



*Четврта студија
преваленције болничких инфекција*

Значај дефиниције случаја у надзору над заразним болестима

Проф. др Дарија Кисић Тепавчевић



Sistem epidemiološkog nadzora teži da otkrije sve "prave" slučajeve bolesti, da obezbedi potrebne informacije za pravovremenu reakciju na pojavu bolesti (mere sprečavanja i suzbijanja) i da precizno "izmeri" napredak ka postavljenim ciljevima – kontroli, eliminaciji, odnosno eradikaciji zaraznih bolesti.

Značaj definicije slučaja u nadzoru nad zaraznim bolesti

- Bolja procena epidemiološke situacije
- Planiranje i sprovođenje mera
- Procenjivanje dostignutih rezultata
- Poređenje epidemiološke situacije među pojedinim regionima unutar Republike Srbije
- Poređenje epidemiološke situacije u Republici Srbiji u odnosu na druge zemlje

Slučaj?

Slučaj u epidemiologiji predstavlja osoba u populaciji ili studijskoj grupi za koju je ustanovljeno da ima određenu bolest, poremećaj zdravlja ili stanje koje je predmet istraživanja.

II

(Non-legislative acts)

DECISIONS

COMMISSION IMPLEMENTING DECISION

of 8 August 2012

amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council

(notified under document C(2012) 5538)

(Text with EEA relevance)

(2012/506/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community⁽¹⁾, and in particular Article 3(c) thereof,

Whereas:

(1) According to Article 2 of Commission Decision 2002/253/EC⁽²⁾, the case definitions laid down in the Annex to that Decision should be updated to the extent necessary on the basis of the latest scientific data.

(2) In accordance with Article 9 of Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control⁽³⁾ (ECDC), the ECDC provided, at the request of the Commission, a scientific opinion on case definitions aiding the Commission and the Member States in the development of intervention strategies in the field of surveillance of and response to communicable diseases.

(3) The case definitions already listed in the Annex to Decision 2002/253/EC for HIV/AIDS, diphtheria, Haemophilus influenzae (invasive disease), hepatitis B and C,

meningococcal disease, mumps, legionellosis, congenital rubella, shiga toxin/verocytotoxin producing Escherichia coli infection (STEC/VTEC), salmonellosis and leptospirosis should be updated on the basis of that scientific opinion provided by ECDC.

(4) A generic case definition of antimicrobial resistance, a generic definition of nosocomial infections, a number of specific case definitions of nosocomial infections, and a case definition for tick-borne encephalitis should also be added to the Annex to Decision 2002/253/EC on the basis of that scientific opinion provided by ECDC.

(5) For the purpose of clarity, it is appropriate to restructure the Annex to Decision 2002/253/EC in order to ensure that case definitions for communicable diseases are in a separate list from those for special health issues, and that, within each list, the case definitions appear in numerical order.

(6) The measures provided for in this Decision are in accordance with the opinion of the Committee set up by Decision No 2119/98/EC,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2002/253/EC is replaced by the Annex to this Decision.

⁽¹⁾ OJ L 268, 3.10.1998, p. 1.

⁽²⁾ OJ L 86, 3.4.2002, p. 44.

⁽³⁾ OJ L 142, 30.4.2004, p. 1.

Definicija slučaja?

- **Skup kriterijuma** koji moraju biti ispunjeni da bi se oboljenje kod neke osobe smatralo slučajem određene bolesti.
- Ona se može zasnivati na **kliničkim, laboratorijskim, kombinovanim kliničko-laboratorijskim kriterijumima** i/ili **epidemiološkoj** povezanosti.

Kriterijumi na kojima se zasniva definicija slučaja

Klinički kriterijumi

- uključuju uobičajene i relevantne znakove i simptome bolesti koji individualno ili u kombinaciji upućuju na jasnu kliničku sliku bolesti.
- daju opšti koncept bolesti i ne moraju uključivati sva obeležja potrebna za individualne kliničke dijagnoze.

Kriterijumi na kojima se zasniva definicija slučaja

Laboratorijski kriterijumi

- čine listu laboratorijskih metoda koje se koriste za potvrdu određene bolesti.
- Obično je dovoljna jedna od navedenih metoda za potvrdu.
- Posebno je navedeno ako je potrebna kombinacija metoda za laboratorijsku potvrdu.
- Tip uzorka potreban za laboratorijske metode naveden je samo ako se određeni uzorci smatraju relevantnim za potvrdu dijagnoze.

Kriterijumi na kojima se zasniva definicija slučaja

Epidemiološki kriterijumi

Epidemiološka povezanost, u vremenu inkubacije, je definisana na jedan od 6 načina:

- 1) Prenos sa čoveka na čoveka— ako je osoba bila u kontaktu sa osobom kod koje je bolest potvrđena, na način koji omogućava prenos infekcije
- 2) Prenos sa životinje na čoveka - ako je osoba imala kontakt sa životinjom kod koje je laboratorijski potvrđena kolonizacija ili infekcija, na način koji omogućava prenos infekcije

Kriterijumi na kojima se zasniva definicija slučaja

Epidemiološki kriterijumi

- 3) Izloženost zajedničkom izvoru – ako je osoba izložena istom izvoru kojem je izložen neki potvrđeni slučaj
- 4) Izloženost kontaminiranoj hrani/vodi za piće – ako je osoba konzumirala hranu ili vodu koja je laboratorijski dokazano kontaminirana, ili prehrambene proizvode proizvedene iz životinje kod koje je laboratorijski dokazana infekcija ili kolonizacija

Kriterijumi na kojima se zasniva definicija slučaja

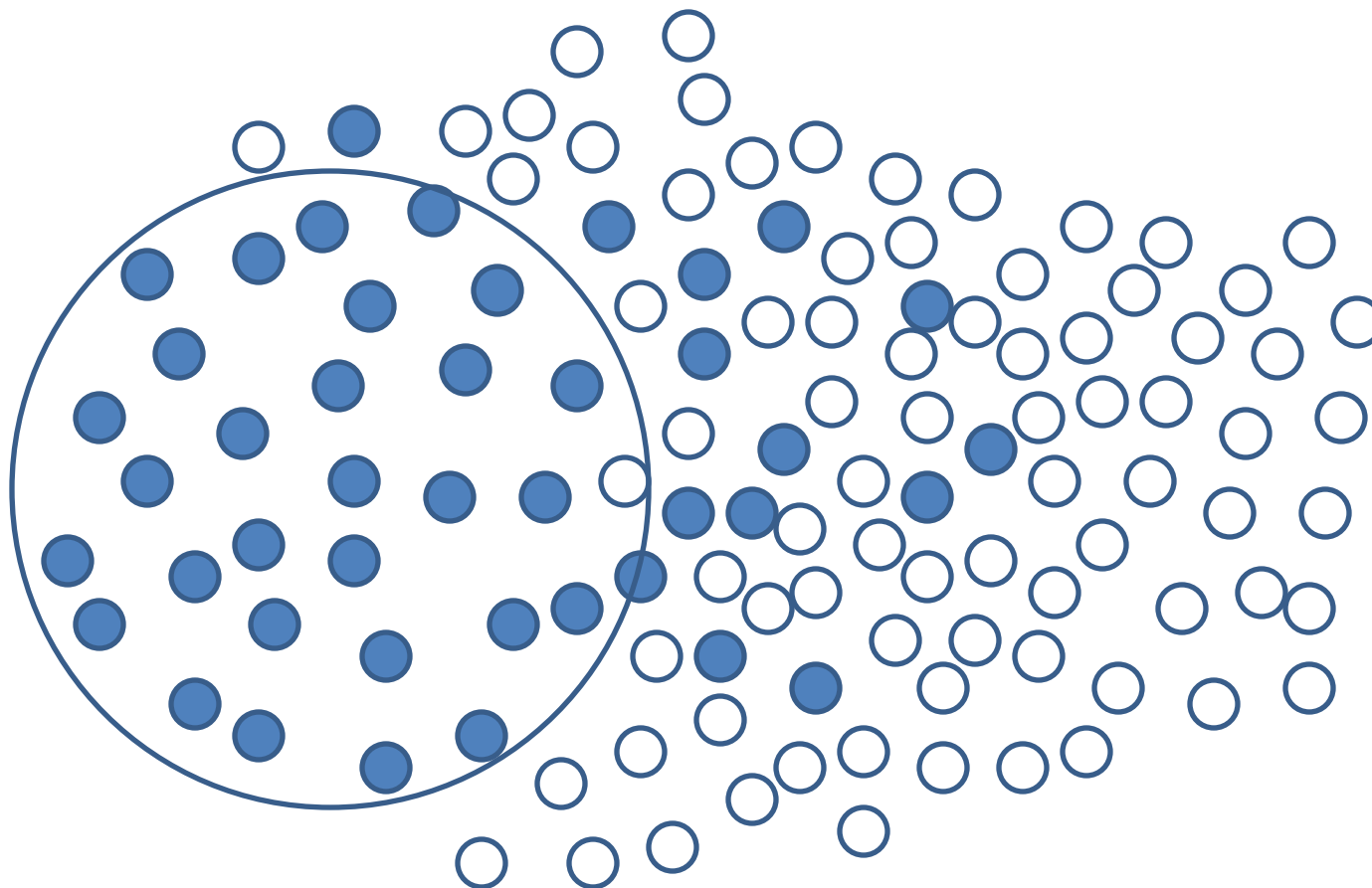
Epidemiološki kriterijumi

- 5) Izloženost faktorima sredine – ako se osoba bila izložena vodi (na način koji nije pijenje, npr. kupanjem) ili imala kontakt sa kontaminiranim površinama, kod kojih je laboratorijski dokazana kontaminacija
- 6) Izloženost u laboratorijskoj sredini – ako osoba radi u laboratoriji u kojoj je moguće izlaganje uzročnicima bolesti.

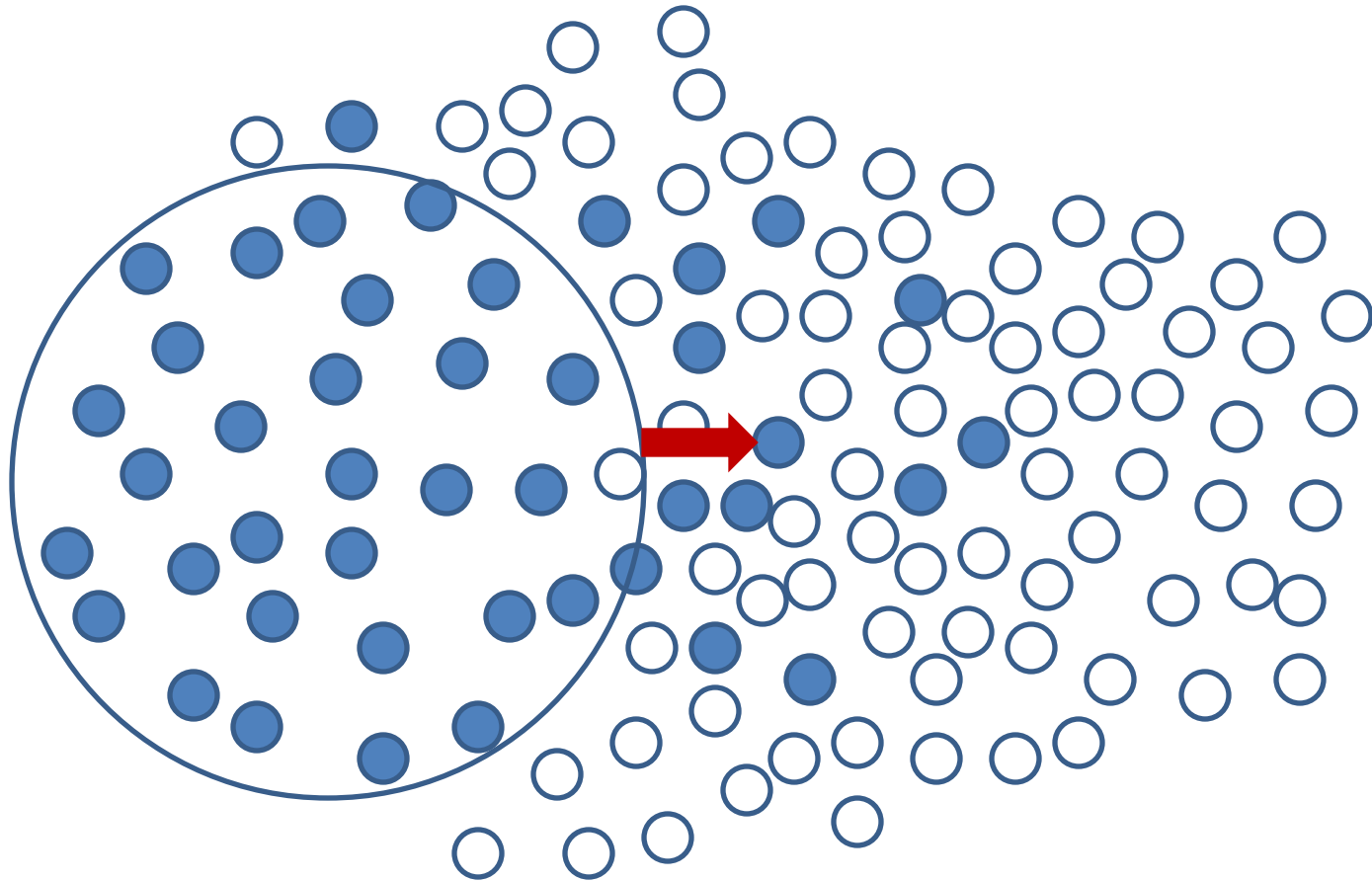
Klasifikacija slučaja

- U epidemiološkom nadzoru slučaj može biti različito klasifikovan, u zavisnosti od stepena verovatnoće da je neko pogođen određenim poremećajem zdravlja.
- Takva vrsta klasifikacije je značajna prilikom ranog prijavljivanja sumnji na oboljenje ili kad je teško postaviti definitivnu dijagnozu.

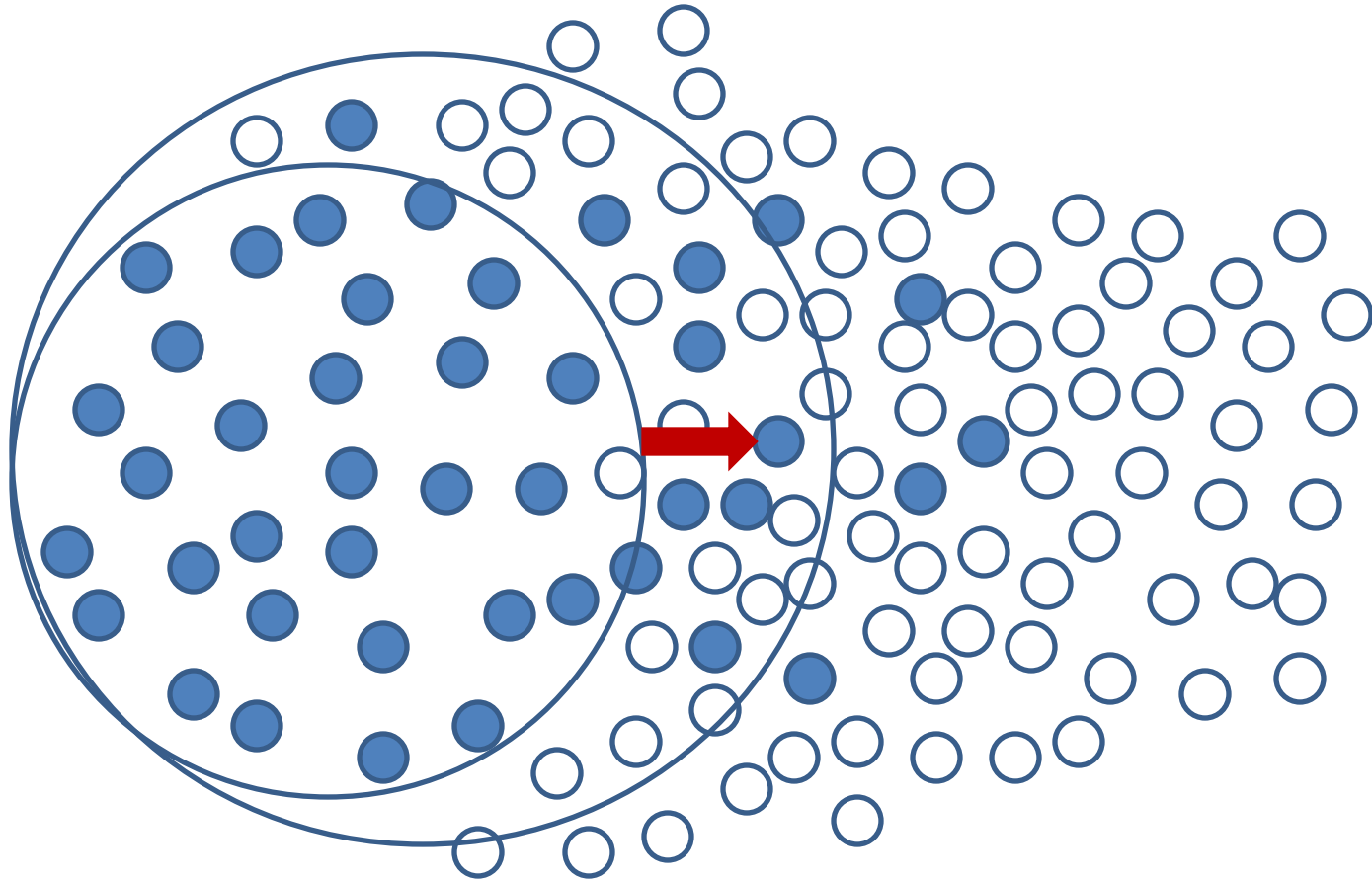
Senzitivnost i specifičnost definicije slučaja



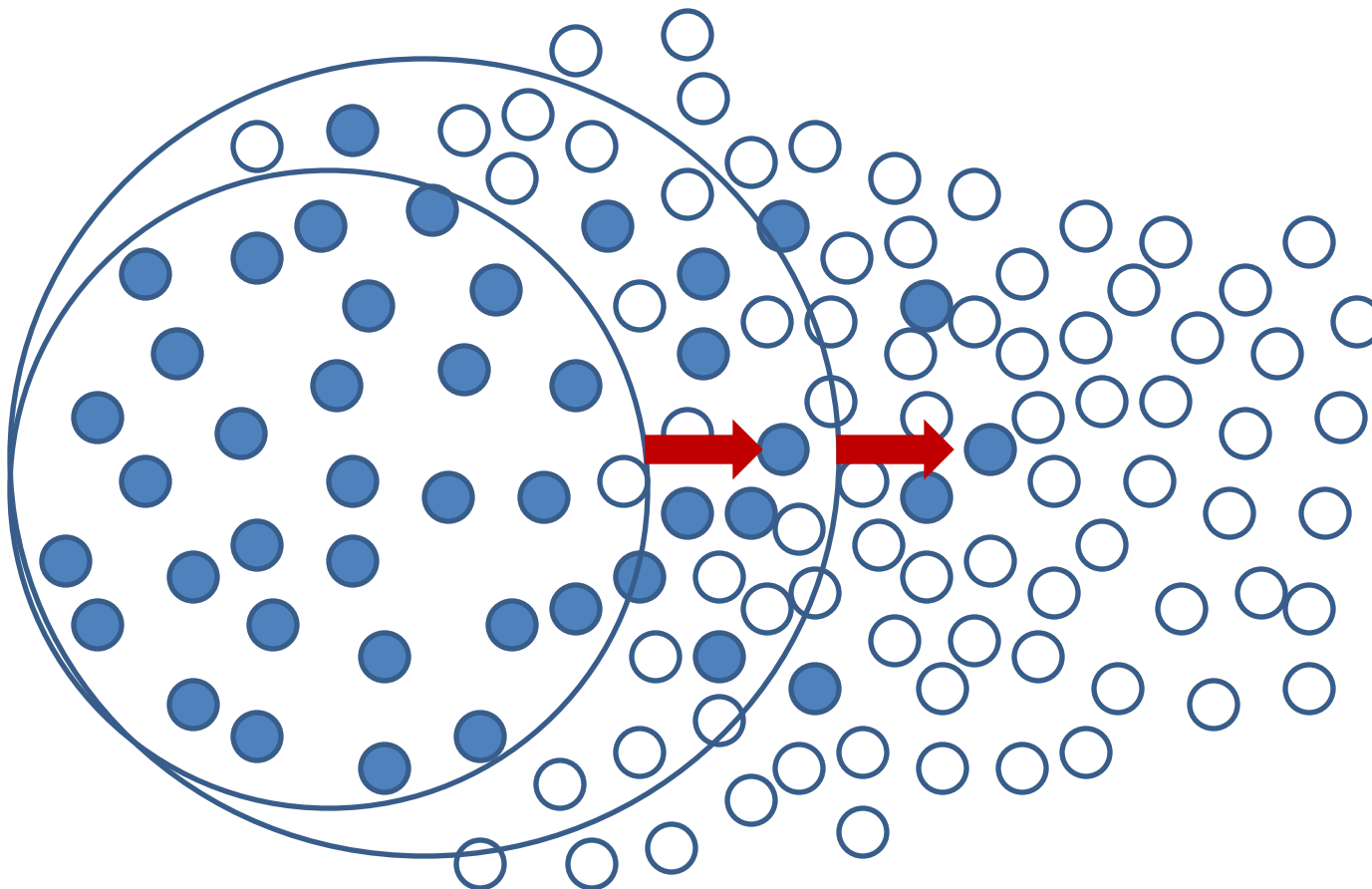
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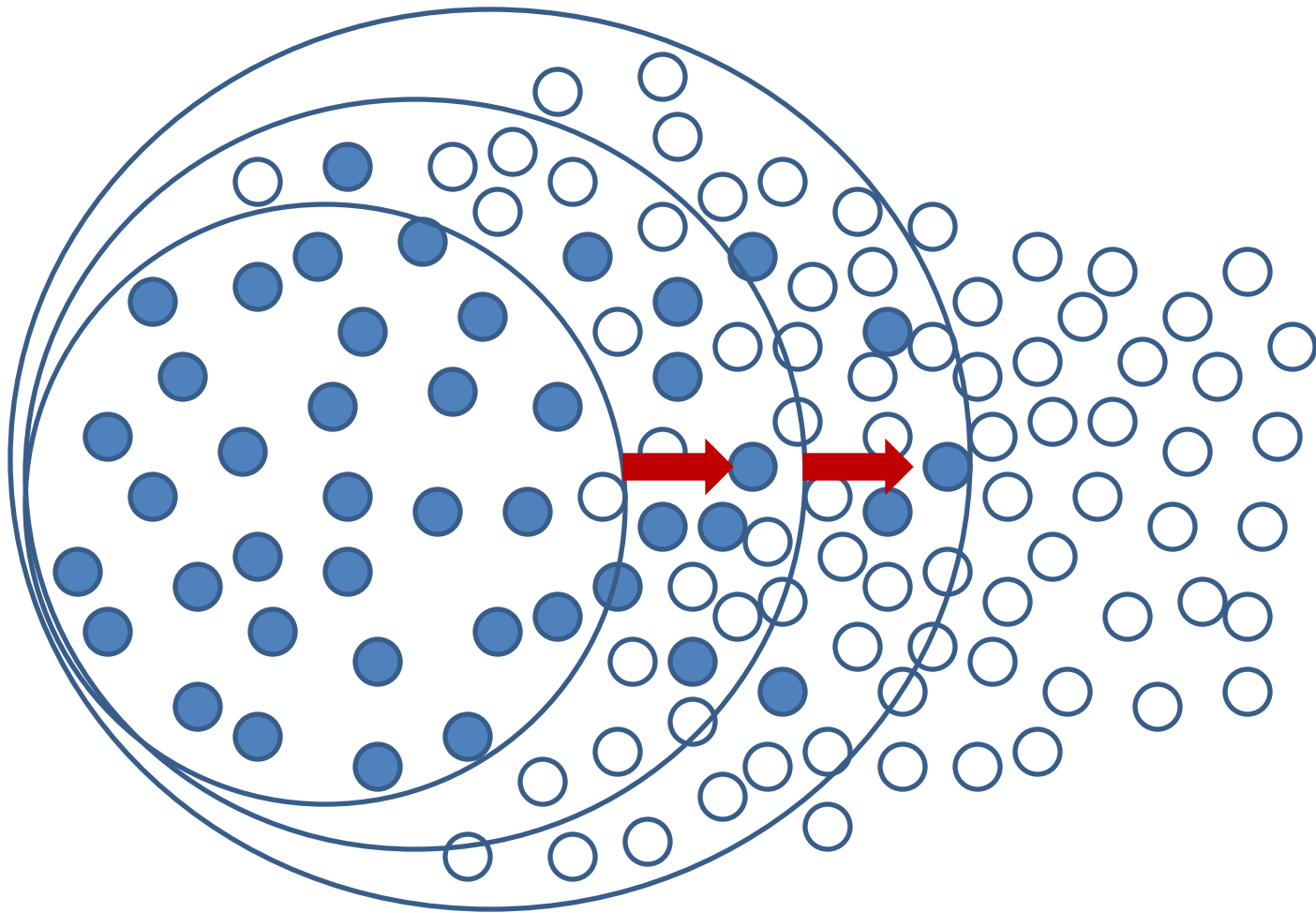
Senzitivnost i specifičnost definicije slučaja



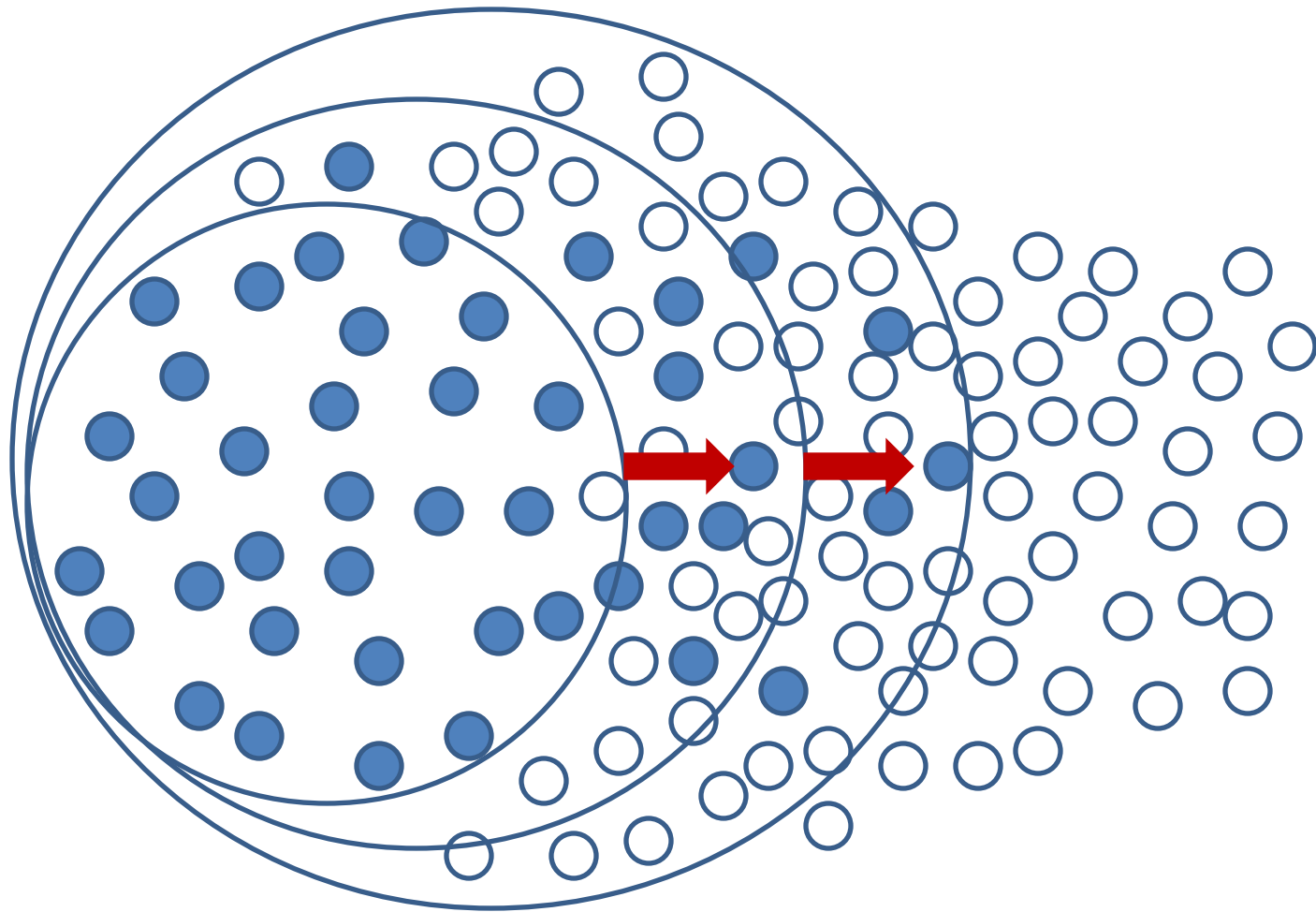
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Senzitivnost i specifičnost definicije slučaja



Senzitivnost i specifičnost definicije slučaja

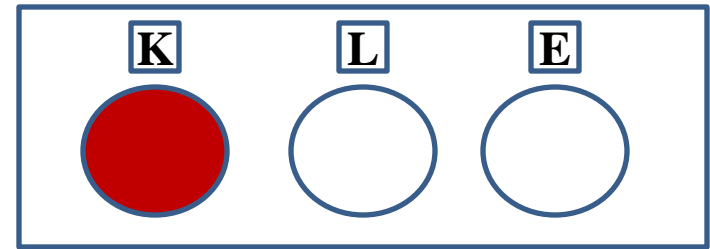


↑ Sn \implies ↑ lažni “slučajevi”; ↓ PPV ; ↓ Sp

Klasifikacija slučaja

- Moguć slučaj
- Verovatan slučaj
- Potvrđen slučaj

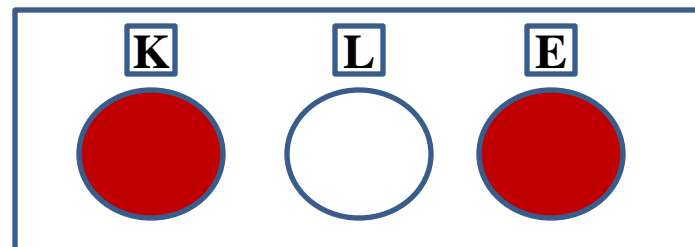
Klasifikacija slučaja



Moguć slučaj

- Najčešće je to slučaj koji zadovoljava kliničke kriterijume kako je opisano u definiciji bolesti bez epidemioloških ili laboratorijskih dokaza.
- Određivanje slučaja kao mogućeg ima visoku senzitivnost i nisku specifičnost.
- Omogućuje otkrivanje većine slučajeva, ali u tu kategoriju budu uvršteni i neki lažno pozitivni slučajevi.

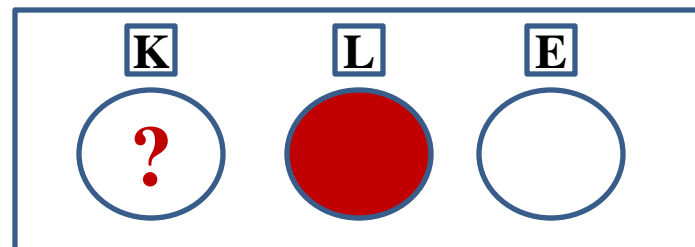
Klasifikacija slučaja



Verovatan slučaj

- Najčešće je to slučaj koji zadovoljava kliničke kriterijume i ustanovljena je epidemiološka povezanost kako je navedeno u definiciji bolesti.
- Laboratorijski testovi za verovatne slučajeve su uključeni samo za neke izuzetke (unapred dogovorene bolesti).
- Ti se laboratorijski kriterijumi sastoje od liste laboratorijskih metoda koje se mogu koristiti da potpomognu dijagnozu slučaja, ali nisu potvrdni

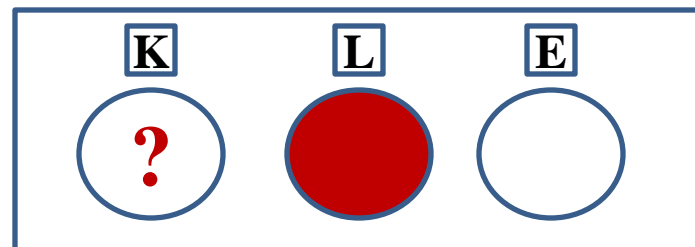
Klasifikacija slučaja



Potvrđen slučaj

- Potvrđeni slučajevi su laboratorijski potvrđeni i mogu, ali i ne moraju ispunjavati kliničke kriterijume koji su opisani u definiciji bolesti.
- Klinički kriterijumi za neke bolesti ne ukazuju da su mnogi akutni slučajevi asimptomatski (npr. hepatitis A, B i C, kampilobakteroza, salmoneloza)
- Određivanje slučaja kao potvrđenog ima **visoku specifičnost**, ali je **manje senzitivan**. Iz tog razloga će većina slučajeva klasifikovanih kao “povrđeni slučajevi” zaista pripadati grupi obolelih, ali će neki ipak ostati neprepoznati i nedetektovani.

Klasifikacija slučaja



1) **Laboratorijski potvrđen slučaj sa kliničkim kriterijumima**

Slučaj ispunjava laboratorijske kriterijume za potvrdu slučaja i kliničke kriterije navedene u definiciji bolesti.

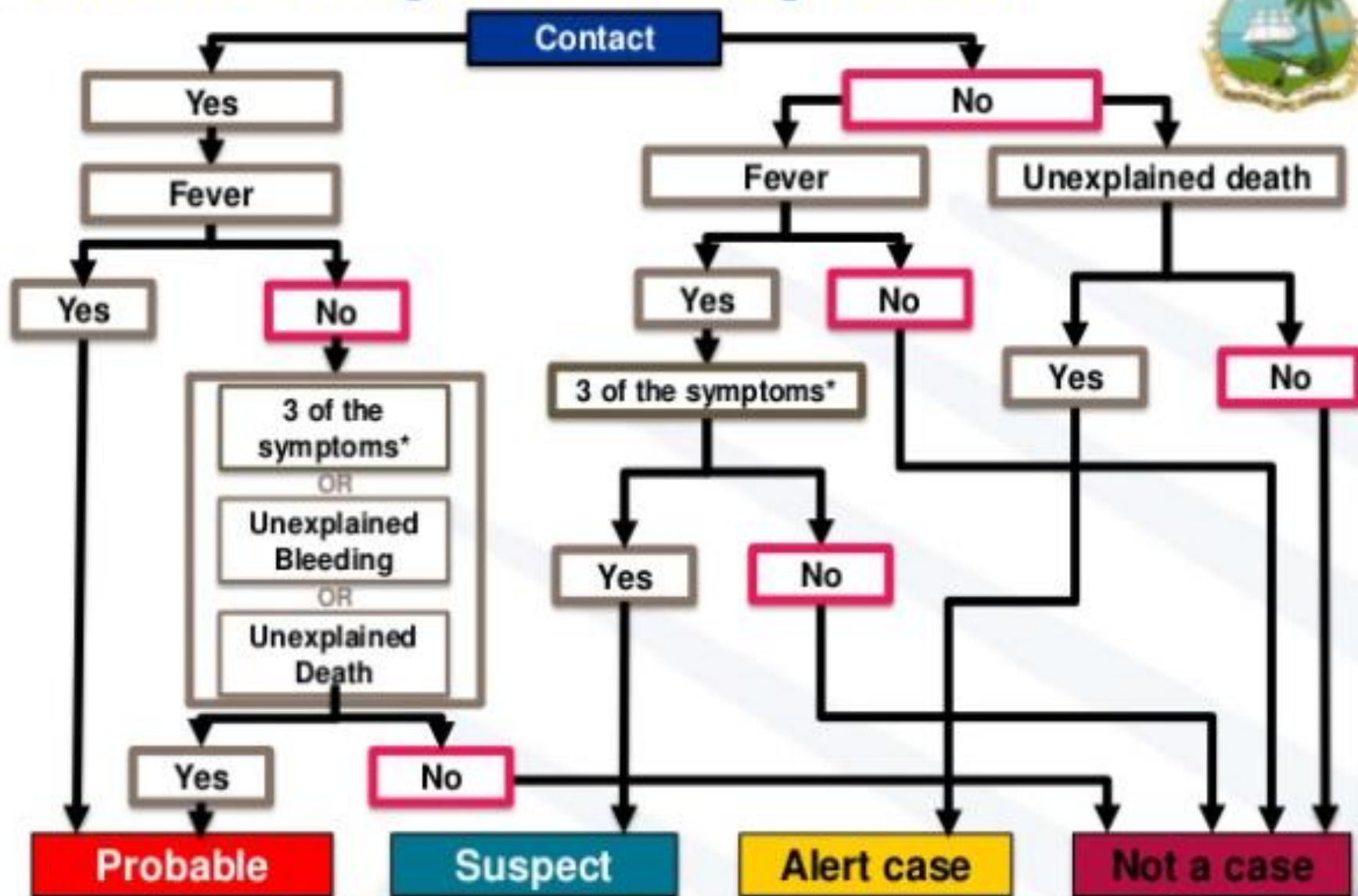
2) **Laboratorijski potvrđen slučaj sa nepoznatim kliničkim kriterijumima**

Slučaj ispunjava laboratorijske kriterijume za potvrdu slučaja, ali nisu dostupne informacije vezane za kliničke kriterijume (npr samo laboratorijski izveštaj).

3) **Laboratorijski potvrđen slučaj bez kliničkih kriterijuma**

Slučaj ispunjava laboratorijske kriterijume za potvrdu slučaja, ali ne ispunjava kliničke kriterije iz definicije bolesti ili je asimptomatski.

EVD OUTBREAK Triage Decision-making Flowchart



*Symptoms include: headache, vomiting, nausea, loss of appetite, diarrhoea, intense fatigue, abdominal pain, general muscular or articular pain, difficulty in swallowing, difficulty in breathing, hiccoughs
 Note: Confirmed cases requires positive laboratory test

Liberia, 2014

Assessing case definitions in the absence of a diagnostic gold standard

David Coggon,^{1*} Christopher Martyn,¹ Keith T Palmer¹ and Bradley Evanoff²

International Journal of Epidemiology 2005;**34**:949–952
doi:10.1093/ije/dyi012



Public health implications of using various case definitions in The Netherlands during the worldwide SARS outbreak

A. Timen¹, G. J. J. van Doornum², M. Schutten², M. A. E. Conyn-van Spaendonck¹, J. W. M. van der Meer³, A. D. M. E. Osterhaus² and J. E. van Steenberghe¹

Clin Microbiol Infect 2006; 12: 1214–1220

Table 1. Criteria for the definition of cases of SARS in The Netherlands during 2003

Case definition (date)	Fever >38°C	Cough and breathing difficulty	Contact with patient with severe respiratory disease (in SARS area)	Travel to or residence in known SARS area	Contact with SARS patient outside affected area	Radiographical evidence of lung infiltrates (pneumonia)
1 (17 March)	+	+	+ ^a	-	-	+
2 (1 April)	+	+	+ ^b	-	-	-
3 (9 April)	+	+	+ ^c or	+ ^d	-	+
4 (2 May)	+	+	+ ^c or	+ ^d or	+	+
5 (10 June)	+	+	+ or	+ or	+	-

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Table 2. Distribution of the criteria for the SARS case definition among cases referred for SARS assessment ($n = 72$)

Criteria	Number (%) $n = 72$	95% CI
Respiratory illness	53 (71)	61.9–83.3
Fever	49 (68)	56–78.6
Travel-associated risk	46 (64)	52.8–75.3
Close contact with individuals from affected areas	17 (23)	13.2–37.7
Pneumonia	11 (19.3)	10–31.9
Diarrhoea	4 (5.6)	1.5–13.6
Fever and travel-associated risk	28 (38.8)	27.8–50.2
Respiratory disease and travel-associated risk	29 (40.2)	28.9–51.5
Respiratory disease and fever	42 (58.3)	46.9–69.9
Respiratory disease, fever and travel-associated risk	25 (34)	23.3–45.2

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Table 3. Comparison of cases on the basis of the first assessment (based on the current Dutch case definition) and the retrospective reassessment (based on the WHO case definition)

First assessment	Retrospective reassessment			Total
	Not-suspect	Suspect	Probable	
Not-suspect	49	14	0	63
Suspect	0	7	2	9
Probable	0	0	0	0
Total	49	21	2	72

Reliability of case definitions for public health surveillance assessed by Round-Robin test methodology

Gérard Krause*, Bonita Brodhun, Doris Altmann, Hermann Claus and Justus Benzler

BMC Public Health 2006, 6:129 doi:10.1186/1471-2458-6-129

Table 2: Distribution of case examples in different groups of participants

Group 1 Local health departments in West German States Set A	Group 2 Set B	Group 3 Set C	Group 4 Set D
<u>Salmonellosis</u> * Hepatitis B Hepatitis C Tuberculosis ⁺	<u>Salmonellosis</u> * Measles ⁺ Adenovirus conjunctivitis Polio ⁺	<u>Salmonellosis</u> * Creutzfeldt-Jakob-Disease (CJD) ⁺ Pathogenic <i>E. coli</i> enteritis EHEC** (enterohaemorrhagic <i>E. coli</i>)	<u>Salmonellosis</u> * Meningococcal meningitis Influenza Haemorrhagic fever
Local health departments in East German States Set E	Set F	Set G	Set H
Like Set A, plus: Pneumococcal disease*	Like Set B, plus: Borreliosis*	Like Set C, plus: Rubella*	Like Set D, plus: Viral meningitis*

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Table 3: Disease specific reporting precision according to disease of the case examples. Reference variable: *Salmonellosis* case examples; outcome variable: reporting precision (n= 5995)

Disease	Odds Ratio *	Confidence Interval
Salmonellosis	-	-
Tuberculosis	0.678	0.477 – 0.965
Measles	0.375	0.277 – 0.509
Hepatitis C	0.277	0.208 – 0.368
Pathogenic <i>E. coli</i> enteritis	0.229	0.173 – 0.304
Adenovirus conjunctivitis	0.173	0.130 – 0.230
Haemorrhagic fever	0.161	0.123 – 0.210
Meningococcal meningitis	0.153	0.117 – 0.201
EHEC (enterohaemorrhagic <i>E. coli</i>)	0.099	0.076 – 0.129
Influenza	0.093	0.071 – 0.121
Hepatitis B	0.057	0.043 – 0.075
Creutzfeldt-Jakob-Disease (CJD)	0.012	0.008 – 0.017
Polio	0.008	0.005 – 0.013

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Conclusion

All the observed quantitative effects and their propagated explanations merge into the one main conclusion: Case definitions must be very carefully formulated in order to assure their unambiguous interpretation by local health department personnel. The detailed evaluation of our study has resulted in a substantially revised edition of the German case definitions [23,24]:

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(Text with EEA relevance)

(2012/506/EU)

3. CASE DEFINITIONS OF SPECIAL HEALTH ISSUES

3.1. GENERAL CASE DEFINITION OF NOSOCOMIAL INFECTION (OR HEALTHCARE-ASSOCIATED INFECTION)

A nosocomial infection associated to the current hospital stay is defined as infection that matches one of the case definitions AND

- the onset of symptoms was on Day 3 or later (day of admission + Day 1) of the current hospital admission OR
- the patient underwent surgery on day 1 or day 2 and develops symptoms of a Surgical Site Infection before day 3 OR
- an invasive device was placed on day 1 or day 2 resulting in an HAI before day 3

A nosocomial infection associated to a previous hospital stay is defined as infection that matches one of the case definitions

AND

- the patient presents with an infection but has been readmitted less than two days after a previous admission to an acute care hospital OR
- the patient has been admitted with an infection that meets the case definition of a Surgical Site Infection i.e. the SSI occurred within 30 days of the operation (or in the case of surgery involving an implant was a deep or organ/space SSI that developed within a year of the operation) and the patient either has symptoms that meet the case definition and/or is on antimicrobial treatment for that infection OR
- the patient has been admitted (or develops symptoms within two days) with *Clostridium difficile* infection less than 28 days from a previous discharge from an acute care hospital.

Hvala vam na pažnji!