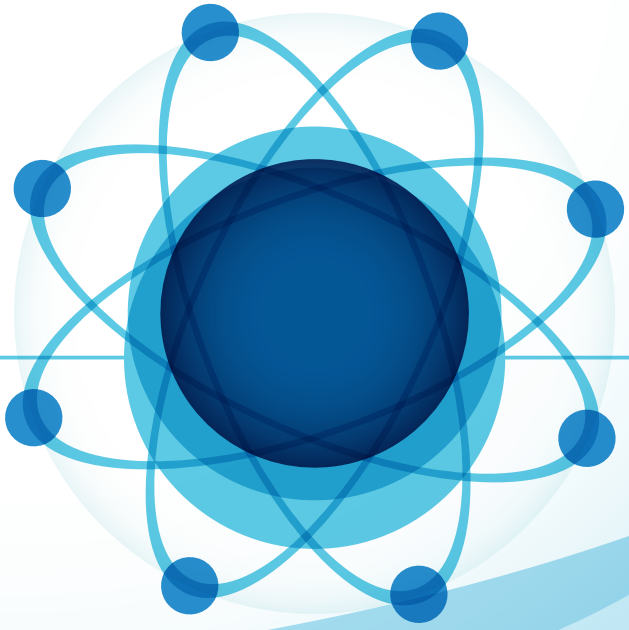
CLINICAL PRACTICE GUIDELINES

MOH/P/PAK/307.15(GU)

Oral Health Division
Ministry of Health Malaysia

# ANTIBIOTIC PROPHYLAXIS IN ORAL SURGERY FOR PREVENTION OF SURGICAL SITE INFECTION

*(Second Edition)*



November 2015

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## GUIDELINES DEVELOPMENT AND OBJECTIVES

## GUIDELINE DEVELOPMENT

These Clinical Practice Guidelines (CPG) were developed by a committee comprising six Oral Surgeons, one Periodontist, one Clinical Microbiologist, three Dental Public Health Specialists and one Pharmacist.

After development, the guidelines were scrutinized by an internal review committee who gave feedback primarily on the comprehensiveness of the guidelines and accuracy of the interpretation of evidences supporting the recommendations in the guidelines.

A respected clinician and academic was invited as external reviewer and provided useful feedback on the guidelines.

The previous edition of the CPG on Antibiotic Prophylaxis against Wound Infection for Oral Surgical Procedures (August 2003) was used as a reference.

Several changes have been made in these updated guidelines. Sections on periodontal surgery, cancer surgery and surgery in previously irradiated bone have been included. The section on trauma has been simplified. There are also some changes in the choice and regime of the recommended antibiotics. In addition to the new and updated information, key messages are given where the available evidence is too weak to make a recommendation.

Clinical audit indicators have been identified for the purpose of monitoring and evaluating outcomes and are recommended for use in individual centres.

In reviewing these guidelines, publications from the year 2003 onwards were retrieved and scrutinized. A literature search was carried out using the following electronic databases: PubMed/MEDLINE; Cochrane Database of Systemic Reviews (CDSR); ISI Web of Knowledge and full text journal articles via the OVID search engine. In addition, the reference lists of all relevant articles retrieved were searched to identify further studies. Free text terms or MeSH terms were used either singly or in combination to retrieve the articles **(Appendix 1)**. Only literature

in English was retrieved. Each article retrieved was appraised by at least two members. The selected articles were assigned their evidence level according to the U.S./Canadian Preventive Services Task Force guide and the key information in each article was presented in an evidence table. These were then discussed during group meetings. Recommendations made were graded according to the Scottish Intercollegiate Guidelines Network (SIGN) guide. All statements and recommendations formulated were agreed upon by both the development group and review committee.

The recommendations in this CPG were made taking into consideration both current scientific evidence as well as local circumstances. Where there was lack of or weak evidence, recommendations were made based on consensus of the group members.

The draft guidelines were also posted on the Ministry of Health website for comments and feedback. The final draft of the CPG was presented to the Technical Advisory Committee for CPGs, the Health Technology Assessment (HTA) division and the CPG Council of the Ministry of Health, Malaysia for approval.

## OBJECTIVE

The main aim of these guidelines is to assist dental practitioners make informed decisions on prophylactic antibiotic use in the prevention of oral surgical site infections.

## SPECIFIC OBJECTIVES

1. To identify the procedures in oral surgery that would benefit from surgical antibiotic prophylaxis.
2. To assist in deciding which antibiotics to prescribe and what regime to follow if prophylactic antibiotics are indicated.

## CLINICAL QUESTIONS

The clinical questions addressed by the guidelines are:

i. When are antibiotics indicated for the prevention of surgical site infections in oral surgery?
ii. What antibiotics are appropriate in surgical prophylaxis?
iii. Could the inappropriate use of antibiotics in surgical prophylaxis be reduced or eliminated?

## TARGET POPULATION

These guidelines are applicable to patients undergoing oral and maxillofacial (OMF) surgical procedures.

## TARGET GROUP/USER

These guidelines will be useful for oral and maxillofacial surgeons as well as dental practitioners involved in the surgical management of patients. Academicians involved in the training of dentists and dental specialists would also benefit.

## HEALTHCARE SETTINGS

Primary and specialist care (public and private sectors).

## LEVELS OF EVIDENCE

| LEVEL | STUDY DESIGN |
|---|---|
| I | Evidence obtained from at least one properly designed randomised controlled trial |
| II-1 | Evidence obtained from well-designed controlled trials without randomization |
| II-2 | Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group |
| II-3 | Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence |
| III | Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees |

Source: Adapted from U.S./Canadian Preventive Services Task Force

## GRADES OF RECOMMENDATIONS

| GRADE | STUDY DESIGN |
|---|---|
| A | At least one meta-analysis, systematic review or RCT or evidence rated as good or directly applicable to the target population |
| B | Evidence from well conducted clinical trials, directly applicable to the target population and demonstrating overall consistency of results; or evidence extrapolated from meta-analysis, systematic reviews or RCT |
| C | Evidence from expert committee reports, or opinions and or clinical experiences of respected authorities; indicates absence of directly applicable clinical studies of good quality |

Source: Modified from the Scottish Intercollegiate Guidelines Network (SIGN)

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## MEMBERS OF THE REVIEW COMMITTEE

These guidelines were reviewed by a panel of independent reviewers comprising both local and international experts. They were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence supporting the recommendations in the guideline. The following internal and external reviewers provided comments and feedback on the proposed draft:

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## 1.0 INTRODUCTION

A landmark animal study by Burke[3, level III] and subsequent clinical studies by Polk[4, level III] and Stone[5, level III] initially defined the scientific basis for the prophylactic use of antimicrobial agents to prevent surgical site infection. From these studies several important principles were established which remain valid to this day:

i) Our body's defence against bacteria depends primarily on its own natural resistance.
ii) The risk of infection can be decreased and sometimes prevented by supplementing the body's natural resistance with antibiotics.
iii) Antibiotics must be delivered before bacterial contamination of the tissue occurs.
iv) Antibiotics serve no purpose if they are administered after the end of the period of active bacterial contamination.

There are however significant risks associated with antibiotic use. When an antibiotic is administered, strains of bacteria sensitive to the antibiotic are killed allowing the proliferation of resistant strains. Repeated 'selection' of resistant strains of bacteria would eventually render the antibiotic ineffective for prophylaxis or treatment of infections associated with these bacteria. Antibiotic choice is becoming increasingly limited by antimicrobial resistance[6, level III] and new antibiotic discovery is not keeping pace with the rates of this antimicrobial resistance.[7, level III]

Also, an antibiotic administered to a patient can act as an antigenic stimulus and hence produce an allergic reaction. Allergic reactions manifest either locally or systemically at varying degrees of severity ranging from minor skin lesions to anaphylactic shock and death.

Antibiotics in general should be used only when the benefits outweigh the risks to the patient and are therefore only indicated when the consequence of infection is severe or when the incidence of infection is high.

## 2.0 INDICATIONS FOR PROPHYLACTIC ANTIBIOTICS

The United States Centers for Disease Control's (CDC) National Nosocomial Infection Surveillance (NNIS) classification system for the risk of Surgical Site Infection (SSI) which is based on a large multicentre study (Study on the Efficacy of Nosocomial Infection Control - SENIC) lists multiple factors that increase the risk of SSI.[8, level II-2] These factors include:

- Patients with underlying medical problems (ASA score)
- Wound class
- Duration of surgery

Other factors such as previous exposure of the site of the surgery to radiotherapy may also increase the risk of SSI.

### 2.1 Patients with underlying medical problems

A Swedish Systematic Review of the Literature did not find any clinical trials on antibiotic prophylaxis in medically compromised patients other than patients with heart disease. The authors noted that despite the lack of evidence, recommendations in Sweden include many different medical conditions for which antibiotic prophylaxis should be used.[9, level 1]

A Cochrane Review stated that though there is some evidence that prophylactic antibiotics can reduce infection and dry sockets following third molar extraction, it was unclear whether the evidence in the review is generalizable to those with concomitant illnesses or immunodeficiency. They however concluded that such patients are more likely to benefit from prophylactic antibiotics, because infections in them are likely to be more frequently associated with complications and be more difficult to treat.[10, level 1]

The French Health Products Safety Agency Recommendations states that patients with certain medical conditions have an increased susceptibility to infection which would include oncological patients, patients with congenital or immunological immunodepression, patients with immunodepression due to medication, patients with infectious immunodepression (AIDS), patients with metabolic disorders (diabetes), and patients with renal and hepatic insufficiency. Such patients would require antibiotic prophylaxis. [11, level III]

The large multicentre trial of CDC's SENIC Project showed that patients with ASA **(Appendix 2)** scores of 1 and 2 had lower infection rates than patients with ASA scores of 3 or more. [8, level II-2]

**RECOMMENDATON 1**

- Antibiotic prophylaxis is indicated for all surgical procedures carried out on medically compromised patients especially those with ASA score of 3 or more. **(Grade B)**

## 2.2 Clean surgery

This category of surgery refers to surgical procedures in the maxillofacial region in which the incision and exposure does not extend into the oral cavity and includes submandibular and parotid gland surgery and TMJ surgery.

Johnson *et al.* [12, level III] reported a very low infection rate of 0.6% for clean surgery in the head and neck region (parotidectomy, thyroidectomy, or submandibular gland excision) without the use of prophylactic antibiotics.

The CDC's SENIC Project had a low infection rate of 1% for clean general surgery cases with no other risk factors. [8, level II-2]

Knight *et al.*[13, level III] presented a very low infection rate of 0.2 % for clean general surgery cases in which antibiotic prophylaxis were not given. It is important to note that this infection rate was similar to that of clean general surgery cases in which antibiotic prophylaxis was given (0.94%).

In an attempt to reduce the inappropriate use of antibiotics Liu et al.[14, level II-3] demonstrated that with continuing medical education 100% of the surgeons at their hospital stopped using prophylactic antibiotics for clean surgery.

Chattopadhyayl et al.[15, level III] and Knight et al.[13, level III] showed that clean surgery of long duration (> 75th percentile for similar procedures / > 2 hours) is not associated with higher infection rates.

Current evidence therefore indicates that clean surgery is associated with low infection rates with or without antibiotics.

**RECOMMENDATION 2**

- Antibiotic prophylaxis is not indicated for clean surgery in healthy patients. **(Grade B)**

### 2.3 Clean-contaminated surgery

This category of surgery refers to surgical procedures in the oral and maxillofacial region limited to the oral cavity or which extends into the oral cavity.

In this category fall a wide range of procedures. They range from minor soft tissue and dentoalveolar surgery to surgery to place dental implants to major oral and maxillofacial surgery.

#### 2.3.1 Minor clean—contaminated surgery

##### 2.3.1.1 Lower third molar surgery

Various randomised controlled trials found that prophylactic antibiotics did not have a statistically significant effect on post-operative infections in third molar surgery and concluded that antibiotics should not be routinely administered when third molars are removed in healthy individuals.[16-20, level 1]

A local retrospective study by Royan et al.[21, level III] also showed no difference in infection rates between patients who were given prophylactic antibiotics and those who were not.

A large multicentre prospective Malaysian study showed that the infection rate in healthy patients given a single dose of antibiotics (0.6%) was lower than that in patients not given antibiotics (2%) or in patients given five days of antibiotics post-operatively (2%). All the infections were also noted to be mild and easily treated. The study concluded that the low infection rate and mild infections in patients not given antibiotics did not justify the use of prophylactic antibiotics. The authors commented that it was not justifiable to give antibiotics to 100 patients to prevent mild infections in two of them.[2, level II-2]

A Cochrane Review stated that there is some evidence that prophylactic antibiotics can reduce infection and dry sockets following third molar extraction. The authors however concluded that due to the increasing prevalence of bacteria which are resistant to treatment by currently available antibiotics, clinicians should consider the fact that because the infection rate is low, giving antibiotics is likely to do more harm than good. [10, level I]

There is no evidence for the use of prophylactic antibiotics in surgery to remove other impacted teeth. However, an inference can be made from the evidence for third molar surgery that the use of prophylactic antibiotics would similarly not be beneficial.

**RECOMMENDATION 3**

- Antibiotic prophylaxis is not indicated for lower third molar surgery. **(Grade A)**

### 2.3.1.2 Periodontal Surgery

The incidence of infection after periodontal surgery is low (0.55% - 2.09%).[22-23, level III] A retrospective study by Callis *et al.*[22, level III] showed that patients who received antibiotics as part of the surgical protocol (pre- and/or post- surgery) had an infection rate of 2.85% compared to an infection rate of 1.81% when no antibiotics were used. This result was not statistically significant.[23, level III] Here again, because of the low infection rate, giving antibiotics is likely to do more harm than good.

**RECOMMENDATION 4**

- Antibiotic prophylaxis is not recommended for routine periodontal surgery. **(Grade B)**

### 2.3.1.3 Minor clean-contaminated surgery with high degree of difficulty / long duration

Clean contaminated surgery of long duration (> 75th percentile for similar procedures) is associated with higher infection rates. [8, level II-2; 13, level III]

This higher infection rate is to be expected as the deeper tissues of the surgical site are exposed to the oral cavity for a longer period of time. Also, surgery with a higher degree of difficulty causes more injury to the tissues resulting in compromised healing and immune responses.

**RECOMMENDATION 5**

- Antibiotic prophylaxis may be indicated for minor surgery with a high degree of difficulty in which the duration of the surgery is predicted to be long. **(Grade B)**

#### 2.3.1.4 Surgery to place dental implants

Despite the high success rates published in the literature, implant failures do occur. Some of the early dental implant losses could be due to bacterial contamination during implant insertion which may lead to infections around the implant. Such infections when they do occur are very difficult to manage. The financial loss of implant failure is also great. In order to minimize early infection after dental implant placement, systemic antibiotic prophylaxis regimes have been advocated.

Two recent Cochrane systematic reviews concluded that there is some evidence suggesting 2g of amoxicillin given orally 1 hour preoperatively significantly reduces failures of dental implants placed in ordinary conditions.[24-25, level 1]

**RECOMMENDATION 6**

- Antibiotic prophylaxis is indicated for surgery to place dental implants. **(Grade A)**

#### 2.3.1.5 Surgery associated with the use of bone grafts

There is a paucity of evidence on whether antibiotic prophylaxis is indicated when bone grafts are inserted intra-orally. The reason for this lack of evidence is probably due to the fact that surgeons consider the financial cost and morbidity too great if a bone graft is lost through infection and therefore prescribe antibiotics.

A search of the literature found only one randomized controlled double blind study. The results of this study showed there was a statistically significant increased risk of having an infection after an intra-oral bone grafting procedure when antibiotic prophylaxis was not used. [26, level 1]

**RECOMMENDATION 7**

- Antibiotic prophylaxis is indicated for minor oral surgical procedures in which a bone graft is inserted. **(Grade A)**

### 2.3.2 Major clean-contaminated surgery

Orthognathic surgery is the archetype of major clean contaminated maxillofacial surgery. This category of surgery also includes surgery for large benign tumours and cysts.

In major maxillofacial surgery, the duration of the surgery is expected to be long with the wound open into the mouth for the duration of the surgery. As discussed above in Section 2.3.1.3, clean-contaminated surgery of longer duration is associated with an increased incidence of SSI. [8, level II-2; 13, level III]

Using proper surgical techniques and prophylactic antibiotics, Peterson [27, level III] stated that it was possible to reduce infection rates to as low as 1.0%.

Tan *et al.* [28, level 1] and Oomens et al. [29, level 1] in their systematic reviews and meta-analysis of clinical trials recommended that prophylactic antibiotics are indicated for orthognathic surgery.

**RECOMMENDATION 8**

- Antibiotic prophylaxis is indicated for major clean contaminated maxillofacial surgery. **(Grade A)**

## 2.4 Cancer surgery

Patients with head and neck cancer are usually older and are often medically compromised. Simo and French [30, level III] advocated the

use of prophylactic antibiotics for clean surgery associated with malignancy as it has a significantly higher infection rate when compared to surgery for benign disease. A prospective controlled study on antibiotic prophylaxis in clean neck dissections done by Seven et al. [31, level II-1] showed a significantly higher incidence of infections in patients who were not given antibiotics.

In clean-contaminated cancer surgery of the head and neck involving major resections and flap reconstruction, Hirakawa et al.[32, level II-3] showed an infection rate 32% and Skitarelic *et al*.[33, level II-3] found an infection rate of 22.0% even with prophylactic antibiotics.

**RECOMMENDATION 9**

- Antibiotic prophylaxis is indicated in all forms of head and neck cancer surgery. **(Grade A)**

## 2.5 Oral and maxillofacial trauma

There is little strong evidence relating to the use of prophylactic antibiotics in trauma surgery. A few points from the literature should however, be highlighted:

- Prophylactic antibiotic therapy reduces the risk of infection in the treatment of mandibular fractures. [34, level II-3]
- There is no good evidence for the use of post-operative antibiotics after open reduction and internal fixation of fractured mandibles.[35, level III; 36, level II-2; 37, level II-3]
- The incidence of SSI following surgery for fractures of the zygoma is low whether antibiotics are given or not. [34, level II-3]
- Infection rates for maxillary fracture treatment are very low. [35, level II-3]

It is also logical to consider that trauma to tissue renders it less resistant to infection.

In view of the lack of strong evidence, the indication for antibiotic prophylaxis in open reduction and internal fixation of facial bone fractures is considered as for clean, contaminated surgery and placement of implants.

**RECOMMENDATION 10**

- Antibiotic prophylaxis is indicated for open reduction and internal fixation of facial bone fractures. **(Grade B)**

- Antibiotics should not be continued postoperatively. **(Grade B)**

### 2.6 Site of surgery involving bone previously exposed to radiotherapy

Patients who have had radiation for the treatment of head and neck malignancy are at risk of osteoradionecrosis following oral surgical intervention to the jaws. While osteoradionecrosis itself is not considered an infection, surgical site infection involving the bone can cause osteoradionecrosis by means of inflammatory and infectious insult to the compromised bone. As a result of the morbidity associated with osteoradionecrosis, antibiotics have been widely used peri-operatively in association with surgery involving bone to try and prevent the occurrence of osteoradionecrosis.

No randomized controlled trial has been conducted to determine if prophylactic antibiotics are effective in preventing the onset of osteoradionecrosis. In one systematic review [38, level II-3] the incidence of osteoradionecrosis following tooth extraction was slightly lower when prophylactic antibiotic was used as compared to when no antibiotics was used (6% vs. 7%). The conclusions of this systematic review were, however, derived from weak evidence consisting mainly of retrospective and non-randomised prospective studies. Prophylactic antibiotics therefore do not appear to be effective in preventing osteoradionecrosis.

There is no difference in the incidence of osteoradionecrosis following tooth extraction whether antibiotics are administered or not.

If osteoradionecrosis does occur, there appears to be a changing trend in its management. There is evidence of the effectiveness of conservative medical management incorporating antioxidant therapy (Pentoxyphyline and Tocopherol).[39, level III] The addition of

low dose doxycycline or biphophonates to this also shows some promise.[40, level III]

## 3.0 ADMINISTRATION OF PROPHYLACTIC ANTIBIOTICS

Once it has been decided that prophylactic antibiotics are indicated, Peterson [27, level III] has suggested that several principles be followed:

- The correct antibiotic must be used.
- The plasma antibiotic level must be high.
- The timing of administration must be correct.
- The shortest antibiotic exposure must be used.

### 3.1 Choice of antibiotic

#### 3.1.1 Surgery confined to the oral cavity

One of the principles followed in choosing antibiotics is their effectiveness against the likely organisms causing the infection. Following this principle alone, the choice of antibiotics for odontogenic infections becomes complicated due to the polymicrobial nature of these infections.

The bacteria involved in odontogenic infections include the facultative anaerobic Gram-positive cocci *(Streptococcus viridans),* the strict anaerobic Gram-negative rods *(Porphyromona, Prevotella and Fusobacterium spp.)* and the strict anaerobic Gram-positive cocci *(Peptostreptococcus spp.)*[41, level III; 42, level II-1] There is agreement that facultative and strict anaerobes act synergistically and not in isolation in causing infection.[41, level III; 42, level II-1; 43, level II-3] Gaetti-Jardim *et al*.[43, level II-3] went on to suggest that it may be sufficient just to break the established synergism between different bacteria, rather than to try and target every single potential organism that may be involved in the infection.

Yuvaraj *et al.*[42, level II-1] showed that in interdependent, synergistic mixed infections, one bacterial species sensitive to penicillin may render the entire pathogenic complex non-pathogenic.

Penicillin and amoxicillin are effective against the organisms causing odontogenic infections and penicillin is still regarded by many authorities as the drug of choice. [42, level II-1; 44, level II-3; 45, level II-3; 46, level 1]

There is emerging resistance to penicillin by the *Streptococcus viridans* group due to modifications of the penicillin binding proteins (PBP). This resistance however can be overcome by increasing the dose of the antibiotic. The resistance of the anaerobic gram negative rods to penicillin is however due to the production of beta lactamase. As a result of this, the use of the amoxicillin-clavulanic acid combination is becoming increasingly popular. [41, level III]

The amoxicillin-clavulanic acid combination is a broad spectrum antibiotic. It should be avoided when other more narrow-spectrum antibiotics could be used. It increases the risk of *Clostridium difficile*, MRSA and other resistant infections.[47, level I] This antibiotic should therefore be prescribed only for appropriate indications so that it remains an effective antibiotic when needed.

Clindamycin has been shown to be effective against the facultative and strict anaerobes involved in odontogenic infections and is therefore often the drug of choice in patients allergic to penicillin. [43, level II-3]

The choice of antibiotic however must be justified by the antibiotic susceptibility patterns in the population. **Table 1** represents the antibiotic resistance patterns of oral organisms isolated in Hospital Sungai Buloh for 2014. The results show that *Streptococcus viridans* is still very sensitive to penicillin G and clindamycin but resistant to ampicillin. It also appears that the anaerobic organisms are showing some resistance to penicillin G and clindamycin.

**Table 1. Antibiotic resistance patterns of oral organisms- Hospital Sg. Buloh, 2014**

| Organism | Total isolate | Ampicillin | Clindamycin | Ceftriaxone | Cefotaxime | Erythromycin | Gentamicin | Imipenem | Metronidazole | Penicillin G | Piperacillin Tazobactam | Trimethoprim/Sulbactam | Tetracycline | Vancomycin |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Streptococcus intermedius | 6 | | 0 | | | | | 0 | 0 | 0 | 0 | | | 0 |
| | | | 6 | | | | | 6 | 6 | 6 | 6 | | | 6 |
| Streptococcus viridans | 11 | | 0 | 0 | 0 | 0 | | | | 0 | | | 9 | 0 |
| | | | 11 | 11 | 11 | 11 | | | | 11 | | | 11 | 11 |
| Peptostreptococcus sp. | 4 | | 0 | | | | | 0 | 0 | 50 | 0 | | | 0 |
| | | | 4 | | | | | 4 | 4 | 4 | 4 | | | 4 |
| Prevotella intermedia | 1 | 0 | 100 | | | | | 0 | 0 | | 0 | | | |
| | | 1 | 1 | | | | | 1 | 1 | | 1 | | | |
| Prevotella bivia | 1 | 0 | 0 | | | | | 0 | 0 | | 0 | | | |
| | | 1 | 1 | | | | | 1 | 1 | | 1 | | | |
| Prevotella oralis | 5 | 100 | 20 | | | | | 0 | 0 | | 20 | | | |
| | | 5 | 5 | | | | | 5 | 5 | | 5 | | | |
| Fusobacterium varium | 3 | 0 | 33 | | | | | 0 | 0 | | 33 | | | |
| | | 3 | 3 | | | | | 3 | 3 | | 3 | | | |
| Fusobacterium mortiferum | 5 | 40 | 0 | | | | | 0 | 0 | | 0 | | | |
| | | 5 | 5 | | | | | 5 | 5 | | 5 | | | |

*NB: The upper figure in each row refers to the percentage resistance and the lower figure refers to the no. of isolates tested.*

Microorganisms intervene in the odontogenic infection in a chronological manner. It is therefore logical to assume that effective antibiotic prophylaxis against the initiating bacteria, which are usually the facultative bacteria (mainly Streptococcus viridans), could prevent the infection. [45, level III]

In the light of these findings, penicillin G and clindamycin would be obvious choices as prophylactic antibiotics.

### 3.1.2 Surgery involving the oral cavity extending onto the skin

The pathogenic organisms involved in surgical site infections for surgery extending onto the skin may also include methicillin sensitive *Staphylococcus aureus* in addition to the oral organisms. The penicillinase resistant antibiotics cloxacillin and cefazolin (1st generation cephalosporin) would be the drugs of choice. Cloxacillin needs to be prescribed together with penicillin as it is effective only against *Staphylococcus aureus* and not the oral organisms. Cefazolin however can be prescribed alone as it is effective against both. Clindamycin is the antibiotic of choice for patients allergic to penicillin and is effective against all the organisms involved. [48, level III]

**RECOMMENDATION 11**

- Amoxicillin, Penicillin G and Clindamycin are appropriate choices of antibiotics for oral surgical prophylaxis. (**Grade B)**
- Cloxacillin, cefazolin or clindamycin should be considered if the surgery extends onto the skin. **(Grade C)**

## 3.2 Dose of antibiotic

The dose of the antibiotic should be based on its pharmacokinetic and pharmacodynamic properties and on patient factors. The clinical guidelines by Bratzler *et al.*[49, level II-2] and Mangram *et al.*[50, level II-3] have recommended that full therapeutic doses for antibiotics be used for prophylaxis. In obese patients, it is suggested that the dosage be increased although relevant studies are lacking. The recommendations for initial dose strengths of various antibiotics are as in **Table 2.**

**RECOMMENDATION 12**

- The dose of antibiotic to be administered for surgical prophylaxis should be at the full therapeutic dose of the antibiotic. **(Grade B)**

**Table 2. Initial dose strengths of various antibiotics**

| Route | Antibiotic | Initial dose strength |
|---|---|---|
| Oral | Amoxicillin | 1.0 g |
| | Clindamycin | 600mg |
| | Amoxicillin/ clavulanic acid | 1.0 g of the amoxicillin component |
| | Cefuroxime | 500mg |
| Parenteral | Benzyl Penicillin | 2 mega units |
| | Clindamycin | 600 mg |
| | Amoxicillin/ clavulanic acid | 1.2g |
| | Cloxacillin | 1.0g |
| | Cefazolin | 2.0g |
| | Cefuroxime | 1.5g |

## 3.3 Timing of first dose of antibiotic

Peterson suggested that for prophylaxis against wound infection to be effective, the tissue antibiotic levels must be high at the time of surgery which would necessitate the administration of the antibiotic preoperatively. The first dose of the antibiotic should be administered within 60 minutes prior to the surgical incision.[44, 50, level II-3]

A number of studies have demonstrated that there is an increased rate of SSI when antibiotics are given earlier than 60 minutes before incision.[49, level II-2; 50, level II-3; 51, level II-2] A Dutch study of 1922 patients showed that the highest risk of SSI was found in patients who were given prophylaxis after incision. [52, level II-2]

It should be noted however that an important animal study in 1990 by Berney and Francioli led to the establishment of the "two hour rule".[53, level III] This rule states that antibiotics given less than two hours from the start of the procedure is still effective as prophylaxis against wound infection. Beyond this time, antibiotics

will be ineffective as prophylaxis. This "two hour rule" might be considered if prophylactic antibiotics were not administered pre-procedure and it was subsequently felt either during or immediately after the procedure that antibiotics are needed. Such situations may arise due to a decision error or if the duration of the procedure lasts longer than initially expected.

**RECOMMENDATION 13**

- The first dose of the antibiotic should be administered within 60 minutes prior to the surgical incision. **(Grade B)**

### 3.4 Additional doses (duration) and dose intervals of the antibiotic

Mangram et al. suggests that additional doses of the antibiotic be given if the length of the surgery exceeds two half-lives of the drug or if there is excessive bleeding (more than 1500 ml). [50, level II-3]

Another suggestion by Sancho-Puchades et al.[41, level II-1] is that if the surgical intervention extends in time or if the tissue damage is considerable, another antibiotic dose can be administered at the equator (half) of its therapeutic interval. This is to ensure adequate serum and tissue concentrations of the drug until the wound is closed. The interval between doses is measured from the time of the first preoperative dose.

If additional doses of the antibiotic are to be administered, the dose given should be the same as the initial prophylactic dose of the antibiotic.[49, level II-2] The additional dosing suggested for the recommended antibiotics are as in **Table 3.**

Post-operative antibiotic administration is not necessary for most surgical procedures as it does not proffer any added advantage in preventing surgical site infections.[50, Level II-3; 33, level 1]

**RECOMMENDATION 14**

- Additional doses of prophylactic antibiotics should be administered if the length of surgery exceeds either two half-lives or half the therapeutic interval of the drug. **(Grade B)**

- The additional dose strength should be the same as the initial prophylactic dose of the antibiotic. **(Grade C)**
- Post-operative antibiotics should not be prescribed for surgical prophylaxis. **(Grade B)**

**Table 3. Additional dosing recommendations for long operations**

| Antibiotic | Additional dose strength | Dose Interval |
|---|---|---|
| Benzyl Penicillin | 2 mega units | 2 hours |
| Clindamycin | 600 mg | 6 hours |
| Amoxicillin/Clavulanic Acid | 1.2g | 3 hours |
| Cloxacillin | 1.0g | 4 hours |
| Cefazolin | 2.0g | 4 hours |
| Cefuroxime | 1.5g | 4 hours |

## 4.0 CONCLUSION

These guidelines are the current recommendations of the committee towards good practice with respect to the appropriate use of antibiotics in surgical prophylaxis. Dental practitioners may have individual preferences but all decisions made must be in the light of available evidence, resources and the circumstances presented by their patients.

It is important to emphasize that the appropriate use of antibiotics in patient care is of paramount importance and that antibiotic prophylaxis in surgery is an adjunct to and not a substitute for good surgical technique. Antibiotic prophylaxis should be regarded as one component of an effective policy for control of surgical site infection.

## 5.0 IMPLEMENTING THE GUIDELINES

The first edition of these clinical practice guidelines (CPG) on antibiotic prophylaxis against wound infection for oral surgical procedures was developed and published in 2003. An audit carried out in 2010 however found that more than half of the respondents did not use the CPG. [1, level III] It also found that the most important sources of information that clinicians used were their own clinical experience and the opinions of their colleagues.

A study done in 2012 by the IHSR [2, level III] found a wide variation in the use of antibiotics by doctors for patients undergoing dento-alveolar surgery. At the start of the study it was discovered that doctors followed 3 patterns of prescribing, either i) they did not prescribe any antibiotics, ii) prescribed only a single dose of antibiotic pre-operatively or iii) prescribed 5 days of antibiotics post-operatively. For the doctors who prescribed antibiotics post-operatively, 77% prescribed one antibiotic while the rest prescribed two. There was also a wide range of the types of antibiotics prescribed which included amoxicillin, bacampicillin, co-amoxiclav, metronidazole, cloxacillin and cefuroxime.

It is important to ensure that the use of prophylactic antibiotics in oral surgery is evidence-based. The rational use of antibiotics by all healthcare professionals will help to prevent the emergence of resistant organisms. Appropriate antibiotic use will assist in successful treatment outcomes and reduce adverse reactions. In addition, the financial cost in the management of patients.[2, level III] could be reduced.

### 5.1 Facilitating and Limiting Factors

Existing facilitators for application of the recommendations in the CPG include:

a) Wide dissemination of the CPG to healthcare professionals via printed and electronic copies.
b) Continuing professional education for healthcare professionals.

Existing barriers for application of the recommendations of the CPG include:

a) Non-standard teaching related to prophylactic antibiotic use
b) Variation in treatment practice and preferences

## 5.2 Potential Resource Implications

To implement the CPG, there must be strong commitment to:

a) Ensure widespread distribution of the CPG to healthcare professionals.
b) Reinforce training of healthcare professionals to ensure information is up to date.

To assist in the implementation of the CPG, the following are proposed as clinical audit indicators for quality management:

### a. Lower third minor surgery

Indicator: Percentage of patients undergoing lower third molar surgery requiring antibiotic prohylaxis < 10%.

$$\frac{\text{No. of impacted lower third molar surgery cases given antibiotics}}{\text{No. of impacted lower third molar surgery cases}} \times 100\%$$

### b. Trauma

Indicator: Percentage of patients undergoing open reduction and internal fixation (ORIF) of simple mandibular fractures given post-op antibiotics < 2%.

$$\frac{\text{No. of patients given antibiotic prescriptions post-ORIF}}{\text{No. of patients undergoing ORIF}} \times 100\%$$

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## SEARCH STRATEGY

The following MeSH terms or free text terms were used either singly or in combination, search was limit to English, human and 2003 to current:

**Microbiology**

- oral bacteria
- oral microorganisms
- microflora
- Antibiotic sensitivity
- Antibiotic resistance
- Odontogenic infections
- Surgical site infections

**Treatment**

- Oral surgery
- Dental surgery
- Maxillofacial surgery
- Clean surgery
- Clean-contaminated surgery
- Minor oral surgery
- Wisdom teeth surgery
- Periodontal surgery
- Traumatic injuries to face and jaws
- Cancer surgery
- Orthognathic surgery
- Osseointegrated implants
- Osteoradionecrosis
- Bone grafts
- Skin incisions

**Antibiotics**

- Therapy
- Prophylaxis
- Penicillin
- Amoxicillin
- Clindamycin
- Co-amoxiclav
- Antibiotic regime
- Dosage
- Duration
- Re-dosing protocol
- Pre-operative antibiotics
- Post-operative antibiotics

## ASA PHYSICAL STATUS CLASSIFICATION SYSTEM

Last approved by the ASA House of Delegates on October 15, 2014

Current definitions (NO CHANGE) and Examples (NEW)

| ASA PS Classification | Definition | Examples, including, but not limited to: |
|---|---|---|
| **ASA I** | A normal healthy patient | Healthy, non-smoking, no or minimal alcohol use |
| **ASA II** | A patient with mild systemic disease | Mild diseases only without substantive functional limitations.<br>Examples include (but not limited to):<br>Current smoker, social alcohol drinker, pregnancy, obesity (30 < BM < 40), well controlled DM/ HTN, mild lung disease |
| **ASA III** | A patient with severe systemic disease | Substantive functional limitations; One or more moderate to severe diseases.<br>Examples include (but not limited to):<br>Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents. |

| | | |
|---|---|---|
| **ASA IV** | A patient with severe systemic disease that is a constant threat to life | Examples include (but not limited to):<br>recent ( < 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis |
| **ASA V** | A moribund patient who is not expected to survive without the operation | Examples include (but not limited to):<br>Ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/ system dysfunction |

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