

# Antibiotic Prophylaxis for Surgical Procedures

A Systematic Review

# SBU Board of Directors and Scientific Advisory Committee

## Secretariat

MÅNS ROSÉN  
Executive Director, SBU

## Board of Directors

NINA REHNQVIST  
Karolinska Institute, Solna  
(Chair)

BJÖRN KLINGE  
Karolinska Institute,  
Solna

MARGARETA TROEIN  
TÖLLBORN  
The Swedish Society  
of Medicine

EVA NILSSON BÅGENHOLM  
The Swedish Medical  
Association

MÅNS ROSÉN  
SBU

MATS ULFENDAHL  
The Swedish Research  
Council

HÅKAN CEDER  
The National Board  
of Health and Welfare

KARIN STRANDBERG NÖJD  
The Swedish Association  
of Local Authorities and  
Regions

SABINA WIKGREN ORSTAM  
The Swedish Association  
of Local Authorities and  
Regions

ANNA-KARIN EKLUND  
Swedish Association  
of Health Professionals

HÅKAN SÖRMAN  
The Swedish Association  
of Local Authorities and  
Regions

## Scientific Advisory Committee

DAVID BERGQVIST  
Uppsala University  
Hospital (Chair)

MATS G HANSSON  
Uppsala University

ULF NÄSLUND  
Norrland University  
Hospital, Umeå

BJÖRN BEERMANN  
Medical Products Agency,  
Uppsala

MIKAEL HELLSTRÖM  
Sahlgrenska Hospital,  
Gothenburg

JOAKIM RAMSBERG  
i3 Innovus, Stockholm

CHRISTINA BERGH  
Sahlgrenska Hospital,  
Gothenburg

MARGARETA MÖLLER  
University Hospital,  
Örebro

BO RUNESON  
Karolinska Institute,  
Solna

CECILIA BJÖRKELUND  
Gothenburg University

JÖRGEN NORDENSTRÖM  
Karolinska University  
Hospital, Solna

GUNNEL SVENSÅTER  
Malmö University

SÖLVE ELMSTÅHL  
University Hospital,  
Malmö

OLOF NYRÉN  
Karolinska Institute,  
Solna

ANIA WILLMAN  
Blekinge Institute of  
Technology, Karlskrona

*Summary and Conclusions of the SBU Report:*

# Antibiotic Prophylaxis for Surgical Procedures

A Systematic Review

August 2010

## **Project Group:**

Maria Ahlberg (Project Assistant)	Anders Heimdahl Bengt Jeppsson (Chair)	Inga Odenholt Nina Rehnqvist (Assistant Project Director)
Susanna Axelsson (Project Director)	Elisabeth Källgren (Project Assistant)	Bo Risberg
Christina Bergh	Jonas Lindblom (Literature Search)	Elisabeth Ståhle
Anna Elander	Lars-Åke Marké	Richard Wallensten
Magnus Grabe	Anders Norlund	Eva Westman
Bengt Gårdlund		

## **Co-authors:**

Mats Bergström  
Örjan Friberg

## **Scientific Reviewers:**

Thomas Davidson	Torsten Sandberg
Olof Nilsson	Anna Stjernquist-Desatnik
Ragnar Norrby	Ingrid Wikström
Per-Olof Nyström	

*Report: Antibiotic Prophylaxis for Surgical Procedures • Type: Systematic Review  
ISBN: 978-91-85413-36-2 • ISSN: 1400-1403 • Report no: 200 • Published: 2010  
English Translation of the Summary: Joan Bevenius Carrick, Transodont*

# SBU's Conclusions

The medical/clinical advantages of antibiotic prophylaxis must be weighed against the risk of increasing numbers of antibiotic resistant strains of bacteria. Development of resistance is more gradual in Sweden than in other countries, but resistant bacteria spread beyond national boundaries.

SBU's scientific scrutiny of antibiotic prophylaxis for surgical intervention, a survey of established practice in this field and a consequence analysis, have led to the following conclusions with respect to areas with potential for improvement:

*Correctly used, antibiotic prophylaxis can reduce the total use of antibiotics.*

There is strong scientific support that antibiotic prophylaxis reduces the development of infection after:

- Operations and endoscopic procedures in the large intestine, the rectum, and the stomach (including appendectomies and penetrating abdominal trauma), and after percutaneous endoscopic gastrostomy (PEG)
- Cardiovascular surgery, and insertion of pacemakers
- Breast cancer surgery
- Hysterectomy
- Reduction of simple fractures and prosthetic limb surgery
- Complicated surgery for cancer in the ear, nose, and throat regions

- Transrectal biopsy and resection of the prostate (febrile urinary tract infection and blood poisoning).

In most cases the scientific evidence is inadequate to determine which type of antibiotic is most effective for antibiotic prophylaxis.

*A transition to single-dose prophylaxis would probably reduce the risk of development of resistant strains of bacteria without increasing the risk of infection.*

Antibiotic resistance is determined by the total use of the antibiotic. When the purpose of antibiotic treatment is to prevent infection, a single dose is in most cases as effective as multi doses (this does not apply to resection of the prostate).

*There is inadequate scientific evidence to support the administration of antibiotics to prevent post-operative infection following hernia and gallbladder surgery, arthroscopy, and tonsillectomy in patients that not at special risk.*

*If all surgical units introduced procedures for registration of post-operative infection, the effectiveness of antibiotic prophylaxis could be documented and applied as a baseline value for improving quality.* To be effective, such a register would need to be based on simple administrative routines, a clear definition of the term post-operative infection, and adequate long-term follow-up of patients.

Infection of the heart valves, bacterial endocarditis, is a potentially life-threatening condition that can arise after oral surgery. The collective scientific evidence is inadequate for any evidence-graded conclusions. Patients with artificial heart valves and complicated congenital heart defects, in whom the development of endocarditis could have more serious consequences, may be considered for prophylaxis.

There is inadequate scientific evidence to determine the effect of antibiotic prophylaxis with respect to many of the surgical interventions for which it is applied today.

Because of the lack of empirical studies, there is inadequate evidence to determine the cost-effectiveness of antibiotic prophylaxis. A few empirical studies and model studies, comparing outcomes with and without antibiotic prophylaxis, support its cost-effectiveness.

# SBU's Summary

## Background and aim

Antibiotic prophylaxis is the administration of antibiotics before or at the time of a surgical intervention, with the aim of preventing the development of infection. Antibiotic prophylaxis is used for surgical procedures that can give rise to spread of bacteria, which can cause infection after the surgery. Patients with infections, immune deficiency disorders, obesity or diabetes, and smokers, can be at increased risk of infection after surgery.

Infections cause suffering for the patient and are an added expense for the healthcare sector and society. At the same time, it is important to try to limit the total use of antibiotics in order to reduce the risk of development of highly resistant strains of bacteria. The severity of effect and the importance of infections vary greatly: while an infection after cardiac surgery can be life-threatening and an infection after joint surgery can result in loss of the implant, superficial infection of an abdominal wound causes only mild discomfort.

Although antibiotic prophylaxis is common clinical practice, some aspects have not been clarified and it was therefore considered important to review and evaluate the scientific evidence on which the practice is based.

## Limitations

The project concerns antibiotic prophylaxis for surgical procedures for diagnosis or treatment in the following fields:

- Procedures in the gastrointestinal canal and the abdominal wall
- Vascular procedures (excluding percutaneous catheter-based procedures)
- Obstetrics and gynaecology
- Orthopaedics
- Plastic surgery
- Cardiac surgery
- Implantation of permanent pacemakers
- Other thoracic surgery
- Closed insertion of thorax drains
- Urology
- Ear, nose, and throat surgery
- Oral and maxillofacial surgery

The review of the literature has been limited primarily to elective surgery. Exception has been made for acute appendicitis and acute caesarean section, open abdominal wounds, and open fractures. Some of these clinical conditions are relatively common and there are often no routines for antibiotic administration, and it was therefore considered important to examine the scientific evidence supporting antibiotic administration for these conditions.

The report does not include antibiotic prophylaxis for ophthalmic surgery, neurosurgery, or transplant surgery.

The report has been limited to antibiotic prophylaxis to prevent post-operative infection. Other measures that can influence the frequency of post-operative infection have not been included.



## Questions addressed

- Is antibiotic prophylaxis effective in preventing local and general infections after a surgical procedure? How well does the underlying scientific evidence support these effects?
- Which antibiotic preparations, what doses and treatment times give the best effect, relative to the risk for side effects and development of resistant strains of bacteria?
- Under what conditions is antibiotic prophylaxis ineffective or a disadvantage to patients?

A specific aim has also been to evaluate the scientific evidence that antibiotic prophylaxis prevents bacterial endocarditis after surgery on patients at particular risk of developing this condition.

## Method

SBU has established a thorough and systematic method by which available databases are searched, to identify all literature relevant to the issues to be addressed in a project. Each study included in the evaluation has been assessed for quality and tabulated according to a specially developed method. The review comprised screening the studies for relevance to the subject and then for methodological qualities – study design, internal validity (reasonable protection from systematic errors), statistical power, and generalisability. Quality assessment of the health economics articles was carried out as a collaborative effort between medical experts and health economists. The results were then graded according to the strength of the underlying scientific evidence.

## Facts 1 Study Quality, Relevance and Evidence Grading.

**Study quality** refers to the scientific quality of an individual study and its capacity to answer a specific question in a reliable way.

**Evidence grade** refers to the assessed strength of the collective body of scientific evidence and its capacity to answer a specific question in a reliable way. SBU uses an international evidence grading system called GRADE. Study design is the primary factor considered in the overall assessment of each outcome measure. Secondary factors that can increase or decrease the strength of the evidence include: study quality, relevance, consistency, transferability, effect size, data precision, risk of publication bias, and other aspects, e.g. the dose-response relationship.

Evidence grades – four levels

### **Strong scientific evidence (⊕⊕⊕⊕)**

Based on high or medium quality studies with no factors that weaken the overall assessment.

### **Moderately strong scientific evidence (⊕⊕⊕○)**

Based on high or medium quality studies with isolated factors that weaken the overall assessment.

### **Limited scientific evidence (⊕⊕○○)**

Based on high or medium quality studies having factors that weaken the overall assessment.

### **Insufficient scientific evidence (⊕○○○)**

Scientific evidence is deemed insufficient when scientific findings are absent, the quality of available studies is low, or studies of similar quality present conflicting findings.

The stronger the evidence, the lower the likelihood that new research findings would affect the documented results within the foreseeable future.

### **Conclusions**

SBU's conclusions present an overall assessment of benefits, risks, and cost effectiveness.

## Results graded according to the strength of the evidence

### Procedures in the upper gastrointestinal tract and the abdominal wall

The upper gastrointestinal tract comprises the throat, the stomach, the duodenum, the liver, the bile ducts, and the pancreas. Although the throat, stomach, and duodenum contain significantly fewer bacteria than the large intestine and the rectum, post-operative infections are common.

- With respect to open or laparoscopic gall bladder surgery, there is inadequate evidence of a demonstrable effect of antibiotic prophylaxis in patients without risk factors (strong scientific evidence ⊕⊕⊕⊕).
- Antibiotic prophylaxis reduces the number of post-operative infections in patients with risk factors (diabetes mellitus, gall bladder inflammation, gallstones, and jaundice caused by biliary tract obstruction) following gall bladder surgery (both open and laparoscopic surgery) compared with no prophylaxis or placebo (limited scientific evidence ⊕⊕○○). It is not possible to determine from the evidence which antibiotic is most effective.
- Antibiotic prophylaxis also results in fewer post-operative infections in cases of gastric surgery, percutaneous endoscopic gastrostomy (PEG), appendectomies, and penetrating abdominal trauma (strong scientific evidence ⊕⊕⊕⊕). In gastric surgery, the third-generation cephalosporins are more effective than the second-generation (strong scientific evidence ⊕⊕⊕⊕).
- Multiple-dose prophylaxis for gall bladder surgery and for surgery in cases of penetrative abdominal trauma does not result in fewer post-operative infections than single-dose prophylaxis (strong scientific evidence ⊕⊕⊕⊕).

- Antibiotic prophylaxis does not significantly reduce post-operative infection associated with endoscopic exploration of the biliary and pancreatic ducts and hernia operations (strong scientific evidence ⊕⊕⊕⊕).

There is little or no scientific evidence on which to determine the value of antibiotic prophylaxis for surgery to the liver, throat, and pancreas.

### **Procedures involving the large intestine and the rectum**

Without antibiotic prophylaxis, post-operative infections would occur in 30 to 40 percent of surgery to the large intestine and rectum. The frequency of post-operative wound infections is greater in rectal surgery than in surgery to the large intestine. Tumours are the main reason for elective surgery to the large intestine.

- Antibiotic prophylaxis decreases the frequency of post-operative wound infection, from 35 to 40 percent to 5 to 10 percent. A single dose is as effective as multiple doses (strong scientific evidence ⊕⊕⊕⊕).
- The prophylactic effect is greater if an antibiotic effective against aerobic bacteria is combined with one that is effective against anaerobes (strong scientific evidence ⊕⊕⊕⊕).
- Studies comparing the effect of different cephalosporins have shown no differences in their effect (strong scientific evidence ⊕⊕⊕⊕).
- When using antibiotics with a short half-life (1–2 hours), the dose should be administered 30–60 minutes pre-operatively (moderately strong scientific evidence ⊕⊕⊕○).



## Vascular procedures

Post-operative infection following a vascular procedure can be very serious. The graft material used in reconstruction of a blood vessel is often synthetic. Infection in such a graft can lead to severe, life-threatening bleeding. According to the literature, the mortality rate for post-operative infection of an aortic graft is 40 to 50 percent.

- In vascular surgery, antibiotic prophylaxis reduces the risk of post-operative wound infection by 83 percent (strong scientific evidence ⊕⊕⊕⊕).
- There is insufficient scientific evidence to determine:
  - which type of antibiotic is most effective
  - whether vascular grafts impregnated with antibiotics reduce the risk of graft infection
  - whether antibiotic prophylaxis reduces the risk of late-onset graft infection
  - the most appropriate duration of treatment for prophylaxis.

## Obstetric and gynaecological procedures

The panorama of infection associated with obstetric and gynaecological surgical procedures is characterised by the copious, specific, and varied bacterial flora of the vagina. In certain procedures, e.g. hysterectomy, there is direct contact between the abdominal cavity and the vagina; heavy contamination of the abdominal cavity with the vaginal microflora cannot be avoided. In cases of emergency caesarean section, there is also the risk of contamination of the abdominal cavity with vaginal bacteria. In elective caesarean section, the risk of contamination is considerably less.

- Antibiotic prophylaxis significantly reduces the risk of post-operative infection, especially endometritis, following emergency and elective caesarean section (moderately strong scientific evidence ⊕⊕⊕○). The effect of a single-dose pro-

phylaxis is comparable with multiple doses (strong scientific evidence ⊕⊕⊕⊕). There is insufficient scientific evidence to determine which type of antibiotic is most effective (⊕○○○). A combination of several antibiotics is more effective than a single preparation for caesarean section (limited scientific evidence ⊕⊕○○). There is insufficient evidence to determine the most appropriate time for administration of the antibiotic prophylaxis (⊕○○○).

- Antibiotic prophylaxis significantly reduces the risk of post-operative infections such as abdominal wound infections and vaginal infections after hysterectomy (moderately strong scientific evidence ⊕⊕⊕○). The effect of a single-dose prophylaxis is comparable with that of multiple doses (strong scientific evidence ⊕⊕⊕⊕). There is insufficient scientific evidence to determine which type of antibiotic is most effective.
- There is a conflicting scientific evidence to determine whether antibiotic prophylaxis reduces the frequency of infections in abortions (⊕○○○).
- There is insufficient scientific evidence to determine whether antibiotic prophylaxis has a positive effect on forceps deliveries, perineoplasty (repair of perineal damage), or manual removal of the placenta (⊕○○○). The same applies to surgical intervention in cases of incomplete miscarriage (expulsion of the foetus but not of the placenta), urinary incontinence and prolapse surgery, sterilisation by means of minilaparotomy, laparoscopic surgery on the ovaries and the oviducts, and intrauterine surgical procedures on the uterus via the cervical route (⊕○○○).
- Antibiotic prophylaxis does not reduce the frequency of infection associated with insertion of an intrauterine device, compared with a placebo (strong scientific evidence ⊕⊕⊕⊕).

## Orthopaedic surgery

Infection of the joints can have serious consequences. Bacterial joint infections can rapidly destroy the cartilage, resulting in pain and impairment of function. Infectious skeletal infections are difficult to treat and not infrequently become chronic. In most orthopaedic surgery, synthetic implants are inserted, increasing the risk of infection. If infection occurs, further surgery may be necessary to remove the implant.

- For operation of closed fractures and in prosthetic surgery there is support for the use of antibiotic prophylaxis (strong scientific evidence ⊕⊕⊕⊕). For amputation and open fractures the scientific evidence is moderate (⊕⊕⊕○). There is no support for antibiotic prophylaxis lasting more than 24 hours for any of the above procedures (moderately strong scientific evidence ⊕⊕⊕○).
- For prosthetic surgery there is support not only for the administration of systemic antibiotic prophylaxis but also for the use of cement impregnated with antibiotics (limited scientific evidence ⊕⊕○○).
- None of the antibiotics studied (various generations of cephalosporins, isoxazolyl penicillin, penicillin, penicillin with beta-lactamase inhibitor, quinolone, teicoplanin, macrolide, aminoglycoside, and clindamycin) has been shown to be superior to the others (strong scientific evidence ⊕⊕⊕⊕).
- For closed fractures and elective prosthetic surgery, there is scientific support for limiting prophylaxis to a pre-operative dose only (moderately strong scientific evidence ⊕⊕⊕○).



## Plastic surgery

A tissue-sparing surgical technique that preserves the blood circulation in the tissues is a basic prerequisite for good wound healing and a cosmetically acceptable outcome. Transplantation of tissue or grafting of foreign material is associated with increased risk of infection.

- Antibiotic cover together with local anaesthesia for skin tumour therapy, with or without raising a flap, or a transplant, gives a significantly lower frequency of post-operative wound infection (moderately strong scientific evidence ⊕⊕⊕○).
- There is insufficient scientific support to assess the value of antibiotic prophylaxis in breast reconstruction after cancer, breast reduction, breast enlargement with implants, abdominoplasty and cleft palate surgery (⊕○○○).

## Breast cancer surgery

- Single-dose antibiotic prophylaxis reduces the risk of infection in breast cancer surgery (strong scientific evidence ⊕⊕⊕⊕).

## Cardiac surgery

In cardiac surgery, wound infection in the sternum, with infection in the mediastinum (the space between the lungs) is a grave, life-threatening complication requiring long and complicated hospital care. Wound infections at other surgical sites, such as access sites to veins to obtain a graft, such as the site of the vena saphena magna – great saphenous vein – which in a bypass operation will conduct the blood supply around a narrowed segment of a coronary artery – are usually not fatal but may lead to delayed healing, requiring a long period of hospitalisation and a prolonged period of impaired quality of life.

Endocarditis/prosthetic endocarditis is a very grave condition that must often be treated by re-operation to remove the infected heart valve and insert a new one. The procedure is associated with a high risk of infection and the new valve is also subsequently at risk of infection.

Sepsis is a very grave, potentially fatal complication, especially in a patient who has recently undergone cardiac surgery. There is a high risk that blood-borne infection will reach the field of operation, i.e. the breastbone and implanted foreign/synthetic materials such as grafts and prosthetic heart valves.

- Antibiotics administered intravenously reduce the risk of post-operative wound infection compared with a placebo (strong scientific evidence ⊕⊕⊕⊕).
- There is a lack of scientific evidence to allow differentiation of the effect of antibiotic prophylaxis in patient groups undergoing different types of cardiac surgery (⊕○○○).
- Cephalosporins reduce the total risk of post-operative wound infection compared with a placebo (moderately strong scientific evidence ⊕⊕⊕○).
- Beta-lactamase stable penicillin reduces the number of post-operative infections, often at the mediastinum and the site of access to veins, compared to a placebo (moderately strong scientific evidence ⊕⊕⊕○).
- There is a lack of scientific evidence to support the administration of intravenous antibiotic prophylaxis for longer than 48 hours (⊕○○○).

- Locally administered gentamicin reduces the risk of wound infection in the mediastinum after cardiac surgery involving sternotomy (limited scientific evidence ⊕⊕○○).

### **Implantation of permanent pacemakers**

Complications in the form of infection after implantation of a pacemaker can range from local infection and pus formation around the pacemaker or systemic infection with sepsis and infection in intravenous parts of the electrode system. The frequency of infection in the absence of antibiotic prophylaxis is reported to increase from 1 to a few percent, but with wide variations. While the frequency of infection may appear quite low, antibiotic prophylaxis is a well-established routine in clinical practice because of the very grave consequences of an infection.

- Intravenous prophylaxis with beta-lactamase stable penicillin or cephalosporin reduces the frequency of infection associated with the installation of pacemakers (moderately strong scientific evidence ⊕⊕⊕○). There are no studies to determine the optimal duration of prophylaxis, but indirect comparison indicates that a single dose is as effective as multiple doses (⊕○○○). It is not possible to determine whether the various antibiotics used for prophylaxis have different effects (insufficient scientific evidence ⊕○○○).

### **General thoracic surgery**

The results presented in this section apply to pulmonary surgery involving thoracotomy (incision between the ribs). In Scandinavia such surgery is usually undertaken for pulmonary malignancy, but treatment of pneumothorax (accumulation of air or gas in the pleural space) is also common. After pulmonary surgery, three main types of complication due to infection can occur: wound

infection, empyema (pus formation in the pleural space), and pneumonia. In the absence of antibiotic prophylaxis, the incidence of wound infection is estimated to be 13 to 22 percent, empyema 3 to 9 percent, and pneumonia 21 to 32 percent.

- Antibiotic prophylaxis reduces the frequency of post-operative infection after pulmonary surgery (moderately strong scientific evidence ⊕⊕⊕○). Studies indicate that in order to prevent pneumonia and empyema it is important that the prophylaxis is effective against both Gram positive cocci and the most common Gram negative bacteria (limited scientific evidence ⊕⊕○○).
- There is insufficient scientific evidence to determine whether 24 hour prophylaxis is as effective as 48 hours (⊕○○○). With respect to wound infections, there are insufficient large-scale studies to support any particular prophylactic regimen (⊕○○○).

### **Insertion of closed pleural drainage**

Insertion of a closed pleural drain (referred to as Büla-drainage) in the pleural cavity is undertaken in order to remove air (pneumothorax), blood (haemothorax), or other fluids. The most common cause of blood in the pleural cavity is trauma due to external violence. Pleural drainage is a common procedure. The frequency of post-operative infections is around 1.5 to 3 percent. It has not been determined whether the intervention to establish drainage or the primary trauma to the thorax constitutes the primary risk for infectious complications. Insertion of a drain in the pleural cavity could result in formation of pus in the pleural cavity, or infection at the point of insertion through the chest wall, but bacteria can also gain access through the trauma area itself. No studies were found of antibiotic prophylaxis in cases of pleural drainage in the absence of trauma, e.g. spontaneous pneumothorax, possibly because in such cases infection was never identified as a clinical problem.

- The frequency of empyema (accumulation of pus in the pleural cavity) after trauma to the thorax is low, even in the case of penetrating injury; the absolute reduction in risk attributable to antibiotic administration appears to be minor (around 1 to 3 percent). This must be weighed against the risk of superinfection with resistant bacteria. Prophylactic antibiotics probably give a minor reduction in the frequency of pus accumulation in the pleural cavity following installation of drainage (limited scientific evidence ⊕⊕○○). This conclusion is based on patient data from large U.S. trauma centres with a high proportion of penetrating injuries (knife and firearms wounds) and the results may not be readily extrapolated to Swedish conditions.

### **Procedures involving the urinary tract and male sex organs**

For common urological disorders, open surgery has largely been replaced by cystoscopy with access through the urinary tract and laparoscopic surgery. The instruments for diagnosis and treatment have been refined to such an extent that procedures can be carried out with minimum trauma to the tissues. The most common infectious complications associated with urological procedures are urinary tract infections and wound infections.

- Antibiotic prophylaxis for transrectal (through the rectum) prostate biopsy reduces the frequency of infection (moderately strong scientific evidence ⊕⊕⊕○) and can be limited to a single dose in men without other known risk factors (strong scientific evidence ⊕⊕⊕⊕). For cystoscopy and urodynamic investigation, the presence of bacteria in the urine (bacteriuria) and symptomatic infections is low (<5 percent). Antibiotic prophylaxis reduces the frequency of bacteriuria, but the clinical, practical importance of this effect has not been documented scientifically.

- In transurethral resection of the prostate, antibiotic prophylaxis reduces the frequencies of bacteriuria, lower urinary tract infections, febrile infections, and sepsis (strong scientific evidence ⊕⊕⊕⊕). There is a lack of relevant documentation with respect to the effect of antibiotic prophylaxis in the transurethral resection of bladder tumours.
- The frequencies of bacteriuria and symptomatic infections after shockwave lithotripsy are low (<5 percent). Antibiotic prophylaxis reduces the frequency of bacteriuria but the clinical, practical importance of this effect has not been documented scientifically. There is insufficient documentation with respect to urethroscopy and the percutaneous extraction of stones (⊕○○○).
- There is no scientific documentation of the effect of antibiotic prophylaxis in open or laparoscopic surgery without involvement of the urinary tract (e.g. nephrectomy and scrotal surgery) (⊕○○○).
- There is no scientific documentation of the effect of antibiotic prophylaxis in open or laparoscopic surgery involving the urinary tract (e.g. plastic surgery of the renal pelvis, bladder surgery, and prostatectomy) (⊕○○○).
- There is no documentation of the role of antibiotic prophylaxis in open or laparoscopic surgery involving the intestine (e.g. cystectomy with urinary diversion) (⊕○○○).

### **Ear, nose, and throat surgery**

Surgical procedures in the ear, nose, and throat region (ENT) are of widely varying character, ranging from clean procedures without contamination of the surgical wound to procedures involving areas in which the normal flora have the potential to cause

infection. The risk of post-operative infection varies; it is high in cancer surgery where the surgery involves skin and mucous membrane and also in cases where tissues are transposed and implants of synthetic material are inserted. However, the frequency of infection is low in cases of clean head and neck surgery of benign tumours, such as procedures involving the salivary glands and the thyroid gland.

- In tonsillectomies, antibiotic prophylaxis does not affect post-operative haemorrhage (moderately strong scientific evidence ⊕⊕⊕○), pain, or consumption of analgesics (limited scientific evidence ⊕⊕○○), i.e. the substitute measures customarily used as indicators of infection in this region.
- In cancer surgery in the ENT area with risk of contamination with microbial flora that can give rise to infections, there is strong scientific evidence supporting the administration of antibiotic prophylaxis (strong scientific evidence ⊕⊕⊕⊕). Administration of antibiotics for longer than 24 hours does not give a better effect (moderately strong scientific evidence ⊕⊕⊕○). The prophylactic effect is greater if the antibiotic or combination of antibiotics covers both aerobic and anaerobic bacteria (limited scientific evidence ⊕⊕○○).
- There is insufficient scientific evidence to determine whether antibiotic prophylaxis reduces the risk of meningitis in cases of fractures of the base of the skull (⊕○○○). The same applies to the preventive effect of antibiotic prophylaxis on post-operative infections after nasal surgery or the insertion of cochlear implants (⊕○○○).
- Antibiotic prophylaxis does not reduce post-operative infections or complications following clean surgery of the middle ear (limited scientific evidence ⊕⊕○○)

## **Jaw surgery**

Intraoral surgery always causes transfer of micro-organisms from the mucous membrane to the surgical wound, resulting occasionally in infection of the wound. Intraoral injuries can be similarly infected, e.g. in cases of traumatic injury to the teeth, or jaw fractures penetrating the oral cavity.

- Antibiotic prophylaxis for the installation of dental implants, treatment of fractures of the mandible (lower jaw), and dental anomalies results in a decrease of loss of implants and wound infections respectively (limited scientific evidence ⊕⊕○○). A single pre-operative dose does not lead to more infections than extended prophylaxis (limited scientific evidence ⊕⊕○○). There is insufficient scientific evidence to determine which antibiotic is most effective (⊕○○○).
- There is conflicting scientific evidence about the effect of antibiotic prophylaxis on post-operative complications associated with the extraction of wisdom teeth (⊕○○○).
- There is insufficient scientific evidence to evaluate the effect of antibiotic prophylaxis on other surgery in the oral cavity or the jaws (⊕○○○).

## **Infectious endocarditis**

Infectious endocarditis is an uncommon but potentially fatal condition. Despite advances in treatment, primarily with antibiotics, the condition is serious and has a high mortality rate (up to 20 percent) particularly in patients with prosthetic heart valves.

The cause of the disease is the blood-borne spread of micro-organisms that can attach to damaged heart valves and endothelium, multiply, and result in infectious endocarditis. The micro-organisms most commonly implicated originate on the skin and in the oral cavity.



The collective scientific evidence does not allow evidence-graded conclusions. Antibiotic prophylaxis should be considered for patients with synthetic heart valves and complex congenital heart defects, in whom endocarditis would be expected to have particularly grave consequences.

### **Health economics**

A few empirical studies of economics have been assessed as relevant to Swedish health services and have also met the criteria for moderate to high study quality, and have therefore been included. Because of the dearth of empirical studies, there is insufficient scientific evidence on which to draw conclusions about the cost-effectiveness of antibiotic prophylaxis.

In relation to the overall cost of care of surgical patients, the cost of antibiotic prophylaxis for surgery is minor. As there is evidence of the effect of antibiotic prophylaxis in preventing wound infection, the administration of antibiotics to cover surgical procedures can be considered to be cost effective. Relatively little is known, however, about the risks of development of resistant strains of bacteria and the associated costs.

### **Ethical and social aspects**

Antibiotic prophylaxis is administered without question to large groups in the community, exposing the entire population to increased risk of antibiotic resistance. At the same time, pre-operative administration of antibiotics protects the individual patient undergoing surgery from developing post-operative infection, which can have serious consequences. Even a minor absolute reduction in risk can be important. The outcome of the ethical analysis also depends on the importance of the individual patient's autonomy, i.e. to choose or refuse prophylaxis, in relation to the responsibility of society to meet the need of every citizen for treatment and care.

## **Consequence analysis**

For surgical or other procedures for which there is evidence that antibiotic prophylaxis is of value, this should be administered at stipulated times prior to the procedure and in as few doses as possible. This results in more effective utilisation of antibiotics for the prevention of infection, which in turn can improve the results of a surgical intervention, reduce the risk of the development of resistant strains of bacteria, reduce the total use of antibiotics, and possibly reduce the cost of care.

In order to follow up the use of antibiotic prophylaxis in surgery and establish quality assurance, it is important that all surgical units introduce routine procedures for the registration of post-operative infections. Registration must be based on a simple administrative routine, include a clear definition of the infections to be registered, and include an adequate patient observation time. In the installation of foreign/synthetic material, rare, serious side effects can occur. A systematic complete register can give valuable information about such events, which can otherwise be difficult to detect and possibly prevent.

## **Gaps in knowledge and the need for future research**

The review of the literature shows that there is a need for further, high-quality studies.

Today, antibiotic prophylaxis is used for procedures for which the effectiveness of the prophylaxis is not supported by scientific evidence. In order to restrict antibiotic use to fields where it has unquestioned medical value, it is important to investigate the need for antibiotic prophylaxis for the following procedures:

- Correction of abdominal wall hernia with implant
- Plastic surgery procedures e.g. breast enlargement with implants
- Endovascular procedures, especially those involving the insertion of foreign material into the body
- Incontinence and prolapse surgery
- Transcervical intrauterine procedures
- Removal of kidney stones
- Fractures of the base of the skull
- Nasal and ophthalmic surgery
- Dento-alveolar and dental implant surgery
- Laparoscopic and endoscopic surgery.

Under the present conditions of low frequencies of post-operative infections, studies need to include very large groups of patients in order to disclose an effect. Studies designed to investigate whether alternative methods, e.g. measures to reduce the number of bacteria accessing the wound, would be of value, not least because of the risk of an increase in antibiotic resistant strains of bacteria.

A review of the literature on health economics discloses a dearth of studies relevant to Swedish healthcare. Variations in relative costs and differences in the organisation of healthcare make it difficult to extrapolate the results of foreign studies to Swedish conditions. There are no studies at all of the effect of antibiotic prophylaxis in clinical practice (“effectiveness” studies), which would be of value in setting policies in surgical units.

Moreover, there is a need for studies comparing different antibiotics with respect to cost-effectiveness, not just from the health-care perspective but also from a societal perspective.

It is important to monitor the development of bacterial strains that are resistant to antibiotics. The development of resistance is more gradual in Sweden than in many other countries, but resistant bacteria spread over national borders. There is also a need for studies that analyse economic consequences to public health of the development of resistant bacteria associated with increased use of antibiotics.

# Reports published by SBU

## SBU Reports in English (2001-2011)

---

Dementia, three volumes (2008), no 172E

---

Obstructive Sleep Apnoea Syndrome (2007), no 184E

---

Interventions to Prevent Obesity (2005), no 173E

---

Moderately Elevated Blood Pressure (2004), Volume 2, no 170/2

---

Sickness Absence – Causes, Consequences, and Physicians' Sickness Certification Practice Scandinavian Journal of Public Health, Suppl 63 (2004), 167/suppl

---

Radiotherapy for Cancer (2003), Volume 2, no 162/2

---

Treating and Preventing Obesity (2003), no 160E

---

Treating Alcohol and Drug Abuse (2003), no 156E

---

Evidence Based Nursing: Caring for Persons with Schizophrenia (1999/2001), no 4E

---

Chemotherapy for Cancer (2001), Volume 2, no 155/2

---

## SBU Summaries in English (2005–2011)

---

Antibiotic Prophylaxis for Surgery (2010), no 510-52

---

Treatment of Insomnia in Adults (2010), no 510-51

---

Rehabilitation of Patients with Chronic Pain Conditions (2010), no 510-50

---

Triage and Flow Processes in Emergency Departments (2010), no 510-49

---

Intensive Glucose-Lowering Therapy in Diabetes (2010), no 510-48

---

Patient Education in Managing Diabetes (2009), no 510-47

---

Self-Monitoring of Blood Glucose in Noninsulin-Treated Diabetes (2009), no 510-46

---

How Can Drug Consumption among the Elderly be Improved? (2009), no 510-45

---

Vaccines to Children – Protective Effect and Adverse Events (2009), no 510-44

---

Open Angle Glaucoma – Diagnosis, Follow-up, and Treatment (2008), no 510-43

---

Peripheral Arterial Disease – Diagnosis and Treatment (2008), no 510-42

---

Tympanostomy Tube Insertation for Otitis Media in Children (2008), no 510-40

---

Caries – Diagnosis, Risk Assessment and Non-Invasive Treatment (2008), no 510-39

---

Moderately Elevated Blood Pressure (2007), no 510-41

---

Methods of Early Prenatal Diagnosis (2007), no 510-38

---

Light Therapy for Depression and Other Treatment of Seasonal Affective Disorder (2007), no 510-37

---

Dyspepsia and Gastro-oesophageal Reflux (2007), no 510-36

---

Obstructive Sleep Apnoea Syndrome (2007), no 510-35

---

---

Benefits and Risks of Fortifying Flour with Folic Acid to Reduce the Risk of Neural Tube Defects (2007), no 510-34

---

Methods of Promoting Physical Activity (2007), no 510-33

---

Mild Head Injury – In-hospital Observation or Computed Tomography? (2007), no 510-32

---

Methods of Treating Chronic Pain (2006), no 510-31

---

Malocclusions and Orthodontic Treatment in a Health Perspective (2005), no 510-30

---

Psychiatric Risk Assessment Methods – Are Violent Acts Predictable? (2005), no 510-29

---

Treatment of Anxiety Disorders (2005), no 510-28

---

Interventions to Prevent Obesity (2005), no 510-27

---

## **SBU Alert Reports**

---

Early assessments of new health technologies. Find them at [www.sbu.se/alert](http://www.sbu.se/alert) in PDF format.

---

## **To Order SBU Reports**

All SBU reports are published in Swedish. The summaries and some reports are also published in English. Summaries and reports can be ordered at [www.sbu.se](http://www.sbu.se), by email ([info@sbu.se](mailto:info@sbu.se)), by phone (+46-8-412 32 00), or by fax (+46-8-411 32 60).

# SBU Evaluates Health Care Technology

Below is a brief summary of the mission assigned to SBU by the Swedish Government:

- SBU shall assess healthcare methods by systematically and critically reviewing the underlying scientific evidence.
- SBU shall assess new methods as well as those that are already part of established clinical practice.
- SBU's assessments shall include medical, ethical, social and economic aspects, as well as a description of the potential impact of disseminating the assessed health technologies in clinical practice.
- SBU shall compile, present and disseminate its assessment results such that all parties concerned have the opportunity to take part of them.
- SBU shall conduct informational and educational efforts to promote the application of its assessments to the rational use of available resources in clinical practice, including dental care.
- SBU shall contribute to the development of international co-operation in the field of health technology assessment and serve as a national knowledge centre for the assessment of health technologies.

## **Antibiotic Prophylaxis for Surgical Procedures**

The report on Antibiotic Prophylaxis for Surgical Procedures from the Swedish Council on Health Technology Assessment (SBU) is a systematic review of the scientific literature in the field.

This document presents the summary and conclusions of the full report approved by SBU's Board and Scientific Advisory Committee.

The full report is available at [www.sbu.se](http://www.sbu.se)