Klinikum St.GEORG
Infektiologie/Tropenmedizin

Zertifiziert als „Zentrum für Infektiologie (DGI)"
dgi DEUTSCHE GESELLSCHAFT FÜR INFEKTIOLOGIE e.V.

Universitätsklinikum Leipzig
Medizin ist unsere Berufung.

ZENTRUM FÜR INFEKTIONSMEDIZIN

STAKOB
Ständiger Arbeitskreis der Kompetenz- und Behandlungszentren für Krankheiten durch hochpathogene Erreger

Neue Leitlinien in der CDI-Behandlung

Prof. Dr. med. Christoph Lübbert, DTM&H
Klinik für Infektiologie und Tropenmedizin, Klinikum St. Georg gGmbH, Leipzig
Bereich Infektiologie und Tropenmedizin, Medizinische Klinik I, Universitätsklinikum Leipzig

130. Kongress der DGIM – Wiesbaden, 14. April 2024

Offenlegung potentieller Interessenkonflikte

Anstellungsverhältnis oder Führungsposition	- Professor für Innere Medizin, Universitätsklinikum Leipzig - angestellter Leiter des Bereichs Infektiologie und Tropenmedizin, Universitätsklinikum Leipzig - angestellter Chefarzt, Klinik für Infektiologie/Tropenmedizin, Klinikum St. Georg, Leipzig
Beratungstätigkeit	- MSD, Pfizer, AstraZeneca, Tillotts
Aktienbesitz	- keiner
Honorare (letzte 3 Jahre)	- Falk Foundation, Shionogi, MSD, InfectoPharm, Moderna, Pfizer, Roche, Daiichi Sankyo, Tillots, Sanofi-Aventis, Bavarian Nordic
Finanzierung wissenschaftlicher Untersuchungen	- Freistaat Sachsen, BMZ/GIZ
Gutachtertätigkeit	- Sozialgerichte, Berufsgenossenschaften
Andere finanzielle Beziehungen	- keine

Akute Gastroenteritis - eine der häufigsten Ursachen von Arbeitsunfähigkeit in D

- Inzidenz in Deutschland: 0,95 Diarrhoe-Episoden/Person p.a.

Table 2. *Proportions and average means for associated factors and medical actions taken of cases of acute gastrointestinal illness by age and sex (n = 1562)*

	Age group (years)										
	Total	18–29	30–39	40–49	50–59	60–69	⩾70	*P* value for age*	Female	Male	*P* value for sex*
Diarrhoea (%)	88·1	81·0	87·6	87·7	92·3	91·5	94·8	**<0·001**	87·8	88·7	0·671
Vomiting (⩾3 times/day) (%)	22·0	30·4	28·2	20·0	16·1	14·4	14·4	**<0·001**	23·6	20·1	0·214
Bloody diarrhoea (%)	3·6	3·8	4·3	3·9	3·3	3·6	3·3	0·904	3·3	4·0	0·598
Fever (>38·5°C) (%)	10·0	16·4	11·8	10·7	5·5	4·5	6·3	**0·001**	10·4	9·9	0·823
Stool sample (%)	13·8	7·7	8·6	12·4	16·0	22·5	24·4	**<0·001**	16·3	10·9	**0·033**
Travel related (%)	6·6	7·6	7·5	9·5	4·1	6·1	2·7	**0·028**	4·6	9·0	**0·002**
Outpatients (%)†	37·8	38·2	30·2	31·9	36·0	42·9	55·5	**0·002**	37·7	38·0	0·939
Hospitalized (%)	3·4	0·9	4·5	1·5	3·2	5·5	7·6	**0·026**	3·8	3·0	0·557
Work absenteeism (%)	23·2	33·2	32·2	28·6	20·7	n.a.	n.a.	n.a.	20·4	26·5	n.a.
Medication taken (%)	49·8	54·2	40·9	45·9	51·4	52·3	57·3	0·247	52·4	46·7	0·085
Medication prescribed (%)	31·2	30·4	22·9	27·9	30·2	40·4	43·9	**0·002**	30·6	31·9	0·693
Antibiotics prescribed (%)	10·6	10·0	5·6	8·1	11·4	17·3	16·0	**0·011**	11·3	9·8	0·517
Mean number of stools per case of diarrhoea	4·7	4·8	4·7	4·7	5·0	4·6	4·3	0·164	4·7	4·7	0·829
Mean duration of symptoms (days)	3·7	3·9	3·6	3·7	3·6	3·6	4·0	0·863	3·8	3·6	0·564
Mean duration of hospitalisation (days)	9·0	3·6	8·1	5·9	8·8	9·7	13·3	**0·003**	9·0	9·1	0·966
Mean duration of work absenteeism (days)	4·2	3·8	3·9	5·1	4·0	n.a.	n.a.	0·231	4·4	4·1	0·628

Wilking H et al. Epidemiol Infect 2013; 141: 2365-75

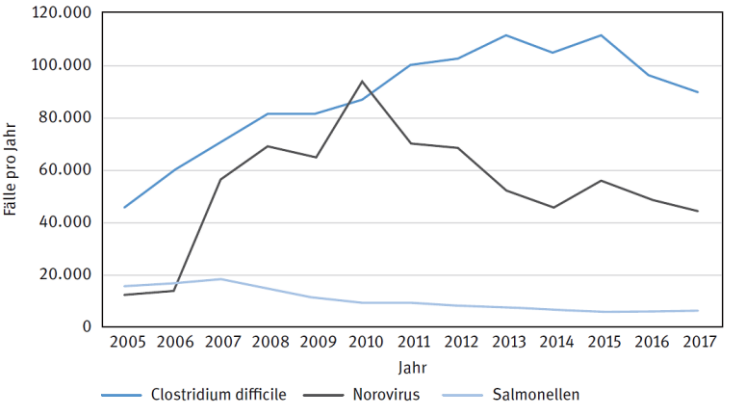
Trends: Erreger stationär behandelter Durchfallerkrankungen in Deutschland

Meldepflichtige Durchfall-erkrankungen im Jahr 2019

Erreger/Erkrankung	Fallzahl
Norovirus-Erkrankung	78.665
Campylobacter-Enteritis	61.526
Rotavirus-Erkrankung	36.874
Salmonellose	13.963
EHEC (außer HUS)	1.877
Giardiasis	3.296
Yersiniose	2.168
Kryptosporidiose	1.974
Shigellose	627
Listeriose	591
Schwer verlaufende CDI	2.262

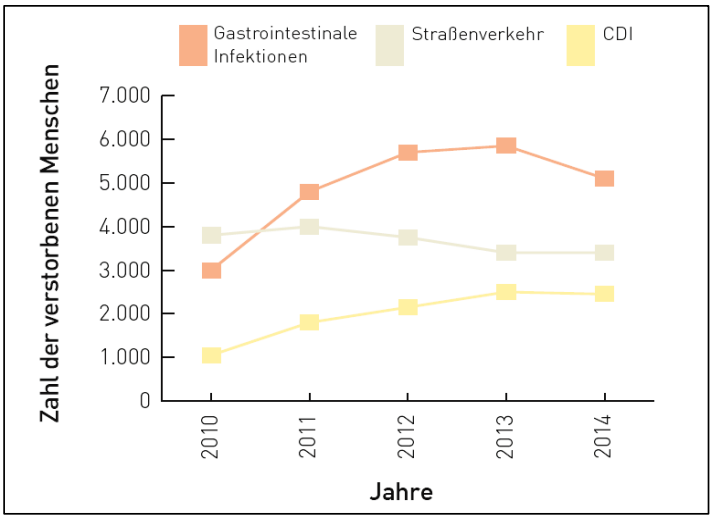
Robert-Koch-Institut, Angaben für 2019

Stationäre Fälle mit ausgewählten GI-Infektionen

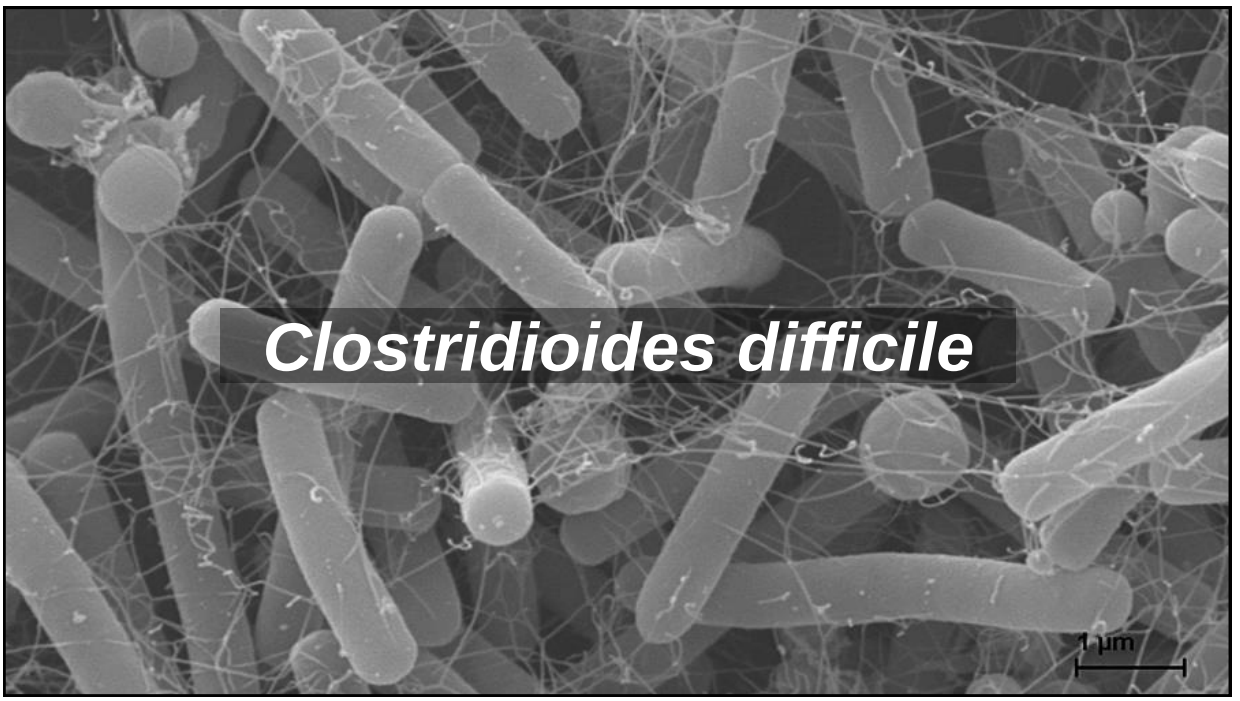


DGVS - Weißbuch Gastroenterologie 2020/21

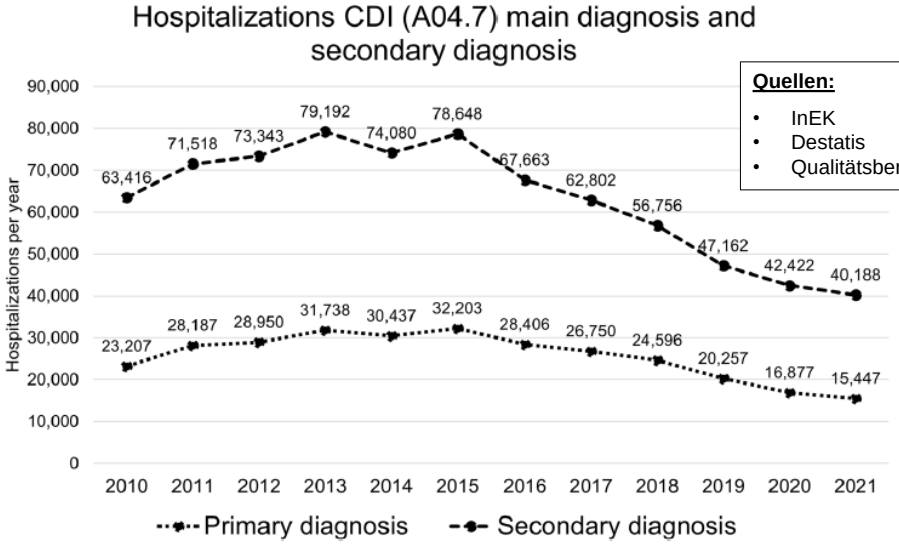
Volkswirtschaftliche Bedeutung - Todesfälle



DGVS - Weißbuch Gastroenterologie 2018



Epidemiologie in D - Sekundärdaten

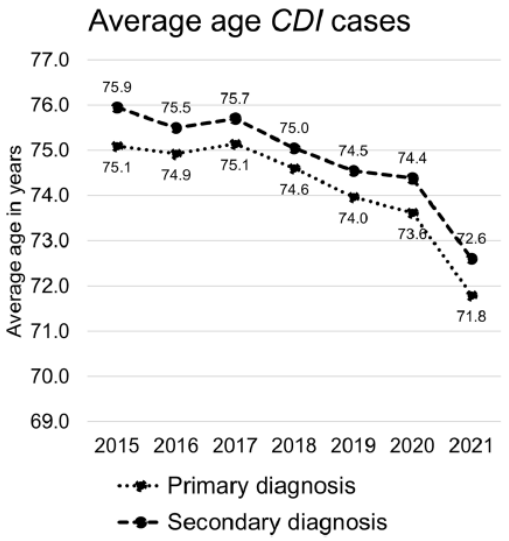


Quellen:

- InEK
- Destatis
- Qualitätsberichte der KH

Vehreschild MJGT et al. Infection 2023

Epidemiologie in D - Sekundärdaten



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- Qualitätsberichte der KH

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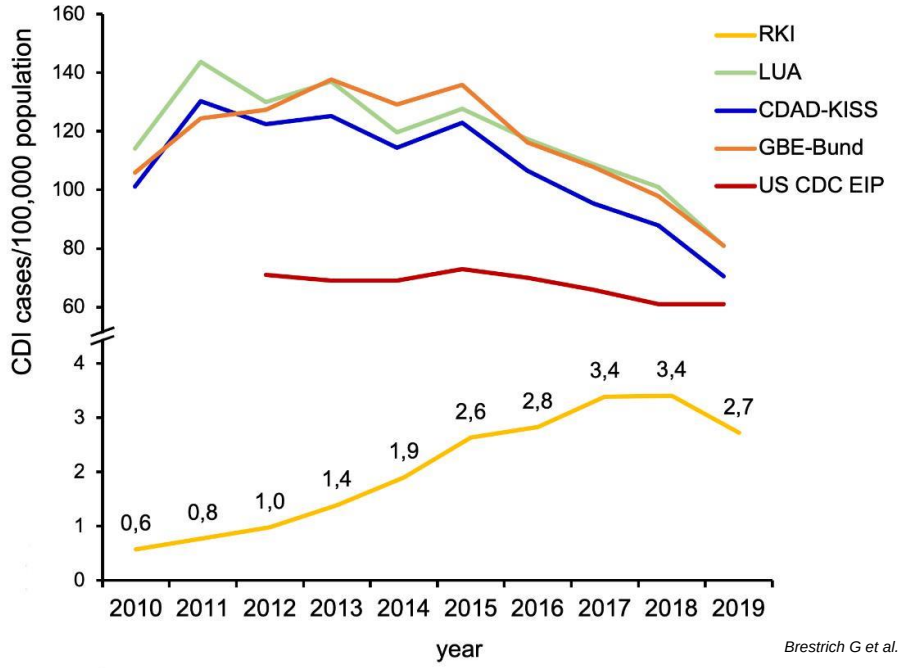
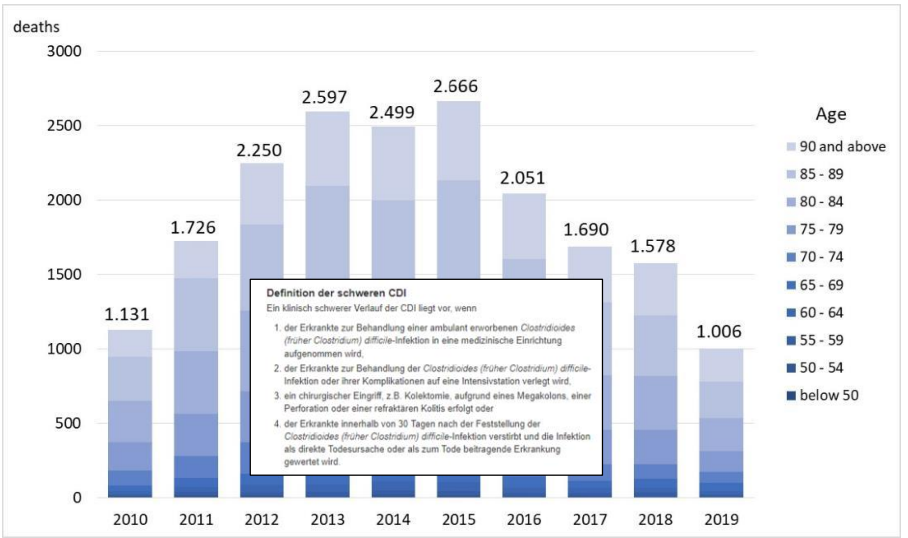


Brestrich G et al. Infect Dis Ther 2023

Schwere CDI – Epidemiologie (RKI)

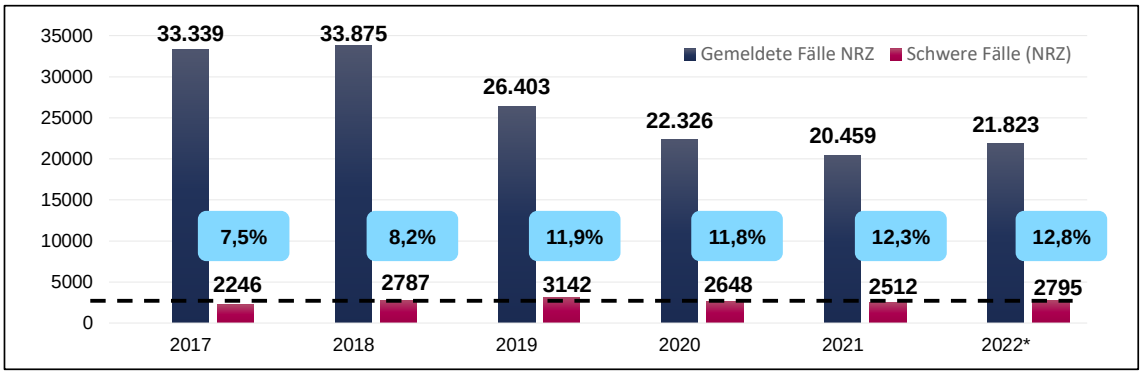


Brestrich G et al. Infect Dis Ther 2023

Schwere CDI – Epidemiologie (NRZ u. KISS)

Nationales Referenzzentrum für Surveillance von nosokomialen Infektionen

Erfassung mitgebrachter und nosokomialer Infektionen mit *Clostridioides difficile* und Fälle von *Clostridioides-difficile*-assoziierter Diarrhö (CDI-KISS, früher CDAD-KISS)



NRZ für Surveillance von nosokomialen Infektionen, Modul CDI-KISS Referenzdaten, https://www.nrz-hygiene.de/KISS-Modul/KISS/CDI (Stand 29.08.2023)

TED-Frage (Slido)

Ein 81-jähriger, rüstiger Patient erleidet nach einer Zahnextraktion mit begleitender Clindamycin-Therapie eine im Labor bestätigte CDI mit ausgeprägten Abdominalschmerzen, 10-15 wässrigen Durchfällen tgl., Leukozytose (16 GPT/l) und leichter Temperaturerhöhung (37,9°C).

Wie gehen Sie in dieser Situation vor?

A) Ambulante Kontrolle und Therapie mit 3 x 500 mg Metronidazol p.o.
B) Ambulante Kontrolle und Therapie mit 4 x 250 mg Vancomycin p.o.
C) Ambulante Kontrolle und Therapie mit 2 x 200 mg Fidaxomicin p.o.
D) Stationäre Aufnahme und Therapie mit 4 x 125 mg Vancomycin p.o.
E) Stationäre Aufnahme und Therapie mit 2 x 200 mg Fidaxomicin p.o.

1913 DGVS
Deutsche Gesellschaft für Gastroenterologie, Verdauungs- und Stoffwechselkrankheiten

S2k-Leitlinie Gastrointestinale Infektionen der Deutschen Gesellschaft für Gastroenterologie, Verdauungs- und Stoffwechselkrankheiten (DGVS)

Version 2.0 – November 2023
AWMF-Registernummer: 021 - 024

Autoren

Carolin F. Manthey[1], Hans-Jörg Epple[2], Klaus-Michael Keller[3], Christoph Lübbert[4], Carsten Posovszky[5], Michael Ramharter[6], Philipp Reuken[7], Sebastian Suerbaum[8], Maria Vehreschild[9], Thomas Weinke[10], Marylyn M. Addo[6, 11], Andreas Stallmach[7], Ansgar W. Lohse[6]

Collaborators

Rüdiger Adam, Christian Bogdan, Antje Flieger, Fabian Frost, Angelika Fruth, Stefan Hagel, Katrin Katzer, Jens M. Kittner, Gerd Klock, Benno Kreuels, Luise Martin, Jakob Malsy, Harald Matthes, Markus Menges, Mark Oette, Jutta Riemer, Camilla Rothe, Stefan Schmiedel, Volker Schmitz, Peter Walger

https://register.awmf.org/de/leitlinien/detail/021-024 -- https://www.dgvs.de/wp-content/uploads/2023/08/Gastrointestinale-Infektionen-v2.0_Leitlinie.pdf

S2k-Leitlinie der DGVS 2023

Empfehlung 3.3: Definition und Prädiktion der schweren CDI

Eine CDI wird klinisch als schwer klassifiziert, wenn mindestens eines der folgenden Kriterien vorliegt:

- Fieber, definiert als > 38.5°C
- Leukozytose, definiert als > 15 GPT/L
- Anstieg des Serumkreatinins auf > 50% des Ausgangswertes

Die schwere komplizierte (oder fulminante) CDI ist gekennzeichnet durch das Vorliegen mindestens eines der folgenden Kriterien:

- Hypotension (systolischer Blutdruck < 100 mmHg)
- septischer Schock
- erhöhtes Serum-Laktat (≥ 20 mg/dl bzw. ≥ 2,2 mmol/l)
- Ileus
- toxisches Megakolon
- Perforation
- fulminante Krankheitsdynamik

Die wichtigsten Prädiktoren für die Vorhersage einer schweren CDI sind:

- Alter > 65 Jahre
- multiple signifikante Komorbiditäten (z.B. Niereninsuffizienz, Immunsuppression u.a.)

[starker Konsens]

S2k-Leitlinie der DGVS 2023

Empfehlung 3.7: Primärtherapie der *C.-difficile*-Infektion

Für die spezifische Primärtherapie der CDI werden folgende Empfehlungen gegeben:

- Die Primärtherapie **soll** mit Fidaxomicin 2 x 200 mg / Tag p.o. oder Vancomycin 4 x 125 mg / Tag p.o. über 10 Tage erfolgen.
  [starker Konsens, starke Empfehlung]
- Bei erhöhtem Rezidivrisiko
  [Konsens, starke Empfehlu
- Eine Behandlung mit Metro ht schwerem Krankheitsbild, fehlenden Risikofaktoren für einen sch werden.
  [Konsens, Empfehlu g offe
- Bei erhöhtem Rezidivrisiko lig 10 mg/kg KG i.v.) zur Sekundärprophylaxe erfolg
  [Konsens, Empfehlung offe
- Wenn keine enterale Therapie möglich ist, **kann** eine parenterale Therapie mit Metronidazol 3 x 500 mg i.v. / Tag oder Tigecyclin 2 x 50 mg i.v. / Tag (Startdosis 100 mg i.v.) erfolgen.
  [starker Konsens, Empfehlung offen]

Risikofaktor	Qualität der Evidenz [205]
Alter > 65 Jahre	Moderat
Vorhergehendes Rezidiv (<3 Monate)	Moderat
Nosokomial erworbene CDI	Niedrig
Vorhergehende Hospitalisierung	Niedrig
PPI-Verschreibung während oder im Anschluss an CDI-Episode	Niedrig

Rekurrente CDI – Risiko Lebensalter

Table 2 Data of hospitalised, recurrent, and severe CDI stratified per age group, for the year 2019

	Age [years]							
	< 50	50–54	55–59	60–64	65–69	70–74	75–79	≥ 80
Hospitalised CDI[a]								
Number of cases	5,653	1,914	3,147	4,182	5,731	6,266	11,096	29,258
Incidence (cases/100,000 population)	12.3	28.2	47.2	75.1	118.6	172.4	278.6	528.6
Recurrent CDI[b]								
Number of cases	204	92	149	240	322	369	662	1638
Incidence (cases/100,000 population)	0.4	1.4	2.2	4.3	6.7	10.2	16.6	29.6
Severe CDI[c]								
Number of cases	220	67	90	117	148	198	333	1088
Incidence (cases/100,000 population)	0.4	1.0	1.3	2.1	3.1	5.4	8.4	19.7

Brestrich G et al. Infect Dis Ther 2023

S2k-Leitlinie der DGVS 2023

Empfehlung 3.9: Therapie von Rezidiven

Für die Therapie des ersten Rezidivs einer CDI gelten folgende Empfehlungen:

- Wurde die initiale Episode mit Vancomycin oder Metronidazol behandelt, **sollte** eine Therapie mit Fidaxomicin (2 x 200 mg p.o. / Tag über 10 Tage) erfolgen.
  [starker Konsens, Empfehlung]
- Wurde die initiale Episode mit Fidaxomicin behandelt, **kann** das Rezidiv zusätzlich zur Therapie mit Fidaxomicin mit Bezlotoxumab (einmalig 10 mg/kg KG i.v.) behandelt werden.
  [Konsens, Empfehlung offen]

Für die Therapie einer multipel rezidivierenden CDI gilt folgende Empfehlung:

- Bei multiplen Rezidiven **kann** ein fäkaler Mikrobiotatransfer (FMT) im Anschluss an eine Standardtherapie erfolgen.
  [starker Konsens, Empfehlung offen]

CDI – Rekurrenz
Versuch einer Definition

Recurrences

Definition of recurrent Clostridium difficile infection. Recurrence is present when CDI re-occurs within 8 weeks after the onset of a previous episode, provided the symptoms from the previous episode resolved after completion of initial treatment [4,11].

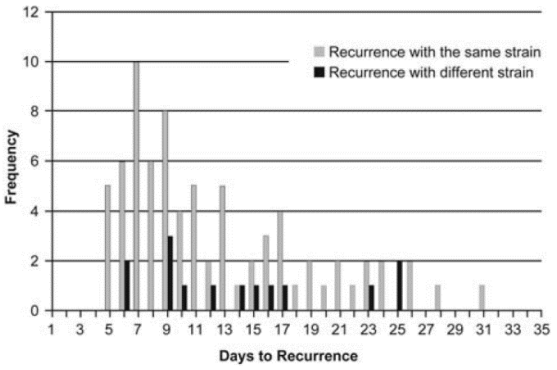
It is not feasible to distinguish recurrence due to relapse (renewed symptoms from already present CDI) from recurrence due to reinfection in daily practice [20,25–28].

Debast SB et al. Clin Microbiol Infect 2014; 20 (Suppl. 2): 1-26

Relapse Versus Reinfection: Recurrent *Clostridium difficile* Infection Following Treatment With Fidaxomicin or Vancomycin

Iris Figueroa,[1] Stuart Johnson,[1,2] Susan P. Sambol,[1,2] Ellie J. C. Goldstein,[3,4] Diane M. Citron,[3] and Dale N. Gerding[1,2]

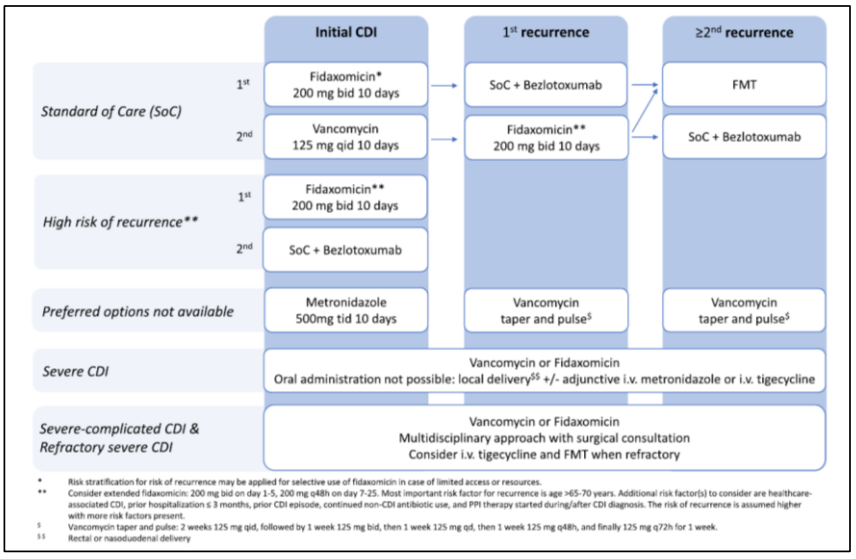
[1]Hines Veterans Affairs Hospital, [2]Loyola University Chicago Stritch School of Medicine, Maywood, Illinois; [3]RM Alden Research Laboratory, Culver City, and [4]David Geffen School of Medicine at University of California, Los Angeles, California



N = 90

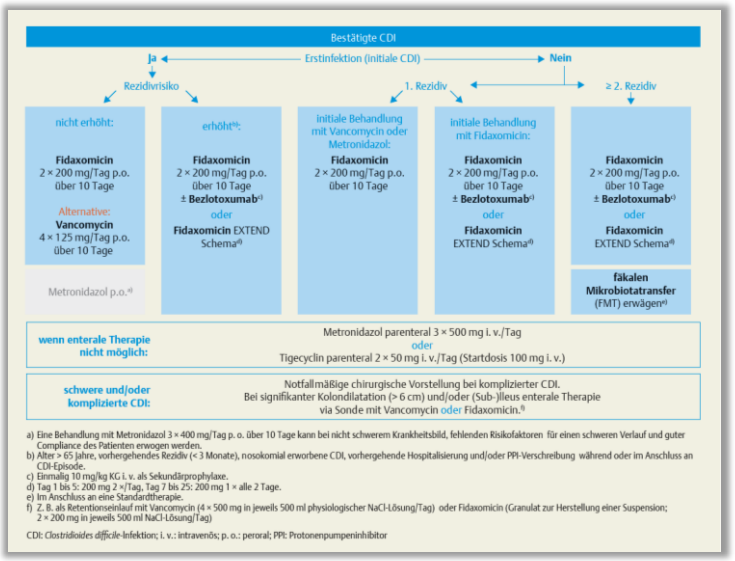
Figueroa I et al. Clin Infect Dis 2012

Leitliniengerechte Therapie von CDI - ESCMID



van Prehn J et al. Clin Microbiol Infect 2021

Leitliniengerechte Therapie von CDI - DGVS



https://register.awmf.org/de/leitlinien/detail/021-024 -- https://www.dgvs.de/wp-content/uploads/2023/08/Gastrointestinale-Infektionen-v2.0_Leitlinie.pdf

Welche CDI-Therapie ist die beste?

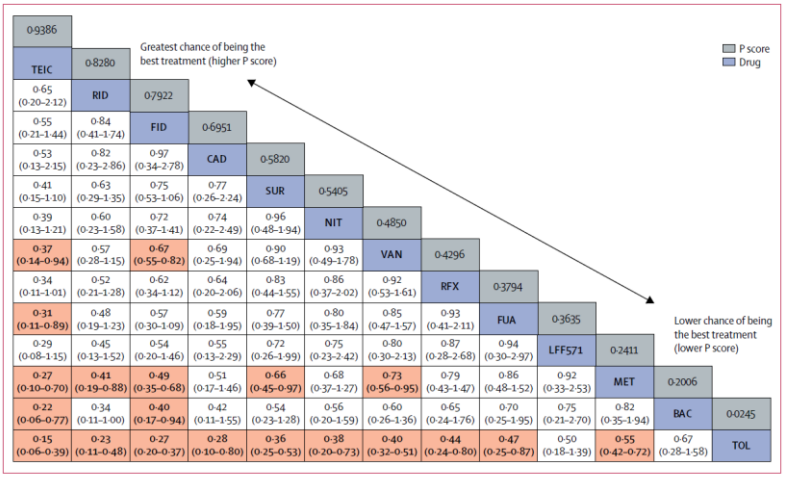
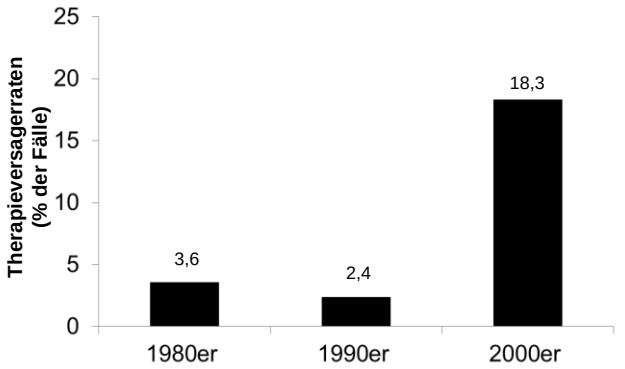


Figure 4: **League table of pairwise comparisons in network meta-analysis for attaining a sustained symptomatic cure**
Treatments are ordered in the rank of their chance of being the best treatment. Numbers in grey boxes are P scores, which are used to rank the treatments. Treatment estimates are provided as odds ratios with 95% CIs. Significant pairwise comparisons are highlighted. TEIC=teicoplanin. RID=ridinidazole. FID=fidaxomicin. CAD=cadazolid. SUR=surotomycin. NIT=nitazoxanide. VAN=vancomycin. RFX=rifaximin. FUA=fusidic acid. MET=metronidazole. BAC=bacitracin. TOL=tolevamer.

Beinortas T et al. Lancet Infect Dis 2018

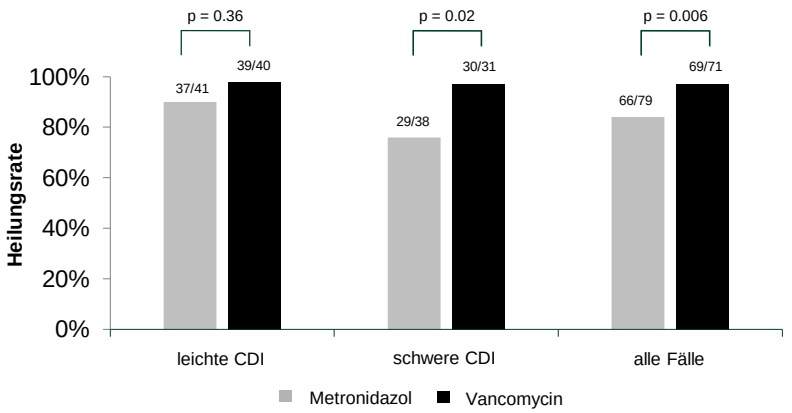
Therapieversager-Raten unter Metronidazol nehmen seit > 20 Jahren zu

Durchschnittliche Therapieversager-Raten bei mit Metronidazol behandelten CDI-Patienten



Aslam S et al. Lancet Infect Dis 2005

Überlegenheit von Vancomycin bei schwer verlaufender CDI



Zar FA et al. Clin Infect Dis 2007

Fidaxomicin - Phase III Studien

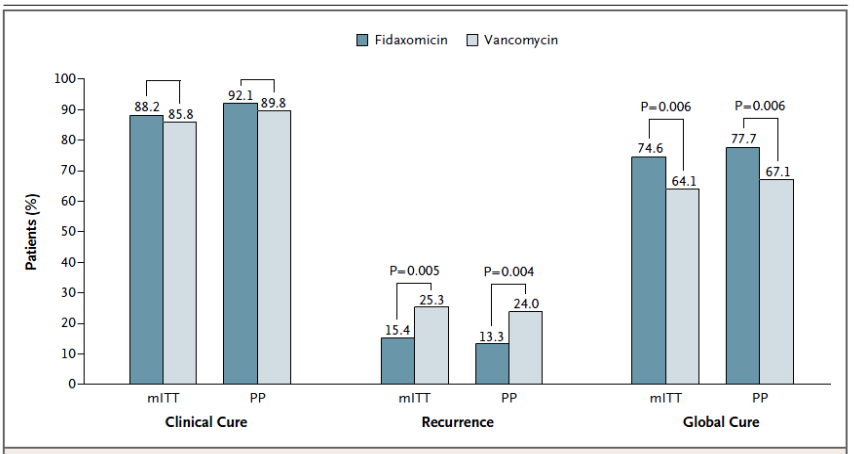
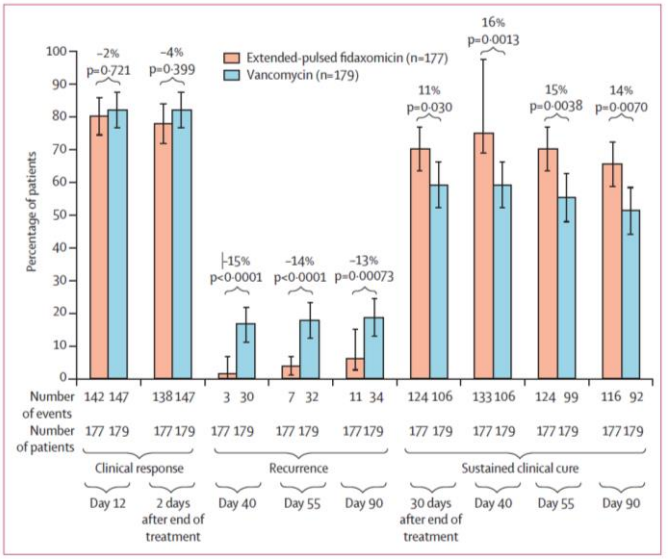


Figure 2. Rates of Primary and Secondary End Points.
For the primary outcome of clinical cure, the lower boundary of the 97.5% confidence interval for the difference in cure rates between fidaxomicin and vancomycin was –3.1 percentage points in the modified intention-to-treat (mITT) analysis and –2.6 percentage points in the per-protocol (PP) analysis.

Louie TJ et al. NEJM 2011

Prolongierte Anwendung von Fidaxomicin



Extended-pulsed fidaxomicin versus vancomycin for *C. difficile* infection in patients 60 years and older (EXTEND): a randomised, controlled, open-label, phase 3b/4 trial

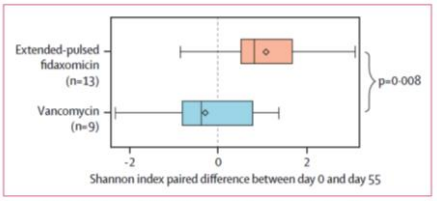


***Figure 3:* Distribution of shift in Shannon index of faecal microbiota α diversity from day 0 to day 55**
Paired comparison of mean (SD) α diversity from day 0 to day 55 for extended-pulsed fidaxomicin was 1·08 (0·96), p=0·0015, and for vancomycin was -0·29 (1·25), p=0·5056. Box shows 25–75th percentile, vertical line shows median, and diamond shows mean. Whiskers show range.

Guery B et al. Lancet Infect Dis 2017

Contents lists available at ScienceDirect

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journal homepage: www.clinicalmicrobiologyandinfection.com

Original article

Use of intravenous tigecycline in patients with severe *Clostridium difficile* infection: a retrospective observational cohort study

B. Gergely Szabo [1, 2, *], B. Kadar [1, 2], K. Szidonia Lenart [1, 2], B. Dezsenyi [1, 2], P. Kunovszki [3], K. Fried [1], K. Kamotsay [4], R. Nikolova [4], G. Prinz [1]

[1] *1st Department of Infectology, Joined Saint Stephan and Saint Ladislaus Hospital–Clinic, Budapest, Hungary*
[2] *Departmental Group of Infectology, 2nd Department of Internal Medicine, Semmelweis University, Budapest, Hungary*
[3] *Budapest University of Technology and Economics, Budapest, Hungary*
[4] *Core Microbiology Laboratory, Joined Saint Stephan and Saint Ladislaus Hospital–Clinic, Budapest, Hungary*

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tigecycline

ABSTRACT

There are only a limited number of antimicrobials for treating severe *Clostridium difficile* infection (sCDI). Tigecycline shows significant *in vitro* effect against *C. difficile* and is approved for management of complicated intra-abdominal infections. Our aim was to analyse the efficacy of tigecycline compared with standard therapy (oral vancomycin plus intravenous metronidazole) in adults treated for sCDI. A retrospective cohort study of such patients hospitalized at our department from January 2014 to December 2015 was performed. Patients receiving tigecycline monotherapy were compared with patients treated with standard therapy alone. Diagnosis and severity of CDI were determined according to guidelines of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID). Primary outcome was clinical recovery, secondary outcomes were in-hospital and 90-day all-cause mortality and relapse, colectomy, and complication rates. Of the 359 patients hospitalized for sCDI, 90 (25.0%) were included, 45 in each group. Patients treated with tigecycline had significantly better outcomes of clinical cure (34/45, 75.6% vs. 24/45, 53.3%; p 0.02), less complicated disease course (13/45, 28.9% vs. 24/45, 53.3%; p 0.02), and less CDI sepsis (7/45, 15.6% vs. 18/45, 40.0%; p 0.009) compared with patients receiving standard therapy. Tigecycline usage was not associated with adverse drug reactions or need for colectomy. Rates of ileus, toxic megacolon, mortality, and relapse were similar between the two groups. Favourable outcomes suggest that tigecycline might be considered as a potential candidate for therapeutic use in cases of sCDI refractory to standard treatment.

Szabo BG et al. Clin Microbiol Infect 2016; 22: 990-5

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Letter to the Editor

Intravenous metronidazole for fulminant *Clostridioides difficile* infection

Giuseppe Pipitone [1, *], Guido Granata [2], Massimo Sartelli [3], Andrea Gizzi [1, 4], Claudia Imburgia [1], Antonio Cascio [4], Chiara Iaria [1]

[1] *Infectious Disease Unit, Azienda di Rilievo Nazionale ad Alta Specializzazione Civico-Di Cristina, Palermo, Italy*
[2] *Clinical and Research Department for Infectious Diseases, Istituto Nazionale per le Malattie Infettive Lazzaro Spallanzani Istituto di Ricerca e Cura a Carattere Scientifico, Rome, Italy*
[3] *Department of Surgery, Macerata Hospital, Macerata, Italy*
[4] *Infectious Disease Unit, University Hospital Paolo Giaccone, Palermo, Italy*

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Bezlotoxumab for Prevention of Recurrent *Clostridium difficile* Infection

M.H. Wilcox, D.N. Gerding, I.R. Poxton, C. Kelly, R. Nathan, T. Birch, O.A. Cornely, G. Rahav, E. Bouza, C. Lee, G. Jenkin, W. Jensen, Y.-S. Kim, J. Yoshida, L. Gabryelski, A. Pedley, K. Eves, R. Tipping, D. Guris, N. Kartsonis, and M.-B. Dorr, for the MODIFY I and MODIFY II Investigators*

ABSTRACT

BACKGROUND

Clostridium difficile is the most common cause of infectious diarrhea in hospitalized patients. Recurrences are common after antibiotic therapy. Actoxumab and bezlotoxumab are human monoclonal antibodies against *C. difficile* toxins A and B, respectively.

METHODS

We conducted two double-blind, randomized, placebo-controlled, phase 3 trials, MODIFY I and MODIFY II, involving 2655 adults receiving oral standard-of-care antibiotics for primary or recurrent *C. difficile* infection. Participants received an infusion of bezlotoxumab (10 mg per kilogram of body weight), actoxumab plus bezlotoxumab (10 mg per kilogram each), or placebo; actoxumab alone (10 mg per kilogram) was given in MODIFY I but discontinued after a planned interim analysis. The primary end point was recurrent infection (new episode after initial clinical cure) within 12 weeks after infusion in the modified intention-to-treat population.

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Wilcox at the Division of Microbiology, Old Medical School, Leeds General Infirmary, Leeds LS1 3EX, United Kingdom, or at mark.wilcox@nhs.net.

*A complete list of investigators in the MODIFY I and MODIFY II trials is provided in the Supplementary Appendix, available at NEJM.org.

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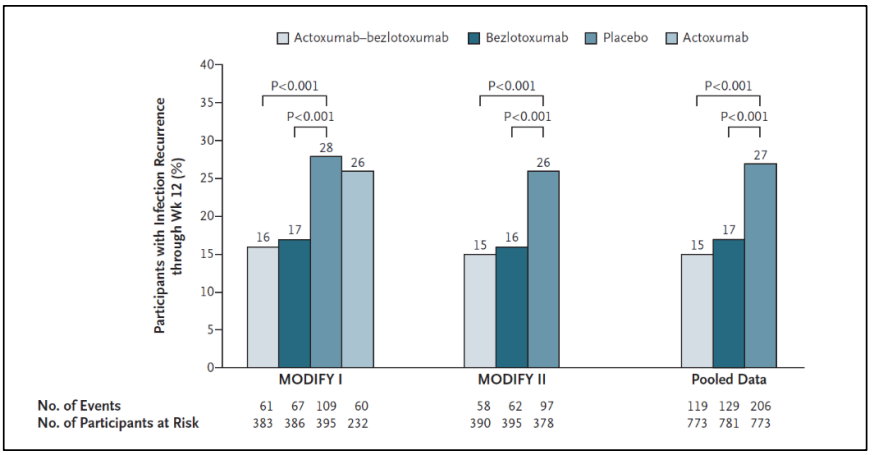


Wilcox MH et al. NEJM 2017; 376: 305-17

Koloskopischer Mikrobiomtransfer

- Protokoll am Uniklinikum Leipzig -

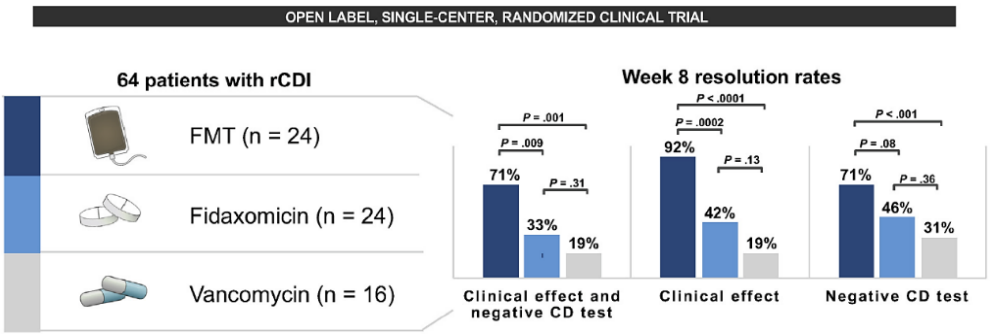
Materialpräparation

Koloskopische Applikation

Welches Verfahren ist wie effektiv?

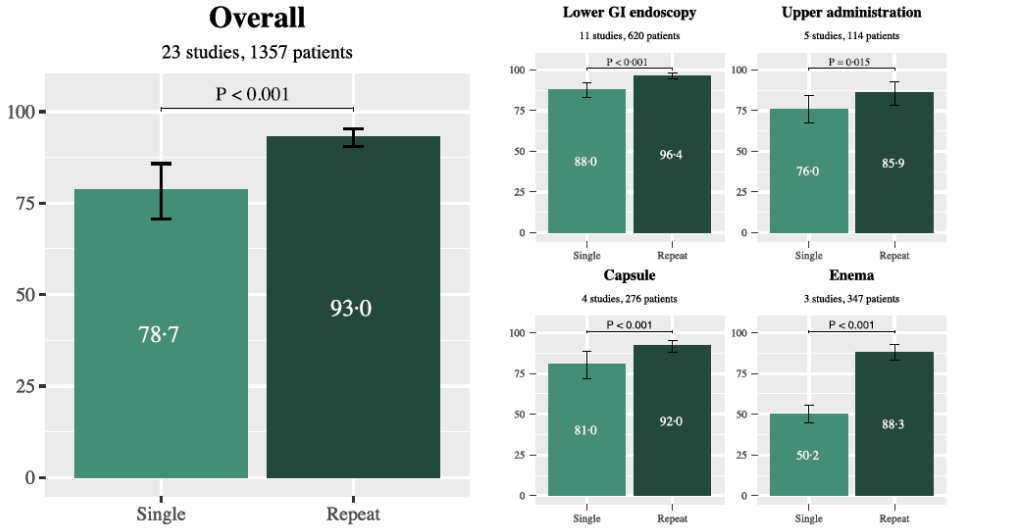
FMT vs. Fidaxomicin vs. Vancomycin bei rekurrenter CDI

Setting: Universitätsklinikum Aarhus (Dänemark)



Lodberg Hvas C et al. Gastroenterology 2019

Welches FMT-Verfahren ist wie effektiv?



Baunwall SMD et al. EClinicalMedicine 2020

Was bewirken Leitlinien?

Impact der US-amerikanischen Guideline zu CDI – Update 2017

Open Forum Infectious Diseases

MAJOR ARTICLE

Impact of Updated Clinical Practice Guidelines on Outpatient Treatment for *Clostridioides difficile* Infection and Associated Clinical Outcomes

Erik R. Dubberke,[1] Justin T. Puckett,[2] Engels N. Obi,[3] Sachin Kamal-Bahl,[2] Kaushal Desai,[3] Bruce Stuart,[4] and Jalpa A. Doshi[5,6]

[1]Division of Infectious Diseases, Washington University School of Medicine, St Louis, Missouri, USA, [2]COVIA Health Solutions, Lansdale, Pennsylvania, USA, [3]Merck & Co, Inc, Rahway, New Jersey, USA, [4]School of Pharmacy, University of Maryland, Baltimore, Maryland, USA, [5]Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA, and [6]Leonard Davis Institute of Health Economics, Philadelphia, Pennsylvania, USA

Dubberke ER et al. Open Forum Infect Dis 2022

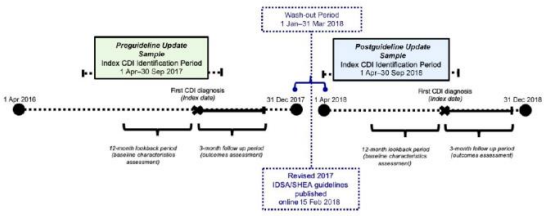


Figure 1. Sample selection schematic. Abbreviations: CDI, *Clostridioides difficile* infection; IDSA/SHEA, Infectious Diseases Society of America/Society for Healthcare Epidemiology of America.

Table 2. Unadjusted Clinical Outcomes, Pre– Versus Post–Guideline Update, Among Medicare Beneficiaries With Initial or Recurrent CDI Episode

	Pre		Post		
Outcome	No.	(%)	No.	(%)	*P* Value
Initial CDI episode					
All patients with initial CDI episode	7389	…	7746	…	
Sustained response (4 wk)	4205	(56.9)	4247	(54.8)	.01
Sustained response (8 wk)	3907	(52.9)	3861	(49.8)	.0002
Among patients with a clinical resolution	6097	…	6415	…	
CDI recurrence (4 wk)	1892	(31.0)	2168	(33.8)	.001
CDI recurrence (8 wk)	2190	(35.9)	2554	(39.9)	<.0001
Recurrent CDI episode					
All patient with recurrent CDI episode	779	…	837	…	
Sustained response (4 wk)	447	(57.4)	437	(52.2)	.0369
Sustained response (8 wk)	415	(53.3)	391	(46.7)	.0084
Among patients with a clinical resolution	663	…	671	…	
CDI recurrence (4 wk)	216	(32.6)	234	(34.9)	.3756
CDI recurrence (8 wk)	248	(37.4)	280	(41.7)	.1064

CDI recurrence was calculated only among patients with evidence of clinical resolution. *P* values are based on χ^2 test.
Abbreviation: CDI, *Clostridioides difficile* infection.

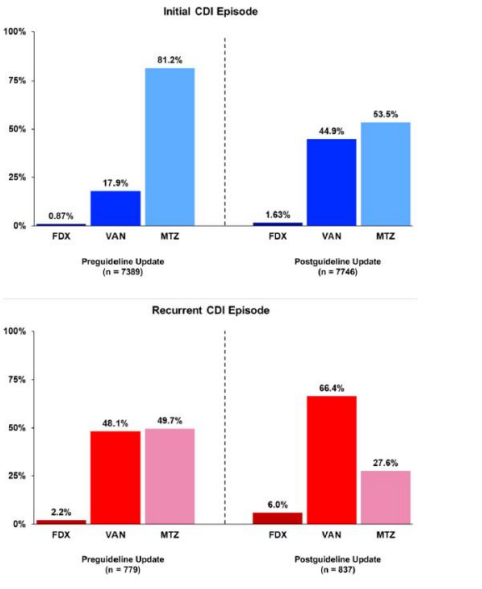


Figure 2. First-line use of *Clostridioides difficile* infection (CDI) treatments, pre– vs post–guideline update, among Medicare beneficiaries with an initial or recurrent CDI episode. *P* < .001 for all results, based on χ^2 test. Abbreviations: CDI, *Clostridioides difficile* infection; FDX, fidaxomicin; MTZ, metronidazole; VAN, vancomycin.

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Vielen Dank für Ihre Aufmerksamkeit!

christoph.luebbert@medizin.uni-leipzig.de