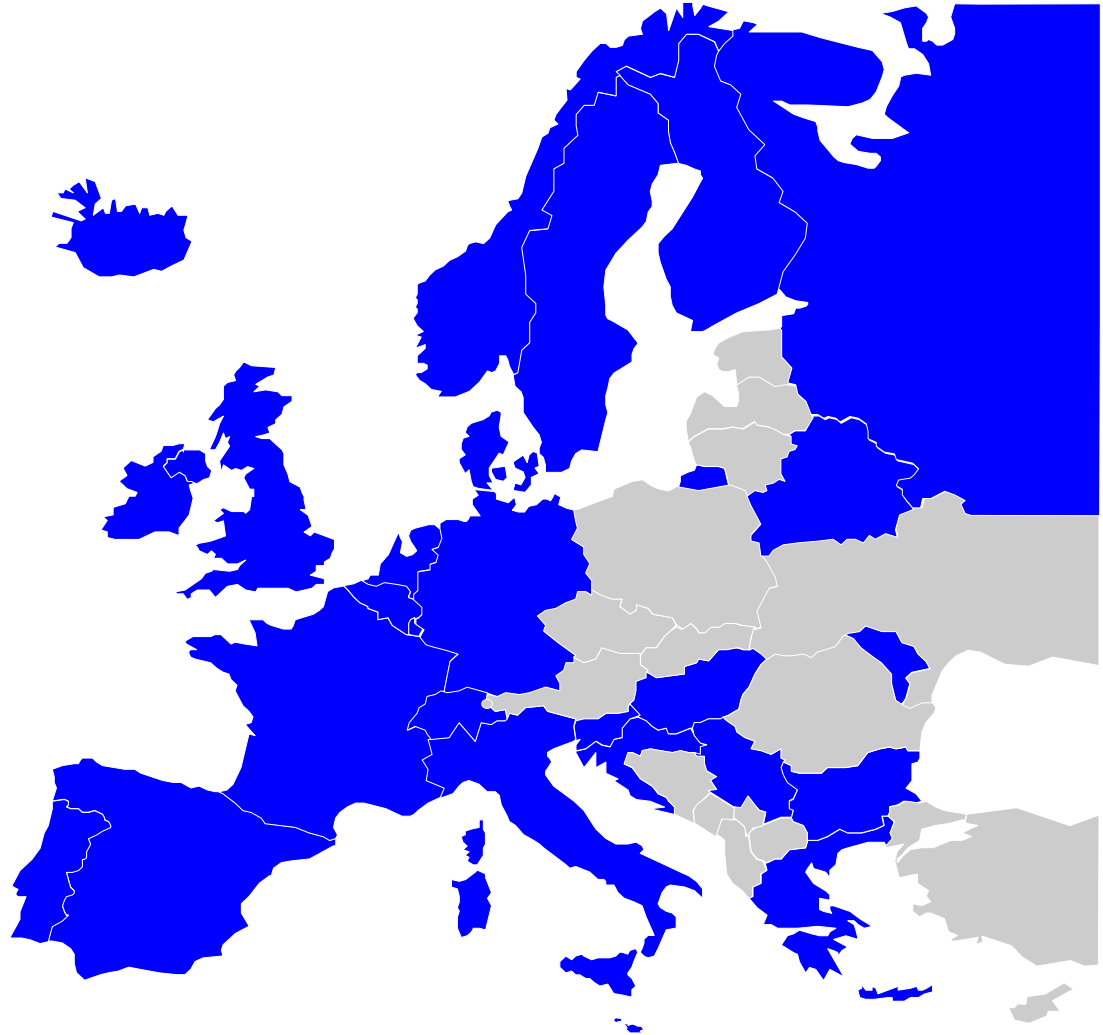
- Based on Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine (2002/77/EC)
- Reports (observations, conclusions, suggestions, examples of best practice)
- 15 initial visits (see map)
- 5 follow-up visits (Czech Rep., Greece x 2 and Hungary x 2)
- **4 additional visits budgeted for 2011**



# WHO First Global Patient Safety Challenge in Europe, 2005-2010



- European countries that have pledged their support to implement hand hygiene and other actions as a mean of combating HAI



18 November 2011

# EUROPEAN ANTIBIOTIC AWARENESS DAY



A European Health Initiative



## 2008

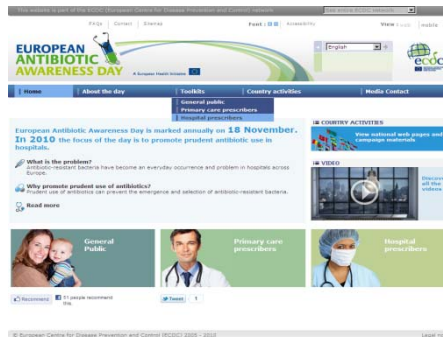
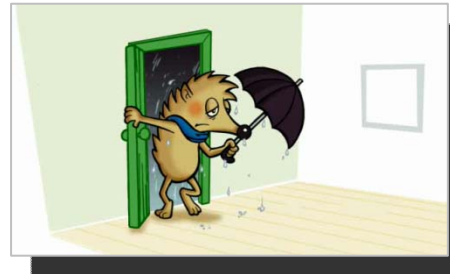
- Materials for general public
- 32 countries participated

## 2009

- Materials for primary care prescribers
- Website translated in all EU languages
- TV spots developed

## 2010

- Materials for hospital prescribers
- 37 countries participated
- Matched campaigns in the U.S. and in Canada



COLD? FLU?



GET WELL  
WITHOUT  
ANTIBIOTICS

18 November  
2009

For more information, visit  
[antibiotic.ecdc.europa.eu](http://antibiotic.ecdc.europa.eu)

# Images from national campaigns on prudent use of antibiotics





# EUROPEAN ANTIBIOTIC AWARENESS DAY



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English



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European Antibiotic Awareness Day is marked annually on **18 November**. In **2010** the focus of the day is to promote prudent antibiotic use in hospitals.



#### What is the problem?

Antibiotic-resistant bacteria have become an everyday occurrence and problem in hospitals across Europe.



#### Why promote prudent use of antibiotics?

Prudent use of antibiotics can prevent the emergence and selection of antibiotic-resistant bacteria.



Read more

#### COUNTRY ACTIVITIES



View national web pages and campaign materials

#### VIDEO



Discover all the videos



General Public



Primary care prescribers



Hospital prescribers

<http://antibiotic.ecdc.europa.eu>

# Challenges for Europe



- Novel antibiotics are unlikely (at least in a near future)
- Holistic approach, but avoid confusion
- Everybody is responsible  
(in their own area of work/responsibility, within their mandate)
- Improvement and better integration of surveillance systems (e.g., EPIS platform)
- Develop structure and process indicators
- Provide help in a way that allows countries to tailor their actions based in their own needs, culture and resources
- Pay special attention to neighbouring countries starting with EU candidate and potential candidate countries



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