Complete Summary

GUIDELINE TITLE

Management of dyspepsia and heartburn.

BIBLIOGRAPHIC SOURCE(S)

New Zealand Guidelines Group (NZGG). Management of dyspepsia and heartburn. Wellington (NZ): New Zealand Guidelines Group (NZGG); 2004 Jun. 119 p. [333 references]

GUIDELINE STATUS

This is the current release of the guideline.

**** REGULATORY ALERT ****

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On September 30, 2004, Vioxx (rofecoxib) was withdrawn from the U.S. and worldwide market due to safety concerns of an increased risk of cardiovascular events. See the U.S. Food and Drug Administration (FDA) Web site for more information.

Subsequently, on April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the FDA Web site for more information.

Most recently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning,

highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the FDA Web siteFDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Undifferentiated dyspepsia
- Gastro-oesophageal reflux disease (GORD)
- *Helicobacter pylori* and peptic ulceration
- Non-steroidal anti-inflammatory drug (NSAID)-induced gastrointestinal complications

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Pharmacists

Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To promote up-to-date recommendations for the safe and efficient management of individuals with dyspepsia and heartburn

TARGET POPULATION

Individuals with dyspepsia and heartburn

INTERVENTIONS AND PRACTICES CONSIDERED

Initial Evaluation

1. Identify risk factors for organic pathology.
2. Refer to oesophago-gastro duodenoscopy (OGD) if alarm signals are present.
3. Evaluate risk of gastrointestinal (GI) complications if nonsteroidal anti-inflammatory drugs (NSAIDS) are used.

Management/Treatment

Undifferentiated Dyspepsia

1. Testing for *Helicobacter pylori* (*H. pylori*)
2. Prokinetics (domperidone)
3. Histamine type$_2$-receptor antagonist (H_2RA)
4. Proton pump inhibitors (PPIs)

Gastro-Oesophageal Reflux Disease (GORD)

1. Step-down drug regimen:
    - Step 1. Full-dose PPI (omeprazole, lansoprazole, pantoprazole)
    - Step 2. Half-dose PPI
    - Step 3. H_2RA (famotidine, ranitidine)
    - Step 4. Antacids/alginate
2. OGD
3. Step-down PPI for grades 0, A, or B
4. Full-dose long-term PPI for grades C or D
5. Reevaluation and follow-up

Peptic Ulcer

1. Testing for *H. pylori*
2. *H. pylori* eradication: triple therapy (PPI, clarithromycin, and amoxicillin or metronidazole)
3. Alternative triple therapy for initial treatment failure: PPI plus two of the following: clarithromycin, amoxicillin, metronidazole, tinidazole, tetracycline, and bismuth **OR** quadruple therapy: standard triple therapy plus bismuth

4. Reviewing compliance factors, testing for bacterial resistance, and retreatment for repeated treatment failure
5. Confirming *H. pylori* eradication
6. PPI or H_2RA for *H. pylori*-negative peptic ulcers

NSAIDS and Gastrointestinal Complications

1. Stopping NSAIDS if possible or choosing least toxic NSAID (e.g., ibuprofen)
2. Prophylactic cotherapy: Misoprostol, PPI
3. Replacement of NSAID with cyclo-oxygenase-2 inhibitor (COX-2)
4. Eradicating *H. pylori*
5. Referring to specialist if necessary

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of oesophago-gastro-duodenoscopy (OGD) and diagnostic tests for *Helicobacter pylori* (*H. pylori*)
- Healing rates with various treatments for erosive oesophagitis
- Effect of proton pump inhibitors and histamine type$_2$ receptor antagonists on dyspepsia and heartburn
- *H. pylori* eradication rates with various drug regimens
- Recurrence rates of gastro-oesophageal reflux disease and peptic ulcer
- Metronidazole resistance rates

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Groups developing the guideline conducted literature searches, including current computer searches (Medline, EMBASE) and surveys of review publications (Cochrane Library, Bandolier). Unpublished papers and research still under way were examined, as well as published papers.

Other dyspepsia guidelines published between 1998 and June 2003 were perused to ensure appropriate information was considered in developing the New Zealand version of the Guideline. As updates of Cochrane Reviews became available, they were also included in the review process to ensure new developments had been considered.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia
Evidence obtained from meta-analysis of randomised controlled trials (RCTs)

Ib
Evidence obtained from at least one randomised controlled trial

IIa
Evidence obtained from at least one well-designed controlled study without randomisation

IIb
Evidence obtained from at least one other type of well-designed quasi-experimental study

III
Evidence obtained from well-designed descriptive studies, such as comparative studies, correlation studies, and case studies

IV
Evidence obtained from expert committee reports or opinions, and/or clinical experiences of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Core Committee of the Dyspepsia and gastro-oesophageal reflux disease (GORD) Working Party established four regional committees, each including general practitioner, gastroenterology and surgical input, to develop the guidelines for specific areas: Dunedin/Christchurch for GORD; Wellington for undifferentiated dyspepsia and non-ulcer dyspepsia (NUD); Waikato/Rotorua/Bay of Plenty for non-steroidal anti-inflammatory drug (NSAID)-related dyspepsia; and Auckland for *Helicobacter pylori* and peptic ulcer.

The four regional working groups each established a systematic search of the literature. Each developed their evidence tables from which their recommendations were made. When the core committee convened they made a decision that the evidence tables would not be published nor would they include the level of evidence for each study in the guideline text. Rather, the committee

would put its emphasis on producing a workbook style guideline with detailed references for those who wish to delve into the original research.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The drafts of the four regional working groups were developed between 1998 and 2001 by which time they had been submitted to the Core Committee for review. Decisions were made by consensus of the various groups, and eventually with the Core Committee. These were then collated and edited by members of the Core Committee and a professional editor/writer. The edited copies were returned to the four working groups to ensure they had maintained their original interpretation. Opportunity was given to update the information with the final drafts being returned in mid-2002.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The guideline recommendations have been graded to reflect the quality of the evidence, based on the quality of the studies supporting the claims made.

Grades of Recommendation

Grade A
Evidence levels Ia & Ib
Requires at least one randomized controlled trial (RCT) as part of the body of literature of overall good quality and consistency addressing specific recommendation

Grade B
Evidence levels IIa, IIb, & III
Requires availability of well-conducted studies but no RCTs addressing specific recommendation

Grade C
Evidence level IV
Requires evidence obtained from expert committee reports or opinions, and/ or clinical experiences of respected authorities
Indicates absence of directly applicable clinical studies of good quality

COST ANALYSIS

- The cost of medical therapy is significant. According to PHARMAC's 2002 Annual Report, the cost of prescribed pharmaceutical agents in the treatment of dyspepsia has risen yearly to $44 million, equating with nearly 700,000 prescriptions.

- The effectiveness and cost implications of early investigation versus acid inhibition were examined in four trials. No difference was shown in global improvement, and the economic data were also inconclusive.
- A recent study investigated the cost effectiveness of oesophago-gastro duodenoscopy (OGD) in the management of dyspepsia. Twenty-one studies met the inclusion criteria, although they were limited by several factors, including the use of varying tools to measure people's response and the difficulties of comparing studies that did not include *Helicobacter pylori* status with those that did. One randomised controlled trial (RCT) showed higher patient satisfaction and lower costs with initial OGD compared with empiric therapy, but no difference in symptoms or quality of life at one year. The other studies failed to clearly answer the questions posed, by failing to show any significant differences.
- Using economic modelling, one study showed that use of proton pump inhibitors (PPIs) is more cost effective than H_2 receptor antagonists (H_2RAs) because of greater efficacy and lower relapse rate. However, the findings of this British study depend on local drug prices, which are now outdated and do not apply to New Zealand.
- A decision analysis concluded that in healthy people with uncomplicated duodenal ulcer, post-treatment urea breath testing (UBT) after *H. pylori* eradication therapy markedly increased costs, with no significant improvement in outcomes. The authors suggested that post-therapy urea breath testing should be reserved for those with symptom recurrence, complicated duodenal ulcers, comorbidity, and gastric ulcers. Those living in places where treatment facilities are difficult to access might also be considered for confirmation of eradication.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The final draft was reviewed by the Core Committee and further corrections were made. The draft was then sent to the New Zealand Guidelines Group (NZGG) for circulation to reviewers as part of the Appraisal of Guidelines Research and Evaluation (AGREE) process. The results of the AGREE review were circulated to the leaders of the Regional Working groups and members of the Core Committee. Most of the suggestions and comments made by reviewers were addressed before submitting the final version.

Flow diagrams were constructed from the recommendations agreed in the Guideline. They were discussed with representatives of the Best Practice Advocacy Centre Inc who reviewed the draft flow diagrams in association with some of their representatives and general practitioners.

Comparison with Guidelines for Other Groups

Other dyspepsia guidelines published between 1998 and June 2003 were perused to ensure appropriate information was considered in developing the New Zealand

version of the Guideline. See the original guideline document for the complete list of the guidelines considered in the Update.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the Levels of Evidence (Ia to 4) and Grades of Recommendation (A to C, and Good Practice Points) are given at the end of the "Major Recommendations" field.

Note: The Grades of Recommendation represent the strength of the supporting evidence, rather than the importance of the recommendations.

Undifferentiated Dyspepsia

Initial Management of Undifferentiated Dyspepsia

Recommendations

B If there are any alarm signals, or if the person is aged >50 years at first presentation, refer for oesophago-gastro-duodenoscopy (OGD).

A Empiric therapy

- For people with heartburn, manage as gastro-oesophageal reflux disease (GORD) (see recommendations for GORD).
- For people with dyspepsia but no heartburn (reflux) symptoms, either:
    - treat initially with domperidone or H_2 receptor antagonists (H_2RAs) ***OR*** if aged <50 years and in an area of high (>30%) *Helicobacter pylori* prevalence
    - test-and-treat* for *H. pylori.*

*Although data regarding the prevalence of *H. pylori* infection in New Zealand are patchy, the following statements can be made:

- Rates in the South Island are well below 30%.
- Rates tend to be >30% in adult Maori, Pacific peoples, native populations in Asia, and those with lower socio-economic status.
- Rates in adults living in Auckland have generally been found to be >30%.

Good Practice Points

- Review lifestyle factors (e.g., diet, weight, smoking, alcohol).
- If alarm signals indicate organic disease, refer to specialist for OGD.
- If there is heartburn and dyspepsia, treat as GORD in the first instance.
- Review person's intake of all medications, especially nonsteroidal anti-inflammatory drugs (NSAIDs).
- Commence empiric therapy in those without alarm signals or heartburn.

- If there is concurrent use of NSAIDs, evaluate for risk of gastrointestinal (GI) complications, and consider alternative strategies if risk is increased. (See Chapter 5 in the original guideline document: *NSAIDs and GI Complications*.)

Management of Recurring Undifferentiated Dyspepsia

Recommendations

C If there is failure to respond to treatment in 4 to 12 weeks, refer for OGD.

C If previous dyspepsia symptoms recur 1 to 6 months after cessation of treatment, reevaluate person for alarm signals, taking into account timing of relapse and severity of symptoms.

C If previous dyspepsia symptoms recur after 6 months with no alarm signals, repeat empiric therapy.

B If symptoms recur after test-and-treat, refer for OGD.

Management of Functional Dyspepsia

Recommendations

C Provide reassurance regarding the absence of organic pathology.

C Encourage lifestyle changes: diet, weight control, smoking cessation, and alcohol moderation.

A Consider drug therapy in the following order:

1. Prokinetics (domperidone) number needed to treat (NNT) 2.8 (NNT based on total prokinetics studied)
2. H_2RAs NNT=5.9
3. Proton pump inhibitors (PPIs) NNT=11.1

A Test-and-treat people aged <50 years with dyspeptic symptoms (excluding heartburn) and no alarm signals who originate from areas of high *H. pylori* prevalence (>30%).

A Consider *H. pylori* eradication in others.

Good Practice Points

Check patient:

- Does not have heartburn
- Is not taking NSAIDs
- Has normal blood tests (full blood count [FBC], erythrocyte sedimentation rate [ESR], c-reactive protein [CRP])
- Has normal OGD

Gastro-Oesophageal Reflux Disease (GORD)

GORD Symptoms

Recommendations

Consider GORD in people with:

- **A** Heartburn (burning sensation radiating from the epigastrium towards the neck)
- **B** Non-cardiac chest pain, asthma, chronic cough, hoarseness of voice, and erosion of teeth

Initial Management with Empirical Therapy

Recommendations

A If the person's symptoms are suggestive of GORD, treat with a step-down drug regimen, usually in 4- to 8-week steps:

- Step 1. Full-dose PPI (omeprazole 20 mg, lansoprazole 30 mg, pantoprazole 40 mg) daily
- Step 2. Half-dose PPI
- Step 3. H_2RA (famotidine 20-40 mg, ranitidine 150-300 mg) twice daily
- Step 4. Antacids/alginate

B If there is no response to full dose PPI therapy, double the dose.

B Continue treatment for at least 3 to 6 months.

B If the person fails to respond, or if symptoms recur within 1 month after end of treatment, consider OGD rather than long-term empiric therapy.

Good Practice Points

Exclude people with alarm signals from empiric therapy, and refer for OGD.

Treatment of GORD Diagnosed After OGD

Recommendations

A People with grades 0, A, and B

- Treat with a step-down drug regimen (see *Algorithm 3 in the original guideline document: Heartburn +/-Dyspepsia: Empiric Therapy*).
- If symptoms recur at stepped-down dosage, continue on lowest effective dose; intermittent therapy may control symptoms.

People with grades C and D

- Treat with ongoing continuous full-dose PPI treatment.

C Consider surgery as an alternative to long-term drug treatment if:

- Age <50 years
- Age 50 years and over and there is no comorbidity
- There is inability or unwillingness to take medications.
- There is inadequate control with medical therapy.

B If high-dose PPI treatment fails, reevaluate symptoms and consider 24-hour pH telemetry.

B In people with Barrett's oesophagus or unresolved complications (grade D), reevaluate with OGD if necessary.

Helicobacter Pylori **and Peptic Ulceration**

Initial Diagnostic Investigation for *H. Pylori*

Recommendations

Test-and-treat for *H. pylori* in those:

- **A** Who originate from areas of high (>30%) *H. pylori* prevalence
- **A** With present or past history of peptic ulcer
- **B** With Mucosa-associated lymphoid tissue lymphoma
- **C** With a family history of gastric cancer

Recommended diagnostic tests

- **A** Urea breath test (UBT) is the recommended noninvasive test. Stop treatment (other than antacids) for 2 weeks prior to UBT.
- **A** Although UBT and faecal antigen tests are also valid options, serology (validated with sensitivity and specificity of at least 90%) is recommended where the prevalence of *H. pylori* is high (>30%).
- **A** Faecal antigen test is also recommended, although it is not yet universally available in New Zealand. Omeprazole can interfere with the result.
- **B** If OGD is being performed for investigation of dyspepsia, consider testing with the rapid urea test, histology, or culture.

Initial Treatment of *H. Pylori*

Recommendations

A Give triple therapy: regimens containing PPI, clarithromycin, and amoxicillin or metronidazole, have consistently high eradication rates after one week.

A Substitute metronidazole for amoxicillin in penicillin-allergic individuals.

B Emphasise to the person that successful eradication depends on compliance with treatment regimen.

H. pylori Treatment Failure

Recommendations

A For initial treatment failure, use either of the following for 1 week:

- An alternative triple therapy regimen (PPI plus two of the following: clarithromycin, amoxicillin, metronidazole, tinidazole, tetracycline, and bismuth), **OR**
- Quadruple therapy (standard triple therapy plus bismuth)

Repeated treatment failure:

- **B** Review compliance factors and consider testing for bacterial resistance.
- **C** Consider retreatment for 2 weeks.

Confirmation of *H. Pylori* Eradication

Recommendations

B Confirm eradication of *H. pylori* in those with a peptic ulcer complication, important comorbidity factors, symptom recurrence, or residence in isolated areas.

Recommended tests

- **B** UBT is the recommended noninvasive test (serology should not be used because it takes 6 to 12 months to become negative).
- **A** *H. pylori* stool antigen may be used for confirmation of eradication at least 4 weeks after stopping treatment. Omeprazole can interfere with result.
- **C** For people having OGD to check for healing of gastric ulcer, confirm eradication by histology.

Timing of tests

- **B** Perform at least one month after completion of eradication regimen.
- **C** For people taking PPIs, perform at least one week after cessation of PPI.

Management of *H. Pylori*-Negative Peptic Ulcers

Recommendations

A Treat duodenal ulcers with H_2RAs or PPIs for 4 to 8 weeks.

A Treat gastric ulcers with PPIs or H_2RAs for 8 to 12 weeks and confirm healing with OGD.

C Use maintenance treatment with H_2RA or PPI if:

- Ulcer recurrences are frequent (e.g., more than once per 12 months) or severe.
- There is a previous peptic ulcer complication.
- There are comorbid factors that might make any complications life-threatening.

NSAIDS and GI Complications

Individuals at Increased Risk of NSAID-Induced GI Complications

Recommendations

A Begin treatment with either of the following:

- Misoprostol at doses of 200 micrograms/day. Increase dose over two weeks as tolerated, to a maximal dose of 800 micrograms/day.
- Standard doses of PPI once daily

A Eradicate *H. pylori*, if testing is positive.

Treatment of NSAID-Related Dyspepsia

Recommendations

C Review person's history for risk factors.

C Stop NSAID if possible.

C In person with symptoms and risk factors, refer for OGD.

If ongoing symptom relief is needed:

- **A** Continue NSAID with coprescription of PPI or misoprostol *OR*
- **B** Replace NSAID with cyclo-oxygenase-2 (COX-2) selective inhibitor.

A Eradicate *H. pylori* if testing is positive.

Management of NSAID-Induced Peptic Ulcer

Recommendations

A If NSAID can be stopped, treat with an H_2RA (ranitidine 150 mg twice daily or famotidine 20 mg twice daily) or PPI (omeprazole 20 mg, lansoprazole 30 mg, or pantoprazole 40 mg) for 8 weeks for duodenal ulcers and 12 weeks for gastric ulcers.

If NSAID needed:

- **A** Treat with PPI for 8 weeks for duodenal ulcer and 12 weeks for gastric ulcer; if unsuccessful increase dose. Ongoing maintenance treatment is advised (as for individuals at increased risk of NSAID-induced GI complications)
- **C** Consider replacement of NSAID with COX-2 selective inhibitor.*

A Eradicate *H. pylori* if testing is positive.

C Refer individuals with complications (i.e., bleeding, perforations, obstruction) to specialists.

C Check healing of gastric ulcer with OGD.

Definitions:

Levels of Evidence

Ia
Evidence obtained from meta-analysis of randomised controlled trials (RCTs)

Ib
Evidence obtained from at least one randomised controlled trial

IIa
Evidence obtained from at least one well-designed controlled study without randomisation

IIb
Evidence obtained from at least one other type of well-designed quasi-experimental study

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Evidence obtained from well-designed descriptive studies, such as comparative studies, correlation studies, and case studies

IV
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Grades of Recommendation

Grade A
Evidence levels Ia & Ib
Requires at least one RCT as part of the body of literature of overall good quality and consistency addressing specific recommendation

Grade B
Evidence levels IIa, IIb & III
Requires availability of well-conducted studies but no RCTs addressing specific recommendation

Grade C
Evidence level IV
Requires evidence obtained from expert committee reports or opinions, and/ or clinical experiences of respected authorities
Indicates absence of directly applicable clinical studies of good quality

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

1. Dyspepsia and/or heartburn: Initial evaluation
2. Undifferentiated dyspepsia
3. Gastro-oesophageal reflux disease
4. Peptic ulcer
5. Non-steroidal anti-inflammatory drugs and gastrointestinal complications

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The advice on dyspepsia and heartburn given in the original guideline document is based on epidemiological and other research evidence, supplemented where necessary by the consensus opinion of the expert development team based on their own experience. The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved management and treatment of dyspepsia and heartburn including relief of symptoms, safer drug regimens, early identification of complications, early investigation and diagnosis of serious pathology, and reduced mortality from peptic ulcer disease

POTENTIAL HARMS

Adverse Reactions Associated with *Helicobacter pylori* Eradication Therapy

Adverse effects include:

- *Amoxycillin*: diarrhoea and candidiasis
- *Metronidazole*: metallic taste, nausea, diarrhoea, and disulfiram-like reaction to alcohol
- *Clarithromycin*: metallic taste, diarrhoea, nausea, and headache
- *Tetracycline*: nausea, diarrhoea, and photosensitivity
- *Bismuth*: black stools and discolouration of the tongue
- *Antibiotics*: pseudomembranous colitis
- Sensitivity reactions, including anaphylaxis

Adverse effects are very common with traditional bismuth-containing regimens (up to 40%)

Prevention of Non-steroidal Anti-inflammatory Drug (NSAID)-Induced Ulcers

- *Misoprostol*: diarrhoea, abdominal cramps; Misoprostol is an abortifacient, and must be used cautiously by women of child-bearing age.

"Step-Down" Treatment for Gastro-oesophageal Reflux Disease (GORD)

Initial drug cost is higher and there is the possibility of some individuals being over-treated if an appropriate step-down procedure is not followed.

***H. pylori* Resistance with Antimicrobial Therapy**

The major obstacle to effective therapy is the presence of antimicrobial resistance.

Adverse Effects of Cyclo-oxygenase-2 Inhibitor (COX-2) Agents

Epigastric discomforts, heartburn, nausea, diarrhoea, impaired renal function and fluid retention, rash, bronchospasm, angio-oedema (rarely), hepatotoxicity, hypertension, peripheral oedema, interaction with warfarin

Adverse Effects of NSAIDs

There are generally three levels of adverse effects with nonsteroidal anti-inflammatory drugs. The first includes dyspepsia symptoms; the second, the development of intestinal mucosal abnormalities including peptic ulceration; and the third, ulcer complications (predominantly bleeding and perforation).

CONTRAINDICATIONS

CONTRAINDICATIONS

Cisapride: concomitant use of potent CYP3A4 inhibitors (e.g., azole antifungals, macrolides, HIV protease inhibitors), QT prolongation or conditions leading to QT prolongation (e.g., bradycardia, hypokalaemia, medication prolonging QT interval) and family history of congenital long QT syndrome

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Evidence-based best practice guidelines are produced to help health practitioners and consumers make decisions about health care in specific clinical circumstances. Research has shown that if properly developed, communicated, and implemented, guidelines can improve care. While guidelines represent a statement of best practice based on the latest available

evidence (at the time of publishing), they are not intended to replace the health practitioner's judgment in each individual case.
- This guideline is designed to guide management decisions, not to dictate a blanket policy.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Specific Implementation Strategies

The Working Party has aimed to ensure that the recommendations made are practical and can be implemented in the New Zealand setting. The guideline is intended to be discussed and used as a dynamic document, not only for the person's care but also for development and improvement of the provision of care in both rural and urban areas in New Zealand.

Endorsement

Endorsement by stakeholder organisations is essential to the successful implementation of the guideline. At the start of the project, a number of professional groups gave their approval and endorsed committee members to represent their views. An advanced draft of the guideline was sent to the relevant organisations for their comment to ensure all views have been considered. All resulting comments and suggestions were reviewed by the Working Party.

Publication of the Full Guideline

The full guideline and the summary document will be available in an electronic form on the New Zealand Guidelines Group website at http://www.nzgg.org.nz. There will be no charge for downloading these documents.

Publication of a printed copy requires funding and this will be negotiated with the New Zealand Guidelines Group.

Quick Reference Clinical Format

The summary document incorporates the main recommendations of the guideline. Flow charts have been added. Full text is available for reference.

Dissemination

Wide dissemination of the quick reference summary guideline is planned in order to reach all health care practitioners who treat people with dyspepsia and heartburn. Further groups may also benefit from referral to the guideline for academic, educational, or commercial purposes.

Health Care Professionals

- General health care practitioners

- General physicians and surgeons
- Gastroenterologists
- Pharmacists

Care Facilities

- Accident and emergency departments
- Geriatric units
- After-hours clinics
- Hospital wards

Provider Organisations and Professional Bodies

- Primary Health Organisations
- Independent Practitioners Associations (IPAs)
- Academic lecturers, curriculum planners involved in medical training
- Medical colleges
- Professional bodies
- PHARMAC

Other Agencies

- Health insurers
- Support groups
- Community health agencies and interest groups

Commercial Organisations

- Providers of medications discussed or recommended in the guideline

Development of Performance Indicators

- Primary Health Organisations are to be encouraged to identify appropriate clinical indicators e.g., average daily dose of PPIs

Events, Presentation, and Training

The guideline should be presented to health care practitioners to familiarise them with the recommendations. They should be presented at major meetings or small education groups included in postgraduate medical education. This process has already been initiated during the development phase of the guideline. It is anticipated that members of the Working Party will play a key part in disseminating the information to their peers.

National Level

- Formal endorsement and presentation at general practitioner and specialty and subspecialty conferences
- Educational seminars and workshops for practitioners and IPAs

- Specific educational initiatives for particular interest groups, including general practitioners and pharmacists (e.g., develop a toolkit for pharmacy facilitators and other speakers such as PowerPoint for Primary Health Organisations)
- Liaison with bodies controlling funding and resources to ensure that district health board policies and facilities become compatible with the recommendations made.
- Corrective measures need to be taken to ensure that rural areas have access to appropriate investigation and treatment. Representatives of rural communities need to be included in the discussion process.
- Key recommendations may be promoted by groups such as Best Practice Advocacy NZ
- Conferences:
    - The Combined NZ Rural General Practice Network & Rural Nurse National Network Conference, April
    - College of General Practitioners' Conference, July, Wellington
    - General practitioner CME Meeting, July
    - National Gastroenterology Conference, November

Local Level

- Local CME activities can include this guideline as part of their program.
- Local general practitioners and specialists should meet to discuss specifically referral patterns, priorities, and access to investigations and treatments.
- IPA pharmacists can play a very important role in prescriber education and in monitoring and reviewing prescribing habits.

Publicity

The guideline needs to be publicised in the media, including the local medical press. This has already been initiated via certain professional group meetings (e.g., general practitioners, gastroenterologists, pharmacists). Publicity needs to encompass:

- Journals and health professional publications, including the *New Zealand Medical Journal*, *New Zealand Nursing Journal*, and *NZ Doctor*
- A well-publicised formal launch of the guideline and a planned seminar program. This should inform health care practitioners, not only of the contents of the guideline but what is anticipated concerning dissemination and discussion, as stated above.
- Public education to ensure that there is widespread and realistic understanding of the guideline.
- Radio and television interviews, which can be conducted by members of the Working Party. Care needs to be taken to ensure that public expectation and reality are well balanced.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New Zealand Guidelines Group (NZGG). Management of dyspepsia and heartburn. Wellington (NZ): New Zealand Guidelines Group (NZGG); 2004 Jun. 119 p. [333 references]

ADAPTATION

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

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2004 Jun

GUIDELINE DEVELOPER(S)

New Zealand Guidelines Group - Private Nonprofit Organization

SOURCE(S) OF FUNDING

New Zealand Guidelines Group

GUIDELINE COMMITTEE

The Dyspepsia and Gord Working Party

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Dyspepsia and Gastro-oesophageal Reflux Disease (GORD) Working Party Members:

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Core Committee: Philip Bagshaw, Surgeon, Department of Surgery, Christchurch School of Medicine, University of Otago, and Canterbury District Health Board, Christchurch; Kristin Good, General Practitioner, Auckland; Owen Lloyd, Lay Person and Maori Representative, Tairäwhiti Health Care Ltd, Gisborne; Richard

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Waikato/Rotorua/Bay of Plenty (NSAID-induced gastrointestinal complications)

Erica Amon, Pharmacist, Pinnacle, Hamilton; Chris Cochrane, Practitioner, Tauranga; John Petrie, Rheumatologist, Rotorua; David Shaw, Gastroenterologist, Tauranga

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

No current competing interests were reported by any member of the guideline development team.

ENDORSER(S)

Cardiac Society of Australia and New Zealand - Disease Specific Society
Heart Foundation (New Zealand) - Medical Specialty Society
Pharmaceutical Society of New Zealand - Professional Association
Royal Australasian College of Physicians - Professional Association

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the New Zealand Guidelines Group Web site.

Print copies: Available from the New Zealand Guidelines Group Inc., Level 10, 40 Mercer Street, PO Box 10 665, The Terrace, Wellington, New Zealand; Tel: 64 4 471 4180; Fax: 64 4 471 4185; e-mail: info@nzgg.org.nz

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- New Zealand Guidelines Group (NZGG). Guideline summary. Wellington (NZ): New Zealand Guidelines Group (NZGG); 2004 Jun. 12 p.

Electronic copies: Available in Portable Document Format (PDF) from the New Zealand Guidelines Group Web site.

Print copies: Available from the New Zealand Guidelines Group Inc., Level 10, 40 Mercer Street, PO Box 10 665, The Terrace, Wellington, New Zealand; Tel: 64 4 471 4180; Fax: 64 4 471 4185; e-mail: info@nzgg.org.nz

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 29, 2004. The information was verified by the guideline developer on January 12, 2005. This summary was updated on April 15, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs).

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