Agency for Healthcare Research and Quality
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NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Therapeutic drug monitoring of vancomycin: a guideline of the Division of Therapeutic Drug Monitoring, Chinese Pharmacological Society.

Bibliographic Source(s)

Ye ZK, Chen YL, Chen K, Zhang XL, Du GH, He B, Li DK, Liu YN, Yang KH, Zhang YY, Zhai SD. Therapeutic drug monitoring of vancomycin: a guideline of the Division of Therapeutic Drug Monitoring, Chinese Pharmacological Society. Beijing (China): Chinese Pharmacological Society; 2015 Sep 18. 24 p. [24 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the level of evidence (A-D) and strength of recommendation (1, 2) are provided at the end of the "Major Recommendations" field.

What Is the Indication of Vancomycin Therapeutic Drug Monitoring (TDM)?

Recommendation 1: TDM should be performed in patients who receive concomitant nephrotoxic agents, who are admitted to intensive care units (ICUs) or are obese, and those who have burns or impaired renal function. (1C)

Recommendation 2: TDM should be performed in elderly patients and patients with concomitant hepatic diseases. (2C)

Which Variables Should Be Used to Monitor Vancomycin Efficacy and Renal Safety?

Recommendation 3: Trough serum vancomycin concentrations should be monitored to ensure vancomycin efficacy and renal safety. (1C)

What Is the Target Trough Concentration of Vancomycin?

Recommendation 4: Trough serum vancomycin concentrations should be maintained at 10-15 mg/L in adult patients. (1C)

Recommendation 5: Trough serum vancomycin concentrations should be maintained at 10-20 mg/L in adult patients with serious methicillin-resistant *Staphylococcus aureus* (MRSA) infections. (2C)

When to Start Initial Vancomycin TDM?

Recommendation 6: Initial vancomycin TDM should be started on day 3 (48 hours since initiation of vancomycin therapy) for patients with normal renal function. (2D)

Recommendation 7: Initial vancomycin TDM should be started after 72 hours of vancomycin therapy for patients with impaired renal function. (1B)

How Should the Vancomycin Dose Be Administered and Adjusted?

Recommendation 8: Vancomycin dosage should be administered and adjusted individually based on population pharmacokinetic method. (2D)

Is an Initial Loading Dose Needed?

Recommendation 9: An initial loading dose should be given for adult patients with serious MRSA infections. (2D)

Definitions

Level of Evidence and Strength of Recommendation Using Grading of Recommendations Assessment, Development and Evaluation (GRADE) Approach

	Strong Recommendation (1)	**Weak Recommendation (2)**
High Quality (A)	Recommendation can apply to most patients in most circumstances. Further research is very unlikely to change confidence in the estimate of effect.	The best action may differ depending on circumstances or patients or societal values. Further research is very unlikely to change confidence in the estimate of effect.
Moderate Quality (B)	Recommendation can apply to most patients in most circumstances. Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.	Alternative approaches likely to be better for some patients under some circumstances. Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Low Quality (C)	Recommendation may change when higher-quality evidence becomes available. Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.	Other alternatives may be equally reasonable. Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Very Low Quality (D)	Recommendation may change when higher-quality evidence becomes available. Any estimate of effect is very uncertain.	Other alternatives may be equally reasonable. Any estimate of effect is very uncertain.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Gram-positive bacterial infections, including methicillin-resistant *Staphylococcus aureus* (MRSA) infection

Guideline Category

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Critical Care

Geriatrics

Infectious Diseases

Internal Medicine

Pharmacology

Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Pharmacists

Physician Assistants

Physicians

Guideline Objective(s)

- To develop an evidence based guideline for vancomycin therapeutic drug monitoring (TDM) using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach
- To promote standardized vancomycin TDM in clinical practice

Target Population

Patients treated with vancomycin

Interventions and Practices Considered

1. Indications for therapeutic drug monitoring (TDM) of vancomycin
2. Monitoring vancomycin efficacy and renal safety by measuring trough serum vancomycin concentrations
3. Maintaining target trough concentrations of vancomycin
4. Starting initial vancomycin TDM
5. Vancomycin administration and dosage adjustments
6. Administration of initial loading dose of vancomycin

Major Outcomes Considered

- Mortality rate
- Treatment efficacy rate (the rate of clinical efficacy, treatment failure or treatment success)
- Rate of nephrotoxicity
- Cost-effectiveness (return on investment for therapeutic drug monitoring [TDM])
- Proportions of the vancomycin target concentrations that are reached
- Pharmacokinetic parameters
- Length of hospital stay
- Length of vancomycin therapy

- Microbiological eradication rates

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The Guideline Development Group formulated 12 questions and associated PICOs (population, intervention, comparator, outcomes). The following is general search information from the guideline's protocol. Refer to the full systematic reviews and meta-analyses in the "Availability of Companion Documents" field for specific search information and results.

Evidence Retrieval and Synthesis

Databases Searched

The literature was systematically searched (until January 16, 2014) in PubMed, EMBASE, the Cochrane Library and three Chinese literature databases (CNKI, CBM and WanFang).

Search Terms

The search terms were a combination of text free terms and Medical Subject Headings (MeSH) terms such as "Vancomycin". The group also used the search terms "human" in PubMed and "human and (case report or clinical article or clinical protocol or clinical trial or cohort analysis or comparative study or controlled clinical trial or controlled study or major clinical study or medical record review or meta-analysis or multicenter study or observational study or outcomes research or practice guideline or prospective study or randomized controlled trial or retrospective study or systematic review) and (article or article in press or conference paper or conference review or review or short survey) and (bacteremia or bacterial endocarditis or bacterial infection or bacterial meningitis or catheter infection or diarrhea or endophthalmitis or fever or hospital infection or infection or kidney failure or methicillin resistant staphylococcus aureus infection or nephrotoxicity or neutropenia or osteomyelitis or pneumonia or postoperative infection or sepsis or side effect or skin infection or staphylococcus infection or urinary tract infection)" in EMBASE.

Pilot Search

To ensure the consistency of the literature selection standards, the authors of the systematic reviews conducted a pre-test. They randomly selected 64 bibliographical references for the pre-test. By summarizing the results of the literature selection and discussing the inconsistencies, all of the authors had a definite understanding of the inclusion and exclusion criteria.

Literature Selection

A total of 67,406 studies were identified, of which 21,621 were duplicate articles. After excluding 44842 studies that were not relevant using the titles and abstracts, 943 studies were included for full-text reading. Sixteen pharmacists, who were divided into 8 groups, performed the literature selection and reading.

Number of Source Documents

Refer to the individual systematic reviews and meta-analyses (see the "Availability of Companion Documents" field) for a detailed breakdown of the number of studies included and excluded and reasons for exclusion.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Not Given)

Rating Scheme for the Strength of the Evidence

The guideline development group used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to rate the quality of evidence.

Methods Used to Analyze the Evidence

Meta-Analysis

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The following is general information from the guideline's protocol. Refer to the full systematic reviews and meta-analyses in the "Availability of Companion Documents" field for specific information.

Evidence Assessment

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was used to assess the quality of a body of evidence and to develop and report recommendations. According to the GRADE approach, the quality of evidence is categorized as high, moderate, low or very low. Randomized controlled trials are categorized as high-quality evidence, and observational studies are categorized as low-quality evidence. The assessment of evidence was conducted across studies on an outcome-by-outcome basis. The guideline methodologists were responsible for quality assessment, drafting the evidence summaries and presenting these summaries at the Guideline Development Group meeting.

Patients' Values and Preferences

Patients' values and preferences were investigated regarding vancomycin therapeutic drug monitoring (TDM). The results of the investigation were analyzed and considered by the Guideline Steering Group and the Guideline Development Group when the recommendations were formulated. See *Values and Preferences in Therapeutic Drug Monitoring of Vancomycin in Infectious Patients* (see the "Availability of Companion Documents" field) for a detailed description of the survey and results.

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

The guideline was launched at the Chinese Third Annual Conference of Therapeutic Drug Monitoring (TDM) in Shanghai by the Peking University TDM and Clinical Toxicology Center and the Division of Therapeutic Drug Monitoring, Chinese Pharmacological Society in July 2013. Methodological support was provided by the Chinese GRADE (Grading of Recommendations Assessment, Evaluation and Development) Center.

Guideline Development Group and Guideline Steering Group

The Guideline Development Group, the Guideline Steering Group, and the Guideline Secretary Group were established in July 2013. To ensure fair representation by gender and region, the Guideline Development Group consists of 30 members from multiple fields of subjects, as follows: 17 clinical pharmacists, 2 respiratory physicians, 1 infectious diseases physician, 2 evidence-based medical experts, 2 medical laboratory scientists, 2 microbiologists, 1 pharmacologist, and 1 pharmacoeconomist, 1 pediatric physician and 1 nurse. The mission of the Guideline Development Group is as follows: (1) to define the scope of the guideline, draft the PICOs (Population, Intervention, Comparison, Outcome) and choose and rate the outcomes; (2) to grade the quality of the evidence; (3) to draft preliminary recommendations; (4) to write the draft guideline; and (5) to publish and promote the guideline. The Guideline Steering Group consists of 8 members, including 1 pharmacologist, 1 evidence-based medical expert, 3 clinical pharmacists, 2 respiratory physicians and 1 infectious diseases physician. The mission of the Guideline Steering Group is as follows: (1) to approve the PICOs; (2) to supervise the literature search and systematic reviews; (3) to check the grade of the evidence; (4) to draft the final recommendations using a modified Delphi approach; and (5) to approve the publication of the guideline. The Guideline Secretary Group is responsible for conducting systematic reviews and investigation of patients' views and preferences.

Formulating Questions and Choosing Outcomes

After its proposal by the Guideline Development Group and approval by the Guideline Steering Group, the PICOs were finalized. The Guideline Development Group chose the outcomes and rated them by their importance. The scores of the outcomes ranged from 1-9; on this scale, 7-9 is considered critical, 4-6 is important, and 1-3 is not important. For this guideline, the mortality rate, the treatment efficacy rate (the rate of clinical efficacy, treatment failure or treatment success) and the rate of nephrotoxicity are considered critical; the cost-effectiveness and the proportions of the vancomycin target concentrations that are reached are considered important; and the pharmacokinetic parameters (the half-life, volume of distribution, clearance and area under curve [AUC]), trough concentrations, the length of hospital stay, the length of vancomycin therapy and the microbiological eradication rates are considered not important.

The 12 questions and associated PICOs are listed in the guideline protocol document (see the "Availability of Companion Documents" field).

Developing Recommendations

After completion of the GRADE evidence profile, the Guideline Development Group drafted preliminary recommendations based on the quality of the evidence, the balance between the benefits and the harms, the patients' values and preferences and the health resources. The Guideline Development Group developed the draft recommendations through 2-4 rounds of the Delphi process and submitted the draft recommendations to the Guideline Steering Group for final approval. The group referred to the GRADE Grid to reach consensus. Five choices, including "Strong recommendation", "Weak recommendation", "Unclear recommendation", "Weak disrecommendation", and "Strong disrecommendation" were used for each draft item on the questionnaire. For each item, if more than 50% of the experts voted for any choice except the "unclear" one or if more than 70% of the experts voted for one of the 2 choices on the same side, this meant that consensus on the item had been reached. Otherwise, the item was deemed controversial and would need one more round of the Delphi process.

Rating Scheme for the Strength of the Recommendations

Level of Evidence and Strength of Recommendation Using Grading of Recommendations Assessment, Development and Evaluation (GRADE) Approach

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Very Low Quality (D)	Recommendation may change when higher-quality evidence becomes available. Any estimate of effect is very uncertain.	Other alternatives may be equally reasonable. Any estimate of effect is very uncertain.

Cost Analysis

See *Economic Evaluation of Vancomycin Therapeutic Drug Monitoring: a Systematic Review* (see the "Availability of Companion Documents" field), which reviewed five previously published economic studies. Three studies reported cost-effectiveness analyses and two were cost-benefit analyses. Two studies calculated the incremental cost-effectiveness of vancomycin therapeutic drug monitoring (TDM). The review concluded that whether vancomycin TDM has economic advantages depends on the patients' preexisting renal function and their comorbid conditions. Patients with a higher risk of vancomycin-induced nephrotoxicity may benefit from TDM from an economic perspective; however, the available evidence is of low quality. Additionally, well-designed economic evaluation studies are needed to further inform the value of TDM.

The economic evaluation showed that vancomycin TDM was cost effective for intensive care unit (ICU) patients and patients receiving concomitant nephrotoxic agents.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The formulated recommendations were submitted to 40 experts, including clinicians, pharmacists and nurses from 4 hospitals for external review. The external reviewers were not involved in the development of the guideline. The draft guideline was uploaded to the home page of the Division of Therapeutic Drug Monitoring, Chinese Pharmacological Society. The response of the external reviewers was collected for the Guideline Steering Group. The Steering Group discussed the response in a meeting and revised the recommendations based on their response.

The guideline was approved by the Division of Therapeutic Drug Monitoring, Chinese Pharmacological Society and released on September 18, 2015.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence for each recommendation is identified and graded (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Studies to date show that therapeutic drug monitoring (TDM) significantly increases the rate of clinical efficacy and decreases the rate of nephrotoxicity in patients treated with vancomycin who have gram-positive infections.
- Routine monitoring of serum vancomycin concentrations may be particular useful for patient at the greatest risk of altered vancomycin pharmacokinetics.

Potential Harms

Vancomycin has been associated with a number of adverse effects, including nephrotoxicity, infusion-related toxicities and possible ototoxicity.

Qualifying Statements

Qualifying Statements

- The most important barrier to the implementation of this guideline is the lack of available equipment to determine trough concentrations, particularly in undeveloped areas.
- The guideline developers recommend that vancomycin dosage should be administered and adjusted individually based on population pharmacokinetic methods, the model of which, however, has not been established in most hospitals.

Implementation of the Guideline

Description of Implementation Strategy

Promotion, Implementation and Evaluation of the Guideline

After the guideline is published, it will be promoted by the Division of Hospital Pharmacy, Chinese Pharmaceutical Association, and the Division of Therapeutic Drug Monitoring, Chinese Pharmacological Society in the following ways: 1) the guideline will be presented at conferences relating to therapeutic drug monitoring (TDM) or infectious diseases for 3 years; 2) a learning session for the guideline will be organized for physicians, pharmacists and nurses in China; 3) members of the Guideline Steering Group and the Guideline Development Group will write journal articles related to the guideline; and 4) the Chinese version of the guideline will be placed on popular Chinese-language medical Web sites.

Research will be conducted to evaluate the impact of the guideline on vancomycin TDM in China, and the implementation of the guideline will be assessed 3 years after its publication.

Implementation Tools

Foreign Language Translations

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Ye ZK, Chen YL, Chen K, Zhang XL, Du GH, He B, Li DK, Liu YN, Yang KH, Zhang YY, Zhai SD. Therapeutic drug monitoring of vancomycin: a guideline of the Division of Therapeutic Drug Monitoring, Chinese Pharmacological Society. Beijing (China): Chinese Pharmacological Society; 2015 Sep 18. 24 p. [24 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015 Sep 18

Guideline Developer(s)

Division of Therapeutic Drug Monitoring, Chinese Pharmacological Society - Medical Specialty Society

Source(s) of Funding

This work was supported by the Division of Therapeutic Drug Monitoring, Chinese Pharmacological Society, and Open Fund of Key Laboratory of Evidence Based Medicine and Knowledge Translation of Gansu Province (grant number EBM2014003). The meeting expenses of the Guideline Steering Group and the Guideline Development Group were partly funded by Zhejiang Medicine Co., Ltd., Xinchang Pharmaceutical Factory and Eli Lilly China. The guideline developers guarantee that pharmaceutical sponsors were not involved in guideline development, and guideline development was not influenced by pharmaceutical sponsors. Members of the Guideline Steering Group, the Guideline Development Group, and the Guideline Secretary Group did not have contact with pharmaceutical sponsors.

Guideline Committee

Guideline Steering Group

Guideline Development Group

Guideline Secretary Group

Composition of Group That Authored the Guideline

Guideline Steering Group: Guan-Hua Du, Research Fellow, Deputy Director, Institute of Materia Medica, Chinese Academy Medical Institute of Medical Sciences; Bei He, Professor, Director, Department of Respiratory Medicine, Peking University Third Hospital; Da-Kui Li, Professor, Director, Pharmacy Department, Peking Union Medical College Hospital; You-Nin Liu, Professor, Director, Institute of Respiratory Disease, Chines PLA General Hospital; Ke-Hu Yang, Professor, Director, Evidence Based Medicine Center of Lanzhou University; Xiang-Lin Zhang, Chief Pharmacist, Deputy Director, Pharmaceutical Department of China-Japan Friendship Hospital; Ying-Yuan Zhang, Professor, Deputy Director, Institute of Antibiotics, Huashan Hospital Affiliated to Fudan University; Suo-Di Zhai, Professor, Director, Pharmacy Department of Peking University Third Hospital

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Guideline Secretary Group: Zhi-Kang Ye; Ken Chen; Peng Men; Jun-Wen Zhou; Qian-Ru Dong; Ran Xie; Rui Jiao; Yang Xu; Xi-Lan Zhao; Jing-Yi Xue

Financial Disclosures/Conflicts of Interest

All members of Guideline Steering Group, Guideline Development Group and Guideline Secretary Group were required to disclose the potential conflicts of interests, which were reviewed by the chairs. No relevant conflicts of interest were found.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available in English and Chinese from the Division of Therapeutic Drug Monitoring, Chinese Pharmacological Society Web site.

Availability of Companion Documents

The following systematic reviews are available:

- Economic evaluation of vancomycin therapeutic drug monitoring: a systematic review. Beijing (China): Chinese Pharmacological Society; 2015. 18 p.
- Benefits of therapeutic drug monitoring of vancomycin: a systematic review and meta-analysis. PLoS ONE. 2013 Oct;8(10):1-10.
- The relationship between vancomycin trough serum concentrations and clinical outcomes: a systematic review and meta-analysis. Beijing (China): Chinese Pharmacological Society; 2015. 21 p.
- Guidelines for therapeutic drug monitoring of vancomycin: a systematic review. PLoS ONE. 2014 Jun;9(6):1-8.

Available from the Division of Therapeutic Drug Monitoring, Chinese Pharmacological Society Web site. Additional systematic reviews are also available in Chinese.

The following are also available:

- A protocol for developing a clinical practice guideline for therapeutic drug monitoring of vancomycin. Beijing (China): Chinese Pharmacological Society; 2015. 24 p.
- Association between the AUC_{0-24}/MIC ratio of vancomycin and its clinical effectiveness: a systematic review and meta-analysis. PLoS ONE. 2016 Jan 5;11(1):1-11.
- GRADE evidence profile and summary of finding. Beijing (China): Chinese Pharmacological Society; 2015. 9 p.
- Values and preferences in therapeutic drug monitoring of vancomycin in infectious patients. Beijing (China): Chinese Pharmacological Society; 2015. 8 p.

Available from the Division of Therapeutic Drug Monitoring, Chinese Pharmacological Society Web site.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on June 28, 2016. The information was verified by the guideline developers on July 19,

2016.

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