Antimicrobial Stewardship Program (AMSP)

Standard Operative Procedures

All India Institute of Medical Sciences (AIIMS),
Bilaspur, Himachal Pradesh

Table of contents

Introduction

This is a comprehensive standard operative procedure manual on Antimicrobial Stewardship Program of AIIMS Bilaspur. The manual has been compiled by referring to national protocols and guidelines on AMSP, customized to the needs and the infrastructure already available at AIIMS Bilaspur or infrastructure that can be achieved by upgradation. The current version 01 caters to specific recommendations for discharge of hospital services on out-patient basis and covers AMSP guidelines for clinical syndromes pertaining to OPD services. The SOP has been organised to include information on the definition of AMSP and its need. The steps of implementation highlight the various aspects that complete the AMSP process and that would be included at relevant times as the hospital establishes. The SOP further provides guidelines for management of common clinical syndromes at OPD level along with the drug, dose and duration of treatment. All personnel providing OPD services should adhere to the guidelines and contribute in effective functioning of AMSP.

Antimicrobial Stewardship Program

a. Definition

Antimicrobial stewardship program (AMSP) is a multi-disciplinary professional effort, across the spectrum of healthcare, that:[1]

- Involves *timely* and *optimal* selection of the antimicrobial agent, along with its *dose* and *duration*,
- Aims at obtaining best possible clinical outcome of the antimicrobial agent given for treatment or prevention of infection,
- With minimal toxicity to the patient,
- And, causing minimal impact on the contemporary antimicrobial resistance and other ecological adverse effects, including antibiotic-associated diarrhea by *Clostridium difficile.*

According to the Centers for Disease Control and Prevention (CDC), AMSP is all about 'use of the right antibiotic, for the right patients, at the right time, with the right dose, route and frequency, causing least harm to the patient and future patients.'[2]

Antimicrobial Stewardship Program

b. Need for AMSP

AMSP is an integral part of any hospital setting for the following reasons:

1. Antimicrobial resistance (AMR)

AMR is a rising global threat. The increasing resistance to different class of antimicrobial agents by several micro-organisms has become a cause of great concern as there are limited new drugs in the pipeline. Be it the resistance among gram-negative bacilli or *Staphylococcus aureus, Candida auris* or *Aspergillus* spp., *Mycobacterium tuberculosis* or *Neisseria gonorrhoeae*, the growing antimicrobial resistance has greatly reduced the panel of drugs effective against them. These multidrug resistant organisms (MDROs) not only contribute to high morbidity and mortality, but also increase treatment costs. Extensive misuse of antimicrobial agents is the single most important factor for most of these MDROs to undergo mutation and become resistant. They further continue to flourish exponentially in the presence of selective pressure by the antimicrobial agent. Without immediate action, it is estimated that, by 2050, 10 million lives will be lost annually as a direct result of AMR, with a cumulative loss of USD 100 trillion.[3]

2. Misuse and overuse of antimicrobial agents

Paul Ehrlich said, "Drug resistance follows the drug like a faithful shadow". The antimicrobial agents have, no doubt, saved the mankind from several infectious agents and saved millions of lives, but their overzealous use has led to development of resistance much rapidly than forecasted which is rapidly negating much of the health benefit originally gained.[4] This is ultimately hindering the effective control of communicable diseases. AMSP is needed to:

- Curtail over-the-counter sale of drugs without a prescription.
- Check misuse of antimicrobial agents for
    - self-limiting infections,
    - using antibiotic for viral illness,
    - treatment of colonizer and contaminant.

- Stop simultaneous use of antimicrobials with overlapping spectra (redundant drugs).
- Prevent errors in drug administration – dose, frequency, missed dose, duration, etc.

3. Widespread use of antibiotics in other sectors

Mere implementation of the AMSP at healthcare facility will not suffice in controlling the growing resistance, as the antimicrobials used for human therapeutic purposes constitute only 9% of total antibiotic usage globally. 85% of total antibiotic consumption occurs for animal industry and therapy. One Health concept proposes that in the fight against AMR, all four spheres – human, animal, food and environment should be targeted for effective preventive measures, especially in India where all four spheres contribute significantly as drivers of AMR.[5]

4. Antimicrobial prescribing facts – the 30% rule

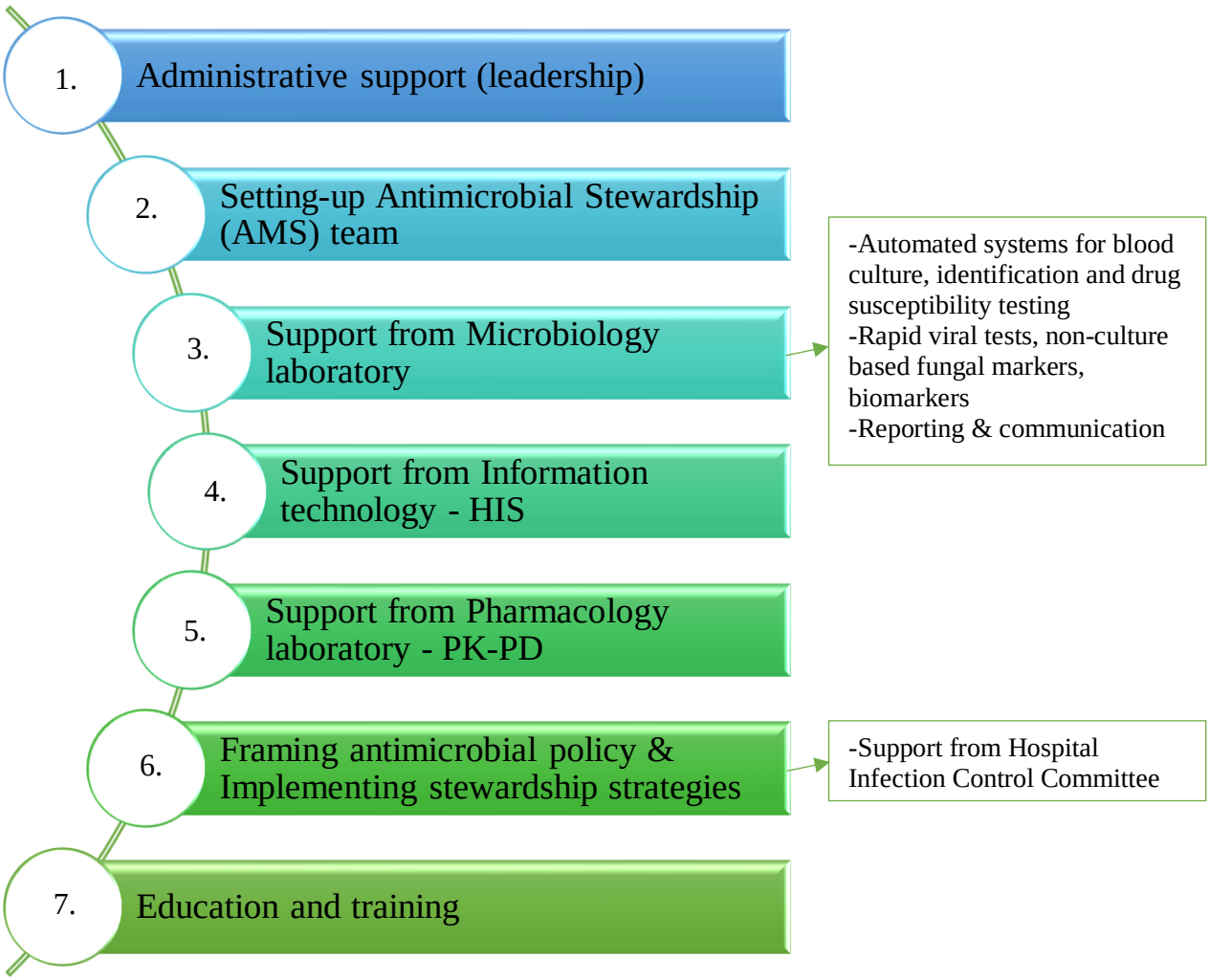
A study describing antimicrobial prescribing practices in 2007[6] revealed that nearly 30% of all hospitalized patients are on antibiotics at a given time; nearly 30% antibiotics prescribed in the community are inappropriately done so; nearly 30% of all surgical prophylaxis are given inadvertently; nearly 30% of hospital pharmacy costs are due to antimicrobial use; and, nearly 10-30% pharmacy costs can be saved by AMSP. Though the exact figures for Indian settings are not known, they are expected to be much higher. Hence, AMSP is needed to regulate the use of antimicrobials by the healthcare setting.

c. Goals of AMSP

The goals of AMSP can be summarized as follows:[7]

d. Steps of Implementation of AMSP

The key steps of implementation of AMSP in a hospital as are follows:[8]



AMSP-based guidelines
for the treatment of clinical syndromes
commonly encountered at OPD services
at AIIMS Bilaspur.

AMSP-based guidelines for treatment of clinical syndromes commonly encountered at OPD services at AIIMS Bilaspur.

a. Instructions to users:

1. The guidelines for treatment of clinical syndromes commonly encountered at OPD services consist of definition of clinical syndrome, clinical aspects, likely investigations and schedule of antimicrobial management. Since no local epidemiological data on antimicrobial resistance pattern is currently available at AIIMS Bilaspur, the national data generated by ICMR has been used.[9] The clinicians managing infections are advised that these guidelines are dynamic in nature and can be customized periodically in accordance with local AMR data. Not only this, the AMR data varies between the different departments of the same hospital, i.e. medicine vs surgery; and with different hospital settings as well, i.e. OPD vs ward vs ICU. These guidelines can be used as basic rational format and goals of AMSP should always be borne in mind before prescribing any antimicrobial.
2. Antibiotic use will need to be classified with respect to type (high- and low-risk) and the patient's place in the treatment pathway (untreated, treated, and post-treatment).
3. Timely use of diagnostic tests or documentation of symptoms supporting the presence of infection to be done. Cultures (two sets of blood cultures and other appropriate samples as clinically indicated e.g. normally sterile body fluids, deep pus etc.) should be taken before starting empiric antibiotic treatment.
4. Empiric antibiotic treatment for common infections should be limited to conditions where early initiation of antibiotics has been shown to be beneficial, e.g. severe sepsis and septic shock, acute bacterial meningitis, community acquired pneumonia, necrotizing fasciitis, etc.
5. Reassessment of the situation within 48 hours based on the test results and examination of the patient is required. If needed, the drug's dosage and duration to be adjusted or de-escalated (to the narrowest spectrum, least toxic and least expensive antibiotic) based upon patient response and culture and susceptibility reports.

b. Community-onset acute undifferentiated Fever

- Case definition:

i. Previously healthy (non-immunosuppressed) community (urban or rural) dwelling adult (ages 19-64 yrs) reporting no previous medical illness or recent hospitalization (in the preceding 30 days) presenting with acute onset of fever > 38.3° C (101.0° F) for > 2 days and lasting up to 14 days and having received no specific treatment for this current illness with antimalarials or antibiotics.

ii. Seen in ambulatory care settings at the primary level (PHC), doctor's office/clinic, emergency room in a community Hospital, including referrals from primary health care or community physicians.

iii. With history of no localizing symptoms (except accompaniments of fever such as – chills, headaches, retro-orbital pain, myalgia, malaise, nausea or vomiting). On examination found to have normal vital signs (excepting fever) and lacking organ or system specific physical signs.*

** A complete and thorough physical examination is mandatory. Record of vital signs is essential. A search is required for hidden foci such as throat examination, sinus tenderness, renal or hepatic tenderness, heart murmurs, chest examination, lymph nodes and splenomegaly. Fundus examination (if headache or bleeding tendency) and examination of the skin for eschar and petechiae or purpura must be made.*

- Diagnostic Investigations

- Complete blood count : Anemia, leucopenia /leukocytosis, elevated hematocrit or thrombocytopenia (dengue, leptospirosis)
- Diagnostic blood cultures for aerobic bacteria (at least two) to be drawn prior to start of empiric antibiotics

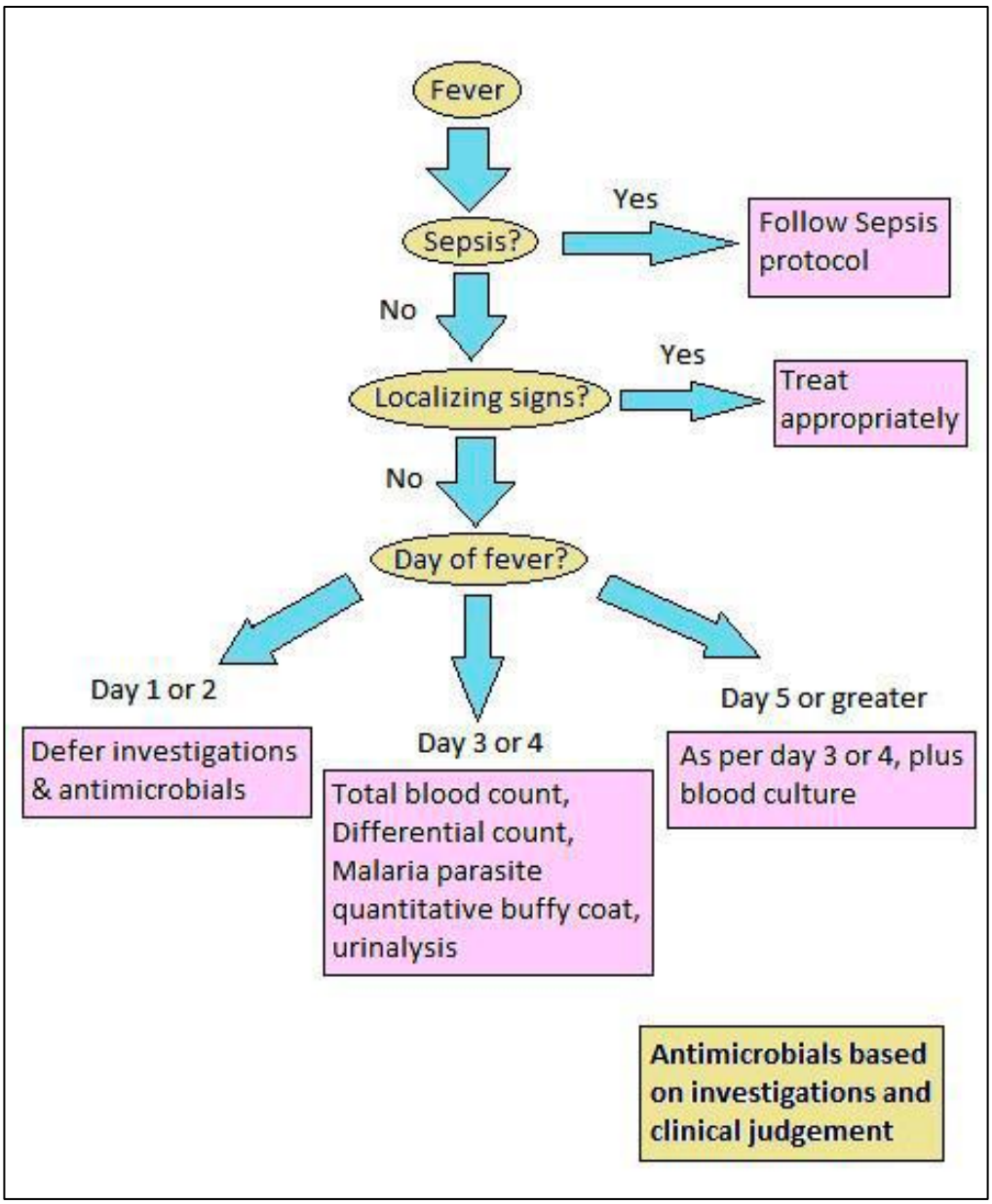
- One blood smear and/or RDT at least is required for malarial parasite detection
- Liver enzymes and bilirubin.
- Urinalysis – white blood cells, proteinuria and hematuria.
- Chest roentgenogram (if chest findings are present, to rule out early pneumonia or TB).
- Ultrasonography of abdomen if fever persists to rule out hepatic, renal or intra-abdominal sources of infection.
- Within 96 hours of onset of fever, antigen based serological tests are likely to be positive whereas antibody tests are generally positive after at least 5-7 days of illness.
    a. Scrub typhus IgM ELISA
    b. Dengue rapid NS1 antigen (fever<5 days) and IgM test (fever>5 days)
    c. Leptospira IgM ELISA

- <u>Principles of empiric therapy:</u>

i. Supportive: Acetaminophen 500 or 650 mg every 6 hours round the clock is advisable, accompanied by tepid sponging for fever or with chills >103 F. Replace fluid and electrolytes as required.
ii. No antibiotics are required for the majority of patients with acute febrile illness without an obvious clinical diagnosis.
iii. Always draw two sets of blood cultures before start of empiric antibacterial therapy.
iv. Start antibiotics for a presumed bacterial infection promptly, but adjust the drug's dosage and duration, switch to a new drug, or end antibiotic therapy when results do not support or justify the need to continue.
v. Reassess the situation within 48 hours based on test results and patient status.
vi. Corticosteroids are not recommended in the treatment of acute undifferentiated fever.
vii. In patients with fever and thrombocytopenia, platelet transfusions are not recommended in general.

viii. Consider platelet transfusion when platelet counts are <10,000 cumm or in the presence of clinical bleeding in cases of dengue hemorrhagic fever.

ix. Empirical treatment with doxycycline for patients with undifferentiated fever and negative rapid diagnostic tests for malaria and dengue is an option for the clinician.



Protocol for the management of adult patients with acute undifferentiated fever.[9]

- Treatment regimen for community-onset acute undifferentiated Fever

	Type of disease	Organism/s	Preferred initial treatment	Alternatives	Remarks
1	Typhoid fever	*Salmonella* Typhi, *Salmonella* Paratyphi A	Oral: co-trimoxazole (1ds tab bd) or azithromycin (10mg/kg/day) Parenteral: ceftriaxone 2g IV od	Cefixime (20 mg/kg/day) or chloramphenicol 500 mg qid or ciprofloxacin 750 mg bd	Change empiric regimen based on susceptibility testing. Duration of treatment: 10-14 days.
2	Empiric therapy of suspected Gram positive infections	*S. pneumoniae, Streptococcus pyogenes, Staphylococcus aureus*	Cefazolin 2 g IV q8h or Cloxacillin 2 g IV q6h	Amoxicilin-clavulanate 1.2 g IV q8h or Penicillin G 20 lakhs IV q4h (if *S. aureus* excluded) or Vancomycin (if anaphylactic penicillin allergy or MRSA clinically possible)	Adjust regimen after receipt of culture and susceptibility data. Duration of treatment will depend on final diagnosis.
3	Empiric therapy for suspected Gram negative infections (e.g. pyelonephritis or intra-abdominal infections)*	*E. coli, Klebsiella pneumoniae,* anaerobes especially *Bacteroides spp.* in IAI	Piperacillin-tazobactam 4.5 g IV q6h or Cefoperazone-sulbactam 3 g IV q12h. 10-14 days for pyelonephritis, 4-7 days for IAI.	Imipenem 1 g IV q8h or Meropenem 1 g IV q8h or Ertapenem 1 g IV od (carbapenems preferred for more seriously ill patients)	De-escalate to ciprofloxacin, co-trimoxazole or third generation cephalosporin if isolate is sensitive.
		* Separate anaerobic coverage unnecessary for IAI, when using BL-BLIs or carbapenems.			
4	Scrub typhus and other Rickettsial infections	*Orientia tsutsugamushi, Rickettsia spp.*	Doxycycline 100 mg po or IV bd	Azithromycin 500 mg po or IV od, chloramphenicol 500mg qid	Duration of treatment: 7 days
5	Leptospirosis	*Leptospira spp.*	Penicillin G 20 lakhs IV q4h or doxycycline 100 mg po or IV bd	Ceftriaxone 2 g IV od	Duration of treatment: 7 days

6	Vivax malaria	*P. vivax*	Chloroquine 25 mg/kg body weight divided over three days i.e. 10 mg/kg on day 1, 10 mg/kg on day 2 and 5 mg/kg on day 3.	Artemether-lumefantrine (1 tab bd for 3 days)	Followed by primaquine (0.25 mg/kg daily for 14 days)
7	Falciparum malaria	*P. falciparum*	Artesunate 4 mg/kg body weight daily for 3 days Plus Sulfadoxine (25 mg/kg body weight) and Pyrimethamine (1.25 mg/kg body weight) on first day.	Artemether-lumefantrine (1 tab bd for 3 days)	Followed by primaquine single dose (0.75 mg/kg). All mixed infections should be treated with full course of ACT and primaquine 0.25 mg per kg daily for 14 days.

c. Upper Respiratory Tract Infections

The upper respiratory tract infections (URTI) are mostly due to viral infections and therefore role of empirical antibiotics is limited. In pharyngitis a throat swab is collected but in other conditions mostly sampling for culture is not possible and not routinely done.

- Case definitions, investigations and prevalent resistance rates

i. **Otitis media** - It is an infection or inflammation of the middle ear.

- Common bacterial pathogens : *Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis.*
- Investigations - Tympanocentesis is not required. Usually it is an empirical therapy. It is important that if there is a perforation we realize that it is likely the organism isolated is a colonizer, and treatment based on that will not be appropriate.
- Prevalent Resistance - *S. pneumoniae* in India is susceptible to penicillin (usually < 4 %) and so β Lactams can be given.
- *H. influenzae* and *M. catarrhalis* produce β Lactamase (around 23% and 73% respectively) and need treatment with amoxycillin-clavulanic acid.

ii. **Bacterial sinusitis** – infection of the sinuses

- Viral etiology is more common and amongst bacteria common causes are *Streptococcus pneumoniae, H. influenzae , Moraxella catarrhalis.*. If symptoms are < 10 days in duration and resolving, there is no need for antibiotics.
- If duration of illness is >10 days with purulent nasal discharge, nasal obstruction and facial pain, then a bacterial cause should be considered.

iii. **Acute pharyngitis** - This is an infection or inflammation of the pharynx or tonsils

- Viruses cause the majority of these infections. Amongst bacterial causes, Group A Beta Hemolytic streptococci is responsible for pharyngitis. Other bacteria to worry about are *Fusobacterium necrophorum* which can cause Lemierre's syndrome and *Corynebacterium diptheriae* which causes a membranous tonsillitis causing respiratory compromise and other manifestations like myocarditis
- A throat swab is collected (if possible 2 swabs should be collected) using a sterile cotton swab, under direct visualization without touching the tongue or buccal

mucosa. The swab should be transported to the lab at room temperature. Most often no treatment is required. But if the patient is febrile for more than 3 days with pus points on tonsils, painful cervical lymphadenopathy only then a short course of antibiotics may be warranted.

- *S. pyogenes* remain sensitive to Penicillin/Ampicillin. The reports on erythromycin resistance from India are now increasing (>45%) and therefore antimicrobial susceptibility should be done.
- Rarely follicular tonsillitis and peritonsillar abscess may occur due to *Staphylococcus aureus* and can also present as URTI. This should be confirmed with culture and antibiotic to be given accordingly.
- Diphtheria may be present in rare cases but due to universal immunization is not included in differential diagnosis unless specific history, symptoms and signs are suggestive.

- Treatment regimen for Upper Respiratory Tract Infections

	Type of disease	Organism/s	Preferred initial treatment	Alternatives	Remarks
1	Acute pharyngitis	Commonly viral. Common bacterial cause is *Streptococcus pyogenes*	None required Oral Penicillin V 500 mg BD or Amoxicillin 500 mg Oral TDS for 7 days	 In case of penicillin allergy, Azithromycin 500 mg OD for 5 days	As most cases are viral, no therapy with antimicrobials required . Erythromycin resistance from India reported
2	Acute bacterial rhinosinusitis	*Streptococcus pneumoniae, H. influenzae, M. catarrhalis*	Amoxicillin-clavulanate 1gm oral BD for 7 days	Azithromycin 500 mg OD for 5 days. Ciprofloxacin 500 mg BD for 7 days	Antibiotics indicated if nasal discharge, headache or cough persists
3	Acute otitis media	*Streptococcus pneumoniae*, *H. influenzae*, *M. catarrhalis*	Amoxicillin clavulanate 1gm oral BD for 7 days	Azithromycin 500 mg OD for 5 days. Ciprofloxacin 500 mg BD for 7 days	Ear discharge swab may isolate colonizer
4	Acute bronchitis	Viral	Antibiotics NOT to be given		
5	Ludwig's angina Vincent's angina	Polymicrobial (including oral anaerobes)	Clindamycin 600 mg IV 8 hourly or Amoxicillin clavulanate 1.2 gm IV	Piperacillin tazobactam 4.5 gm IV 6 hourly	10-14 days and then can be prolonged based on response.

d. Urinary Tract Infections

- Case Definition:

Infections of the urinary tract are divide as:

Anatomy - Upper UTI –Pyelonephritis and Lower UTI – Cystitis

Clinical syndrome – Asymptomatic bacteriuria, Symptomatic bacteriuria and Pyelonephritis

- Investigations

Urine Specimen - Clean catch mid-stream, most common and convenient

Suprapubic aspirate- only in cases of small children where voided urine is difficult to collect or in adults in case diagnosis is not getting confirmed by voided specimen.

- Treatment regimen for Upper Respiratory Tract Infections

	Type of disease	Organism/s	Preferred initial treatment	Alternatives	Remarks
1	Acute Cystitis (in absence of cultures)	*E. coli, Proteus Spp. Klebsiella spp.*	Nitrofurantoin 100 mg BD for 7 days Cotrimoxazole 500/125 mg BD for 3-5 d Ciprofloxacin 500mg BD for 3-5 days	Cefuroxime 250 mg BD for 3-5 days Cefixime 400mg BD for 5 days	Staphylococcus saprophyticus (in sexually active young women) but is not common in India. In pregnancy the duration of treatment is longer.
2	Acute Pyelonephritis	*E. coli, Klebsiella spp. Proteus spp. S. aureus*	Piperacillin tazobactam 4.5 gm IV 6 hourly for 10 d Ertapenem 1 g IV OD for 7 d	Imipenem 500 mg IV 8 hourly for 10 days or Inj Amikacin 5mg/kg IV once daily x 10 days	Urine and blood culture should be done before start of treatment. Monitor renal parameters.
3	Acute prostatitis	*Enterobacteriaceae (E. coli, Klebsiella* spp.)	Doxycycline100 mg BD x2-3 wk Co-trimoxazole 960 mg BD for 2-3wks Ciprofloxacin 500mgBDx2-3 wk	Piperacillin tazobactam 4.5gm IV 6 hourly Cefoperazone sulbactam 3 gm IV12 hourly	Get urine and prostatic massage cultures before antibiotics. Treatment may be needed for longer duration.

e. Gynecological Infections

- Treatment regimen for Gynecological Infections

	Type of disease	Organism/s	Preferred initial treatment	Alternatives	Remarks
1	Pelvic Inflammatory disease (mild to moderate)	*N. gonorrhoeae*, *C. trachomatis* and anaerobes. *E. coli*, *Bacteroides* GBS, GAS, S. aureus, respiratory pathogens (eg, *H. influenzae*, *S. pneumoniae*,	NACO: Tab. Cefixime 400 mg orally STAT PLUS Tab. Metronidazole 400 mg BD X 14D PLUS Cap. Doxycyline, 100 mg bd X 14 D	CDC: Levofloxacin 500 mg OD X 14 days OR Ofloxacin 400 mg OD X 14 days With or without Metronidazole 500 mg BD X 14 days	Other regimen like: Ceftriaxone 250 mg IM single dose plus Doxycycline orally 100 mg BD X 14 days with or without Metronidazole 500 mg BD X 14 days can also be used
2	Pelvic Inflammatory disease (severe) e.g. tubo-ovarian abscess, pelvic abscess	Same as above	Cefotetan 2 g IV BD PLUS doxycycline 100 mg orally or IV BD	Cefoxitin 2 g IV every 6 hours PLUS Doxycycline 100 mg orally or IV every 12 hours OR Clindamycin 900 mg IV every 8 hours PLUS gentamicin loading dose IV or IM (2 mg/kg), followed by maintenance dose (1.5 mg/kg) every 8 hours.	Obtain cultures and de-escalate based on that. Duration is two weeks, but can be extended
3	Vaginal candidiasis	*C. albicans*, *C. glabrata*, *C. tropicalis*	Tab Fluconazole 150 mg orally single dose OR local Clotrimazole 500 mg vaginal tablet once only	Miconazole, nystatin vaginal tablets/creams	Treat for 7 days in pregnancy, diabetes Recurrent infections: 150 mg Fluconazole on day 1,4,7 then weekly for 6 months
4	Vaginal trichomoniasis	*T. vaginalis*	Tab. Secnidazole 2 gm oral, single dose OR Tab.		Alcohol avoided during treatment and 24 hours after

			Tinidazole 500 mg orally, twice daily for 5 days OR Tab. Metronidazole 400 mg, twice daily for 7 days		metronidazole or 72 hours after completion of tinidazole to reduce possibility of disulfiram-like reaction. Partner treatment essential
5	Bacterial vaginosis	Overgrowth of anaerobes *(Gardnerella vaginalis)*	Metronidazole 400 mg orally BD X 7 days OR Metronidazole gel 0.75%, one applicator (5 g) intravaginal x 5 days OR clindamycin Cream 2%, one applicator (5 g) intravaginal x 7 days	Secnidazole 2 g orally OD X one day OR Tinidazole 2 g orally OD X 2 days OR Tinidazole 1 g orally OD X 5 days OR clindamycin orally 300 mg BD X 7 days OR clindamycin ovules 100 mg intravaginally OD HS for 3 days	Refrain from sexual activity or use condoms during the treatment. Clindamycin cream is oil-based and might weaken latex condoms

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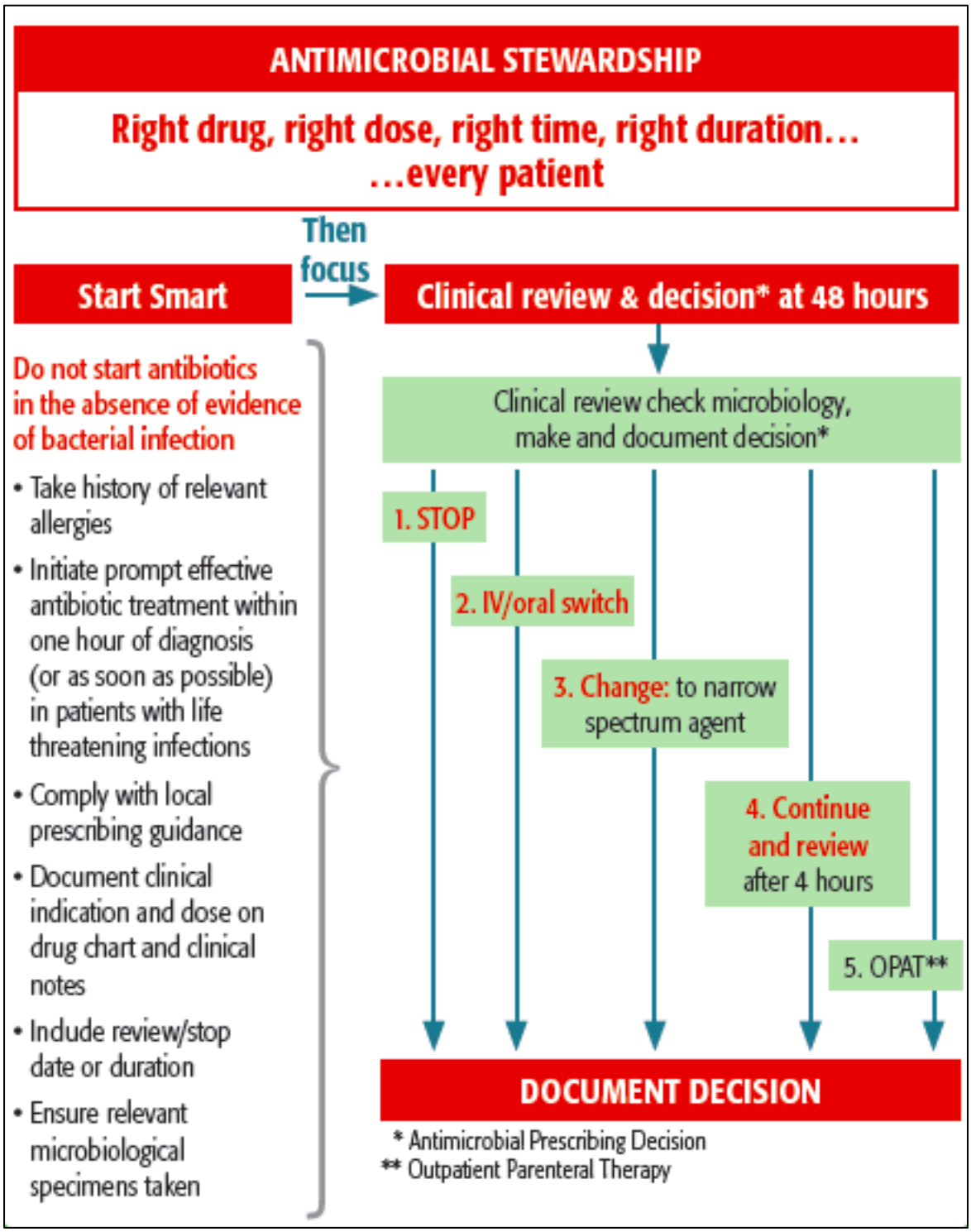
Annexures

(Adapted from Nathani et al[10])

1. START SMART → THEN FOCUS strategy



2. Specific situations where antibiotics should be WITHELD

- Respiratory tract syndromes
  - Viral pharyngitis
  - Viral rhinosinusitis
  - Viral bronchitis
  - Noninfectious cardiopulmonary disorders misdiagnosed as pneumonia
- Acute Otitis Media (AOM) (for selected cases, refer to article)
- Skin and Soft Tissue Infections (SSTI)
  - Subcutaneous abscesses (for selected cases, refer to article)
  - Lower extremity stasis dermatitis
- Asymptomatic bacteriuria and pyuria, including catheterized patients
- Microbial colonization and culture contamination
- Low-grade fever

3. Practice guideline recommendations for duration of therapy.

• Community-acquired pneumonia (CAP)	5 days
• Health care-acquired pneumonia	8 days
• Skin and Soft Tissue Infections (SSTI)	5 days
• Urinary Tract Infections (UTI)	
- Cystitis	3-5 days [a]
- Pyelonephritis	5-14 days [a]
- Catheter associated	7 days [b]
• *S. aureus* bacteremia	
- Low risk of complications,	2 weeks
- High risk of complications	4-6 weeks
• Intra-abdominal infection	4-7 days
• Surgical antibiotic prophylaxis,	1 dose [c]

[a] Depending on antibiotic
[b] Prolonged to 10-14 days for delayed response
[c] Up to 24h, witout exception