

Canada Communicable Disease Report



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EVIDENCE-BASED MEDICINE

Clinical practice guidelines are an important product of the National Committee to Advise on Tropical Medicine and Travel (CATMAT). Recent guidelines have been published on the guiding principles for clinical practice guidelines⁽¹⁾. The ninth principle states, "Clinical practice guidelines should:

- (a) *cite the specific evidence bearing upon the conclusion*
- (b) *indicate the strength of the evidence*
- (c) *specify the date of the most recent evidence considered"*.

In this issue of CDR, we are publishing CATMAT's statement on evidence-based medicine, and the scales used to grade its recommendations.

Evidence-based medicine represents a major paradigm shift in the manner in which expert committees will be generating recommendations for the clinical management of patients. Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research⁽²⁾.

Non-experimental evidence, from the recalled experiences of clinicians or other experts, will tend to over-estimate the efficacy of a therapy or other intervention for several reasons⁽³⁾:

1. Favourable outcomes are more likely to be recognized and remembered by clinicians when their patients comply with management recommendations and keep their follow-up appointments. As high compliance is a marker for better outcomes, even when treatment is useless, uncontrolled clinical experiences may cause us to conclude that

compliant patients must have been receiving efficacious therapy^(4,5).

2. Unusual patterns of symptoms or signs and extreme laboratory test results will tend to return toward the more usual, normal result⁽⁶⁾. As a result, any therapy initiated in the between test period will appear more efficacious than it really is.
3. Routine clinical practice is never "blind", and both patients and their clinicians know when active treatment is being received. Again, the desire of patients and clinicians for success, and the placebo effect, can cause both parties to over-estimate efficacy.

The role of evidence-based medicine is not to discount expert opinion, but whenever possible to permit recommendations to be based on the results of rigorous, controlled scientific studies. When such studies have not been performed, and may never be done, this approach allows the recommendations to be much more circumspect.

By describing the strength of each recommendation and providing the quality of evidence on which the recommendation is made, the reader will be in a better position to apply the recommendations to the individual patient. Two recent publications have taken this approach to clinical guidelines^(3,7).

When possible, the recommendations of CATMAT will follow this format (Table 1). The categories for strength of each recommendation will range from category A (good evidence to support a recommendation for use), through category C (poor evidence to support a recommendation for or against use) to category E (good evidence to support a recommendation against

use). Each strength category will be followed by a grade indicating the quality of evidence on which the recommendation was made. Grade I will be evidence from at least one properly randomized controlled trial and grade III will be evidence from the opinions of respected authorities on the basis of clinical experience, descriptive studies, or reports of expert committees.

An example of this approach follows with the two CATMAT statements in this issue of CCDR.

Table 1 Strength and quality of evidence summary sheet*	
Categories for strength of each recommendation	
CATEGORY	DEFINITION
A	Good evidence to support a recommendation for use.
B	Moderate evidence to support a recommendation for use.
C	Poor evidence to support a recommendation for or against use.
D	Moderate evidence to support a recommendation against use.
E	Good evidence to support a recommendation against use.
Categories for quality of evidence on which recommendations are made	
GRADE	DEFINITION
I	Evidence from at least one properly randomized, controlled trial.
II	Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies, preferably from more than one centre, from multiple time series, or from dramatic results in uncontrolled experiments.
III	Evidence from opinions of respected authorities on the basis of clinical experience, descriptive studies, or reports of expert committees.
* Adapted from Reference 7.	

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Source: DW MacPherson, MD, Regional Parasitology Laboratory, St. Joseph's Hospital, Hamilton, and Chairman, CATMAT.

Editorial Note: For your interest and additional reading on this subject, the Canadian Medical Association Journal (CMAJ) recently published a five-part series on evidence-based care from the Evidence-Based Care Resource Group at McMaster University. The five articles deal with setting priorities, setting guidelines, measuring performance, improving performance, and lifelong learning. These articles appeared in consecutive issues of CMAJ from 15 April to 15 June, 1994.

Committee To Advise on Tropical Medicine and Travel (CATMAT)*

STATEMENT ON TRAVELLERS AND HIV/AIDS

The Traveller with HIV Infection or AIDS

Preparing an HIV-infected individual for international travel requires attention to a number of important issues which, for the most part, are similar to those that must be faced by any immunocompromised traveller. These considerations include the following: 1) restrictions for crossing international borders; 2) vaccination requirements and their effectiveness and safety; 3)

susceptibility to infections present at the destination; and 4) accessibility of health care overseas and the possible need for medical evacuation home.

Restrictions for Crossing International Borders

At least 50 countries, particularly in Eastern Europe and the middle east, currently restrict the entry of travellers with HIV

* Members:

Dr. S. Dumas; Dr. G. Horsman; Dr. C.W.L. Jeanes; Dr. J.S. Keystone; Ms. S. Ladouceur (Advisory Committee Secretariat Officer); Dr. J.D. MacLean; Dr. D.W. MacPherson (Chairman); Dr. R. Saginur; Dr. D. Scheifele (NACI); Mrs. R. Wilson (CUSO).

Ex-Officio Members:

Dr. M. Davies (HPB); Dr. E. Gadd (HPB); Dr. H. Lobel (CDC); Dr. S. Mohanna (MSB); LCol. M.L. Tepper (DND); Dr. M. Tipple (CDC).

infection or AIDS and insist on HIV antibody testing for foreigners as a requirement for entry. These regulations apply mostly to students, workers and others applying for long-term entry permits although, in a few countries, visitors staying for periods as short as 2 weeks are required to be tested. Some countries insist on HIV testing after arrival and will not accept the results of testing done elsewhere. With respect to HIV infection, a list of entry requirements for crossing international borders may be obtained from Tropical Health and Quarantine, Laboratory Centre for Disease Control, Health Canada (telephone 613-954-3236; fax 613-954-5414).

Vaccination Requirements, Safety and Efficacy

The benefits and risks of immunization for international travel need to be carefully considered in individuals infected with HIV. Live viral vaccines, such as yellow fever, mumps, measles, rubella, and oral typhoid, may be given to asymptomatic HIV-infected individuals with normal lymphocyte counts if they are at risk for the disease, but should be avoided in patients with AIDS or low lymphocyte counts. If a specific vaccine, such as the live viral vaccine for yellow fever, is required for entry into a country, a medical exemption from immunization may be given. However, in high-risk situations a live vaccine may still be indicated. It should be noted that the effectiveness of vaccination may be reduced in HIV-infected individuals, especially in those with AIDS. Other means of protection against infection should always be vigorously employed, such as insect repellents and very strict food and water precautions. If health risks cannot be reduced to acceptable levels, alterations in the travel plan may be necessary.

Susceptibility to Infection

Many infections encountered by travellers are associated with increased morbidity and mortality in HIV-infected persons. These individuals are also more likely to have adverse reactions to drugs used to treat infection.

Gastrointestinal pathogens pose the greatest threat to HIV-infected travellers. Achlorhydria, common in patients with AIDS, allows a smaller inoculum of ingested enteric organisms to establish disease. Although enterotoxigenic *Escherichia coli* is the most commonly identified cause of travellers' diarrhea, it does not appear to cause more severe infection in immunocompromised hosts. *Shigella*, *Salmonella*, *Campylobacter*, *Cryptosporidium* and *Isospora* infections are associated with more severe and persistent diarrheal illness in HIV-infected persons. In addition, disseminated infection is well documented in salmonellosis. Because of the increased risk of infection and morbidity from bacterial pathogens, continuous antibiotic prophylaxis for

travellers' diarrhea should be considered for HIV-infected persons travelling for short periods (< 3 weeks).

Respiratory infections, most notably tuberculosis, are a threat to HIV-infected persons. Tuberculosis is low risk for the short-term traveller; the risk increases with the duration of travel. Although morbidity from influenza itself does not increase, bacterial infections that complicate influenza are more severe in HIV-infected persons. Measles, another vaccine-preventable disease, may be severe and occasionally fatal in an HIV-infected person. Progressive, disseminated infection may follow primary exposure to histoplasmosis or coccidioidomycosis during travel to endemic areas.

Several vector-borne diseases may be associated with more severe illness in HIV-infected individuals. Recent reports describe visceral leishmaniasis and Chagas disease as new opportunistic infections in AIDS patients. Theoretically, babesiosis and yellow fever are likely to be more severe in an immunocompromised host. Although malaria is the greatest vector-borne threat to the traveller, it does not appear to be more severe in the HIV-infected person.

Access to Health Care

If the health of an HIV-infected person should deteriorate while abroad, intensive medical interventions and even evacuation may be necessary. Not only are these expensive undertakings, but accessing high quality, specialized medical care in many foreign countries may not be possible. Where medical evacuation is a possibility, the HIV-infected traveller should purchase medical insurance before departing to cover such an eventuality. The patient should be urged to obtain prompt evaluation of symptoms and early treatment of infection. Where possible, a physician knowledgeable about HIV infection should be identified at the point of destination before departing.

The most important question for the HIV-infected person who wishes to travel is: "Do the benefits of travel exceed the risks?" This must be a personal, informed decision that must be weighed carefully with the help of a health care professional who has knowledge of the patient's health status (including the CD4 lymphocyte count) and who can assess the risks associated with travel. A specific "prescription" for safe travelling can then be designed for that particular individual and itinerary.

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Committee to Advise on Tropical Medicine and Travel (CATMAT)

STATEMENT ON TRAVELLERS' DIARRHEA

Diarrhea is the most common affliction of travellers to developing countries⁽¹⁾. Although typically mild in severity, it may impact profoundly on the quality of a vacation or the success of a business trip. Concern about diarrhea may serve to deter travellers from choosing certain destinations. It is of appreciable economic impact.

Epidemiology

Whereas travel between developed countries tends to be a constipating experience, travel from developed to developing countries tends to diarrhea. The risk varies according to many factors, but is about 20% to 50% for a 2-week trip to a high-risk destination, characterized primarily by poor sanitation and usually

warm climate. Travellers' diarrhea is caused by foodborne or waterborne pathogens transmitted by the fecal-oral route.

Food

Recommendation

Travellers to high-risk destinations for diarrhea should exercise caution in selection and preparation of food and dairy products.

Strength of recommendation: C

Quality of evidence: II

Foodborne disease may be a consequence of contamination of the meat or produce at source, for example, fertilizing crops with human fecal material. It may relate to inadequate transport or storage of food, including insufficient or no refrigeration. Culturally accepted methods of food handling, cleaning of utensils, and personal hygiene vary from place to place.

Produce should be freshly peeled, or freshly cooked. Because of the possibility of fecal contamination of lettuce while it is in the field, and the difficulty of cleaning it thoroughly, raw lettuce should not be eaten. Meat should be freshly cooked, and well cooked. Rare meat, or cooked meat that is displayed on a warm surface for an indeterminate period of time should be avoided.

Food obtained from street vendors who lack both adequate sanitary facilities for themselves and refrigeration for perishable food is risky. In cholera-endemic countries, particularly those in South America bordering the Pacific Ocean, seafood and undercooked fish (e.g., ceviche, marinated raw fish) are dangerous.

Dairy products must originate from pasteurized milk and be well refrigerated or should not be ingested. Regulation of dairy herds and standards of pasteurization and storage of dairy products vary⁽²⁾.

Water

Recommendation

Travellers to high-risk destinations for diarrhea must ensure that they have a safe supply of water for drinking and brushing their teeth.

Strength of recommendation: C

Quality of evidence: II

Waterborne disease is due to fecal contamination of the water used to drink or to brush teeth. Risk of diarrhea may be reduced by careful attention to quality of water ingested. Commercially bottled water is a good source. Commercially carbonated beverages are generally safe, being slightly acidic. Beer is free of enteric pathogens. Ice cubes may represent frozen packages of enteric organisms and must be considered contaminated⁽²⁾. Rain water, properly collected and stored, may be considered fit to drink.

Water may be treated by heat, filtration, or with chemicals. Boiling water for one minute is an effective way of killing bacteria, irrespective of altitude^(3,4,5). Tea and coffee prepared from boiling water and served hot are safe drinks. Filters that work according to particle size are effective against bacteria and parasites, but not against viruses. Chemical treatment with iodine, as a liquid, crystal, or in water filters, is effective against all three types of pathogens. Chlorine, available in commercial household bleach, is effective against most pathogens, but relatively

ineffective against *Giardia lamblia* cysts. Efficacy of chlorine is diminished by particulate matter or by cold water temperatures⁽⁶⁾.

Travellers who are camping or who are on a long-term posting should be prepared to boil their water, or ensure that they carry a portable, effective water purification system, of which there are several on the market. Most short-term travellers on business or who are on organized tours or at resort hotels can effectively limit themselves to commercially bottled waters or drinks, thereby avoiding having ice cubes added to their drinks.

Etiology

Bacteria are thought to cause 80% of cases of travellers' diarrhea. The most common isolates from patients have been *Escherichia coli*, particularly enterotoxigenic strains, and *Shigella* sp. A variety of other organisms have been implicated, including *Campylobacter* sp., *Salmonellae*, vibrios, *Aeromonas*, and *Plesiomonas*. The most common protozoan agent is *G. lamblia*. Cryptosporidia and cyclospora (cyanobacteria-like agents) are unusual causes, and *Entamoeba histolytica* is rare. Viruses, notably Norwalk and rotavirus, also cause travellers' diarrhea⁽⁷⁾.

Certain agents have been associated with epidemics of diarrhea. *Vibrio cholerae* may cause epidemic or even pandemic disease, as occurred recently in South America. *Giardia* may contaminate water causing outbreaks in mountainous areas of North America ("beaver fever" [sic]) and "the Trotskys" in St. Petersburg, formerly Leningrad.

Resistance to antimicrobial agents is common in enteric isolates from developing countries⁽⁸⁾. Doxycycline can no longer be recommended for travellers' diarrhea. Resistance to tetracyclines has become rampant. There have been increasing reports of microbial resistance to trimethoprim-sulphamethoxazole (TMP-SMX). Fluoroquinolones, including ciprofloxacin and norfloxacin, are effective against all the common bacterial causes of travellers' diarrhea; however, resistant *Campylobacter* has been reported.

Therapy

Recommendation

Diarrhea must be treated with fluid replacement.

Strength of recommendation: A

Quality of evidence: I

Fluid replacement is of primary importance in managing all cases of travellers' diarrhea⁽⁹⁾. The standard of fluid management of diarrhea is the oral rehydration therapy of the World Health Organization (WHO). This can be approximated using measures outlined in Table I, or with commercial preparations. Fluids should be consumed at a rate to allay thirst and maintain a pale colour of urine.

Further therapy may be directed against bacterial toxins, bowel motility, or against the bacterial pathogens themselves. Bismuth subsalicylate antagonizes the action of a heat-labile enterotoxin produced by *V. cholerae* and certain *E. coli*⁽¹⁰⁾. It is slow to act, and frequent doses are required. If the liquid form is to be used, a large volume of it must be carried by the traveller.

Recommendation

Loperamide may be used alone to treat mild diarrhea in adults and older children (> 2 years).

Strength of recommendation: A

Quality of evidence: I

Antimotility drugs have been used in the management of diarrhea. Diphenoxylate has been associated with toxic megacolon in patients with bacillary dysentery, and is not recommended⁽¹¹⁾. Loperamide reduces duration of diarrhea in mild cases of travellers' diarrhea in adults⁽¹²⁾. However, it may cause intestinal pooling of the fecal stream in young children with diarrhea, making it difficult to estimate the required volume of fluid replacement.

Recommendation

Loperamide may be used as an adjunct to antimicrobial therapy in the treatment of moderate to severe travellers' diarrhea. Loperamide may shorten the duration of diarrhea when given in combination with antimicrobial therapy^(12,13). There is no evidence of any risk in the use of loperamide in bacillary dysentery or in milder syndromes.

Strength of recommendation: B

Quality of evidence: I

Recommendation

Antibiotic therapy, using a quinolone or TMP-SMX, is recommended as presumptive therapy of moderate or severe travellers' diarrhea.

Strength of recommendation: A

Quality of evidence: I

Published studies have indicated that TMP-SMX, trimethoprim alone, or a quinolone is more effective than a placebo^(14,15,16). In view of the progressive increase in incidence of resistance of bacterial isolates to other agents, the agents of choice are quinolones. For children (prior to epiphyseal closure), in whom quinolones are contraindicated, TMP-SMX is the agent of choice.

In pregnancy trimethoprim alone can be used and has been shown to be quite effective in the treatment of travellers' diarrhea, but NOT in the prevention. Tetracycline and the quinolones are contraindicated in pregnancy. TMP-SMX can be safely used up to the last month of pregnancy, but the treating physician and the patient should be aware of the risk of kernicterus when sulpha drugs are used late in pregnancy. In all cases of diarrhea fluid replacement is recommended.

A 3-day course of an antibiotic is conventional. Recent studies have shown similar efficacy of a single, large dose of TMP-SMX or of quinolones^(17,18). Single-dose quinolone therapy has been associated with a 40% failure rate in *S. dysenteriae* type I disease, and relapse of *Campylobacter*^(13,18).

Prevention

• Non-antimicrobial

There are no effective, available vaccines against the agents of travellers' diarrhea. Prevention is effected by judicious choice

of food and water. High doses of bismuth subsalicylate reduce the incidence of diarrhea but are inconvenient to take⁽¹⁹⁾.

Table I
Therapy of travellers' diarrhea

1. Fluid Replacement: WHO oral rehydration salts or commercial replacement salts or homemade replacement salts
Sugar/Salt: 1 tsp [5 mL] of salt + 8 tsp [40 mL] sugar in 1 litre potable water
2. Presumptive Antimicrobial Therapy (Moderate to Severe Diarrhea) (Relatively contraindicated in pregnancy)
a) Conventional
Trimethoprim-sulfamethoxazole (TMP-SMX)* 1 double-strength tablet (160 mg TMP / 800 mg SMX) bid x 3 days
or
A quinolone bid x 3 days (e.g., norfloxacin 400 mg, or ciprofloxacin 500 mg)
or
b) Single dose
TMP-SMX 2 double-strength tablets (320 mg TMP / 1600 mg SMX)
or
A quinolone (e.g., norfloxacin bid or ciprofloxacin 750-100 mg)
3. Antimotility Agents** (Optional)
Loperamide 4 mg initially + 2 mg after each loose stool (up to 16 mg per day)

* In children: 4 mg/kg TMP + 2 mg/kg SMX
** Contraindicated in children < 2 years of age

• Antimicrobial

Preventive antibiotics may be used to prevent diarrhea in highly selected short-term (up to 3 weeks) travellers.

Although certain antibiotics (TMP-SMX, quinolones) have been shown to reduce the risk of diarrhea in short-term travel (up to 3 weeks) in healthy individuals, they are not recommended for most travellers⁽²⁰⁾. Only a minority of such short-term travellers will develop diarrhea. The greater the number of antimicrobial recipients, the greater the number of adverse effects, including allergy, photosensitivity reaction, antibiotic-associated diarrhea, and vaginal candidiasis. Finally, presumptive therapy is highly effective in those individuals who do get sick, resulting in prompt improvement, with cure in one hour to one day.

Strength of recommendation: C

Quality of evidence: III

Antibiotic prophylaxis has not been shown to prevent diarrhea in travellers with achlorhydria or with prior gastrectomy, or in patients particularly likely to suffer from acute diarrhea. It has not been shown to prevent enteric infection in patients with AIDS or

other immunocompromised conditions, nor to inhibit systemic dissemination of *Salmonella* or other enteric organisms.

Preventive antibiotics may be considered in short-term travellers who fit into one of the following four categories:

- 1) their trip is necessary and a brief illness cannot be tolerated;
- 2) they have increased susceptibility to diarrhea because of achlorhydria, prior gastrectomy, poor history on previous trips;
- 3) they have AIDS or another immunodeficient condition predisposing to systemic dissemination (e.g., bacteremia) of enteric pathogens; and
- 4) there is a risk of severe consequence of diarrhea (e.g., chronic renal failure, severe angina or congestive heart failure, insulin dependent diabetes mellitus, inflammatory bowel disease).

Travellers with severe diarrhea, those with severe underlying disease, and those with persistent disease despite therapy should seek medical advice.

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Additional Reading

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Announcements

SAFE FOOD FOR TRAVELLERS

The WHO Programmes on Food Safety and Diarrhoeal Diseases Control have just updated the leaflet entitled *A guide on safe food for travellers*. This publication gives recommendations and advice on how to eat safely and what to do in case of diarrhea. It is endorsed by the World Tourism Organization and the International Tourist Health Association.

Government departments, travel agencies, transport companies, banks, institutions and those interested in distributing the revised WHO leaflet, which is available in Arabic, English, French, German and Spanish, can obtain it from the **Distribution and Sales Service, WHO, 1211 Geneva 27, Switzerland, at the price of Sw. fr. 20/U.S. \$18 for 50 copies (Sw. fr. 14/U.S. \$12.60 for developing countries). A camera-ready film for printing is also available at Sw. fr. 30/U.S. \$27.**

FOURTH INTERNATIONAL CONFERENCE ON TRAVEL MEDICINE

The Fourth International Conference on Travel Medicine will be held on 23-27 April 1995, in Acapulco, Mexico. The conference will be cosponsored by the World Health Organization, the Pan American Health Organization, the World Tourism Organization, the Infectious Diseases Society of Mexico, and the United States Centers for Disease Control and Prevention.

The program will focus on the following subjects: health risks for travellers; health aspects for temporary residents; acquired immunodeficiency syndrome; malaria; vaccine-preventable diseases; travellers' diarrhea; respiratory diseases and other infections; individual preventive measures; vaccines; immunoglobulins; chemoprophylaxis; non-infectious diseases; jet lag and motion sickness; psychologic aspects of travel; injuries; health promotion for travellers; environmental healthy aspects; illness and medical care abroad; self-diagnosis and self-treatment; medical evacuation; and travellers' clinics.

Inquiries should be addressed to the **Fourth International Conference on Travel Medicine (ICTM4), 8000 Westpark Dr., Suite 130, McLean, VA 22102, USA.**

Notice

NACI STATEMENT ON INFLUENZA VACCINATION FOR THE 1994-95 SEASON (CCDR 1994;20:85-92)

Please note that, on page 87, the recommended influenza vaccine dosage by age has changed from previous NACI statements. It is now recommended that previously unimmunized children < 9 years of age receive two doses of split-virus influenza vaccine at an interval of 4 weeks; the second dose is not needed if the child received one or more doses of influenza vaccine prepared for a previous season. This is a change from the *Canadian Immunization Guide*, 4th edition, 1993, page 60. The current NACI Statement is consistent with recommendations in the *1994 Red Book Report of the Committee on Infectious Diseases, American Academy of Pediatrics*.

Reminder

IMMUNIZATION IN THE 90s: CHALLENGES AND SOLUTIONS

**5-7 October, 1994
The Québec Hilton, Québec City**

This 3-day conference, organized by the Laboratory Centre for Disease Control with support from the private sector, will be of interest to medical officers of health, public health nurses, administrators of immunization programs, pediatricians and general practitioners, and public health researchers.

Primary focus will be on childhood immunization with special emphasis on vaccine supply and delivery, multiplication of vaccines and different schedules, assessment of vaccination programs, regulations and legislation, and global immunization efforts. The Health Minister, Diane Marleau, will open the conference.

To obtain additional information and a registration package, contact **Mr. Chuck Schouwerwou, Conference and Committee Coordinator, Childhood Immunization Division, Bureau of Communicable Disease Epidemiology, Laboratory Centre for Disease Control, Tunney's Pasture, Ottawa, Ontario, K1A 0L2, Tel: (613) 957-1352 or FAX: (613) 998-6413.**

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Scientific Advisors:	Dr. John Spika	(613) 957-4243
	Dr. Fraser Ashton	(613) 957-1329
Editor:	Eleanor Paulson	(613) 957-1788
Assistant Editor:	Nicole Beaudoin	(613) 957-0841
Desktop Publishing:	Joanne Regnier	

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