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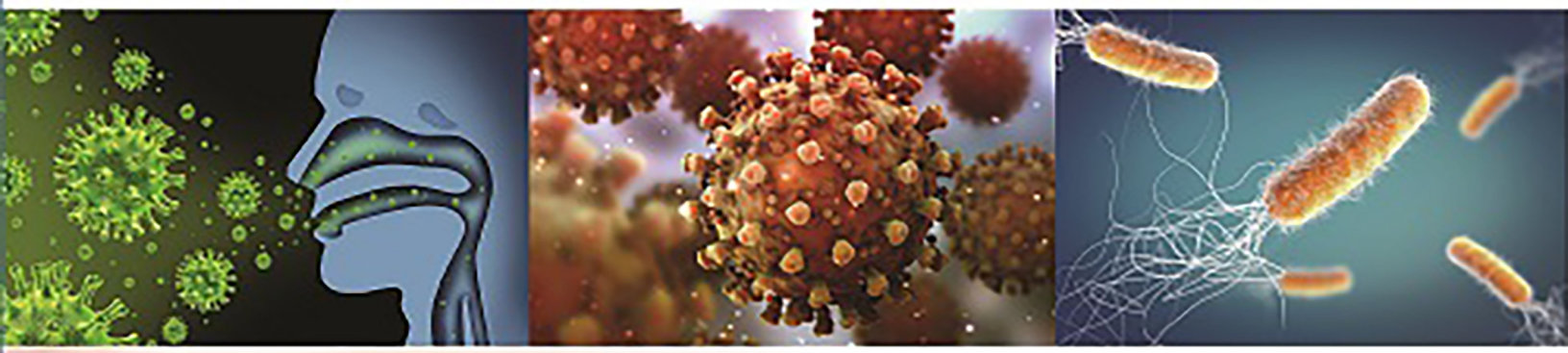
INDIAN ACADEMY OF PEDIATRICS
INFECTIOUS DISEASES CHAPTER

Textbook of PEDIATRIC Infectious Diseases





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1.3 Rational Drug Therapy in Pediatric Infectious Diseases

YK Amdekar, Late Anand Shandilya

INTRODUCTION

Rational drug therapy means "prescribing right drug for right indication, in adequate dose for optimum duration that delivers safe and appropriate benefit to the clinical needs of the patient at lowest cost". The concept of rational drug therapy is age-old, as evident by the statement made by the Alexandrian physician Herophilus, 300 BC that states "medicines are nothing in themselves but are the very hands of God if employed with reason and prudence". The physician should always bear in mind that drugs do not cure. They may be made valuable adjuncts in our endeavor to restore normal function in an abnormal functioning organ. Improving precision and economy in prescribing drugs is a goal whose importance has much more increased with proliferation of new and potent agents and with growing economic pressures to contain healthcare cost.

GENERAL PRINCIPLES OF RATIONAL DRUG SELECTION

Right Indications

Selected drug must be relevant to treatment of concerned disease. Such a drug could be either specific curative drug such as antibiotic or merely a symptomatic reliever. Specific drug therapy is possible only when there exists at least a provisional diagnosis as in case of use of antibiotic for infection. Symptomatic reliever must be used only when symptoms cause a reasonable discomfort to a child. For example, antipyretic should not be used just because of presence of fever. It should be used only if fever is high enough to make a child uncomfortable or pose danger to life as in case of hyperpyrexia. Thus, symptomatic reliever should be used as per the need (on SOS basis) and not on predetermined fixed schedule. It is also true about symptomatic therapy for cough or diarrhea. In fact, there is no cough remedy that "cures" cough. At best, it may relieve discomfort of coughing. Hence, bronchodilator or cough suppressant may be used with caution. It is now well accepted that there is no need for symptomatic control of diarrhea. Besides, stool-binding agents are harmful probiotics are not routinely indicated in diarrhea. Zinc supplement in diarrhea is rational, especially in malnourished children.

Efficacy and Safety

These are most important parameters of rationality. Safety is as much to be ensured as efficacy, more so in case of long-term therapy. It is true that every drug is likely to cause side effects and so, every attempt must be made to use nonpharmacological therapy whenever available, before prescribing a drug. For example, good ventilation, optimum room temperature, and light clothing help to control fever. Similarly, hydration and propped up position help to relieve cough. Maintaining good nutrition and hydration is key to treatment of diarrhea. Control of trigger factors in treatment of asthma is vital to therapeutic success. Such measures often obviate need for a drug or can do with minimum drugs.

Risk–Benefit Ratio

It is rational to evaluate probable outcome of using or not using a drug. One must compare risk and benefit of administering the drug as well as withholding the drug. Similarly, one must choose the best drug with favorable risk–benefit ratio.

Cost

Cost is the concern to less privileged society but even to the affordable population. If alternate drug is cheap, one must not hesitate to use it. It is not true that generic drugs are inferior to branded drugs.

Quality

Unfortunately, there is no way for a doctor to assess quality of the drug. It is personal experience that dictates using a drug manufactured by a particular company. Quality of a drug is to be taken for granted although one must keep in mind the possibility of spurious drugs. Past record of the manufacturer and personal experience of a drug helps to decide the quality.

Appropriateness

Rationality cannot be considered to be fixed or rigid endpoint of drug therapy in all situations. Co-trimoxazole is a rational choice for the treatment of acute respiratory infection (ARI) in ARI control program in the community because it is cheap, safe, oral, fairly effective, and available in simple dosage formulations. But, it is not necessarily the best choice for individual child as specific antibiotic can be considered better, depending upon probable bacteriological diagnosis. Appropriateness should also be decided by capability and competence of local physician to make correct diagnosis and monitor proper therapy. For example, intravenous therapy may be ideal for acute bacterial infection in an infant but may not be feasible due to physician's inability to administer intravenous drug and so intramuscular route may be an

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alternative, although inferior. Single dose of intramuscular injection of benzathine penicillin or aminoglycoside has been used in specific conditions.

Single Ingredient Drug

Fixed dose combination drugs are best avoided in routine practice, except in specific situations such as co-trimoxazole, antituberculosis drugs or antibiotic with enzyme inhibitor. If two drugs are necessary for treatment, as in case of neonatal sepsis, they are best administered separately so that individual dosage and duration can be suitably adjusted. There are many irrational combinations in the market such as combination of quinolone and metronidazole for mixed gastrointestinal (GI) infection. Such mixed infection is rare in children.

RATIONAL ANTIBIOTIC THERAPY

Infections are common in children and fever is a common presentation. Fever does not equate with infection and not necessarily bacterial infection that may justify an antibiotic. After all, viral infections are common in the community and should not be treated with an antibiotic. Further, not all bacterial infections deserve an antibiotic prescription. However, antibiotics are prescribed for majority of children presenting with fever. In fact, they may also be prescribed for children who have no infection as in case of cough due to hyper-reactive airway disease. Thus, antibiotics are often prescribed without proper diagnosis for fear of probable bacterial infection and antibiotics are often changed or multiple antibiotics used due to fear of worsening condition. Misuse of antibiotics in this way leads to increasing drug resistance, which has become a major concern today. Besides, irrational use of antibiotic may suppress but not control infection that would pose difficulty in diagnosis with increased morbidity and risk of mortality. Thus, improper antibiotic use is a threat to the community and also to an individual patient. If this trend continues, it may not be long before even a simple infection may not be amenable to drug therapy.

WHEN SHOULD AN ANTIBIOTIC BE PRESCRIBED?

Attempt a Bacteriological Diagnosis

Antibiotic is indicated only in case of bacterial infection. It is ideal to attempt bacteriological diagnosis in every child with suspected bacterial infection, although it is not practical in routine office practice. However, few conditions demand proof of bacterial infection as in case of urinary tract infection (UTI) and typhoid fever. UTI in children is potentially a serious disease with a risk of permanent renal damage if not properly diagnosed and treated. Typhoid fever being a bacteremic infection, blood culture is often positive and technically, it is easy to culture *Salmonella typhi*. It is, therefore, expected that UTI and typhoid fever are bacteriologically diagnosed as often as possible and empirical treatment is not justified. Gastric lavage for acid-fast bacilli should be tried in the diagnosis of childhood tuberculosis. Throat swab for streptococcal infection is a routine in western countries. In case culture facilities are not available, at least, circumstantial evidence should be collected before embarking on specific antibiotic therapy.

Circumstantial Evidence of Bacterial Infection

Typical clinical syndrome in an acutely febrile child may strongly suggest bacterial infection that may not need further proof for rational antibiotic prescription. Acute tonsillitis is clinically diagnosed by finding beads of pus on inflamed tonsils and tender submandibular lymph nodes. Loose stools with blood and mucus and abdominal cramps suggest acute bacillary dysentery. Localized chest findings in an acutely febrile child who develops tachypnea denotes bacterial pneumonia that may be confirmed by chest X-ray but even without chest X-ray would justify antibiotic therapy.

Laboratory evidence of bacterial infection should not be considered in isolation without clinical correlation. Neutrophilic leukocytosis and high C-reactive protein may favor bacterial infection but not adequate enough by themselves to consider antibiotic therapy. Bacteremic bacterial infections start with moderate degree of fever that becomes more severe by day 3–4 as happens typically in typhoid fever. However, bacterial infections localizing at the site of entry such as tonsillitis or UTI may start with high degree of fever.

WHEN THERE IS NO CLUE TO DIAGNOSIS?

This is the most common situation in routine office practice during first few days of onset of fever. Generally, one can arrive at a reasonably correct diagnosis only after disease evolves over few days after onset of symptoms. It means that correct diagnosis is often not possible in a febrile child in first few days with exception sited above such as tonsillitis and bacillary dysentery. At such stage, it is important to assess risk of waiting without specific antibiotic in an acutely febrile child.

Following situations in acutely febrile child are considered to be at risk of serious bacterial infection that demands urgent specific action:

- Age <3 months
- Severe protein–energy malnutrition
- Immunosuppressed state
- Behavior abnormality—lethargy or extreme irritability
- Tachycardia and tachypnea disproportionate to degree of fever.

In such situations, laboratory tests should be ordered before starting empirical antibiotic and decision taken for need for hospitalization. Laboratory tests may be prioritized on individual merits and they include complete blood cell, urinalysis, chest X-ray, blood and urine culture, and cerebrospinal fluid examination.

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TABLE 1 Clue to probable cause of acute infection.

	Bacterial	*Viral*	*Malaria*
Degree at onset	Moderate	High	High
Rhythm	Regular	Regular	Irregular
Response to paracetamol	Poor	Fair	Erratic
Interfebrile state	Sick	Normal	Normal
Progress on day 3–4	Persisting	Better	Variable
Contact history	None	Positive	None
Extent of disease	Localized	Generalized	—

WHEN THERE IS NO CLUE TO DIAGNOSIS BUT IS SAFE TO WAIT?

In absence of risk factors in a febrile child, it is rational to wait and observe progress without antibiotic therapy. Fever should be controlled with paracetamol. Parents must be counseled about danger symptoms such as behavioral abnormality and reduced urine output that demand reporting to medical facility. Periodic clinical examination is necessary over next few days to pick up clinical clues to diagnosis. Attempt must be made to differentiate acute bacterial infection from acute viral infection. It is possible to a reasonable extent by detailed analysis of history of fever **(Table 1)**.

PRINCIPLE OF CHOOSING AN ANTIBIOTIC

Once need for an antibiotic is rationally decided, next step is to choose right antibiotic. Choice of antibiotic should depend upon several factors.

Site of Disease

Disease above the diaphragm is generally caused by gram-positive cocci and is treated with penicillin, macrolide, and first-generation cephalosporin. Disease below diaphragm is mostly caused by gram-negative bacilli and is treated with aminoglycoside, third-generation cephalosporin or quinolone.

Epidemiological Data

Antibiotic should be selected on the basis of local epidemiological data regarding drug sensitivity pattern. It may be variable in different regions and even in the same region in different institutes. It is ideal to monitor periodical changes that may occur in drug sensitivity pattern. This is important especially in critical care units wherein resistant strains may develop easily.

Source of Infection

Community-acquired infection is likely to be sensitive to first-line of antibiotics, while nosocomial infection is often antibiotic resistant.

Type of Disease

Choice of antibiotic differs depending upon factors such as localized or generalized, superficial or deep, acute or chronic, mild or severe, extracellular or intracellular disease.

Drug Factors

It is always ideal to enquire about history of allergy to drugs. Drug interactions are best avoided by using as minimum number of drugs as possible. One must also keep in mind adverse effects of drugs and communicate effectively with parents so that timely action is taken.

Previous Exposure to Antibiotics

It is likely that organisms may have become resistant to previously used antibiotics in recent past. Hence, it may be rational to use an alternate drug with similar profile. Community-acquired antibiotic-resistant infections are likely to be met with and one must consider such a possibility based on local epidemiology.

DOSAGE, DURATION, AND FREQUENCY OF ADMINISTRATION OF ANTIBIOTICS

Difficult Infections

Intracranial infection must be treated with higher dose for longer time due to variable concentration of drug achieved depending upon blood–brain barrier permeability. Thick wall, acid pH, and presence of hydrolyzing enzymes necessitate higher dose of antibiotics. Higher dose for longer duration is required in endocarditis due to poor penetration at the site of infection. So the deep-seated infections, such as osteomyelitis, also demand long-term therapy.

Host Factors

Dosage and/or frequency of administration may vary as per age, nutrition, immune status, renal, and hepatic function. Frequency of antibiotic administration depends upon plasma half-life of a drug and generally, 4–5 times plasma half-life maintains adequate serum concentration throughout treatment period.

Route of Administration

Oral route is always preferred except in neonates and young infants and, of course, in serious infections. Intramuscular route is not ideal as it is painful and also has erratic absorption. Single dose of penicillin or ceftriaxone has been tried with success. Intravenous route is most ideal as it ensures achieving adequate concentration although, at times, not practical. Antibiotics that are used systemically should not be used topically.

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ANTICIPATING INITIAL RESPONSE TO ANTIBIOTIC

Generally, it depends upon doubling time of organism—greater the doubling time, longer the response time. Partial control of fever may be the first response to antibiotic often accompanied with improvement in other symptoms and general wellbeing. For many common bacterial infections, initiation of response is observed within 2–3 days. It may take 4–5 days for initial response to antibiotic in typhoid fever, while in tuberculosis, initial response may be obtained within 2–4 weeks.

WHEN ANTIBIOTIC FAILS IN SUSPECTED BACTERIAL INFECTION?

Antibiotic rarely fails in routine office practice in treatment of community-acquired infection in a normal host. One should expect response to antibiotic within 3–4 days. If there is no response, it calls for reassessment.

Firstly, confirm whether it is an infection and, if so, a bacterial infection. This may be done by repeated physical examination supported by repeat laboratory tests. Choice of antibiotic and its route of administration may be a factor responsible for poor response. If bacterial infection and choice of antibiotic are reasonably confirmed, look for complications such as empyema in case of bacterial pneumonia or subdural collection in case of meningitis. At times, poor response may be due to iatrogenic factor such as catheter-related infection or nosocomial infection in a hospitalized setting. Only when all such factors are ruled out that one may consider drug resistance. It is ideal even at this stage to send blood culture and then change to best considered empirical antibiotic. However, if this change also fails, bacterial infection is ruled out and one must search for alternate diagnosis. It is not wise to persist with empirical antibiotic trial beyond one change.

WHEN NOT TO PRESCRIBE AN ANTIBIOTIC?

Nonbacterial infections obviously do not call for an antibiotic, and so also noninfective fevers. In routine office practice, it is possible to arrive at a provisional diagnosis by analyzing detailed history and focused physical examination. Typical viral infection starts with high fever at onset of illness that declines by day 3 or 4. Fever is rhythmic, rising every 4–6 hourly. As fever is partly controlled in 20–30 minutes after administration of paracetamol, child becomes active and does not look sick during interfebrile period. Viral infection results in generalized affection of involved system. Thus, it may be accompanied with symptoms and physical signs of upper and lower respiratory tract involvement. There is often history of similar infection in other family members. GI symptoms in the form of vomiting and watery diarrhea denote involvement of upper (stomach) and lower GI tract (intestine) as a result of viral infection. Thus, viral infection is often disseminated, while bacterial infection is often localized.

Malaria presents with erratic pattern of fever that is essentially nonrhythmic. Child does not appear to be sick during interfebrile period.

Tuberculosis rarely presents as acute infection although acute onset of allergic pleural effusion may be a manifestation of tuberculosis in a healthy child. Noninfective conditions may present with fever wherein there is no localization during initial period. Disease evolves over time and at times may take even few months before being correctly labeled. Differentiation between acute bacterial infection and noninfective inflammatory disorder is, at times, difficult and in such a case, trial of antibiotic would fail to reveal correct diagnosis.

PRESENT SCENARIO OF IRRATIONAL ANTIBIOTIC USE

Antibiotics are considered to be the greatest discovery of 20th century. In preantibiotic era, infectious diseases accounted for significant morbidity and mortality, and invasive procedures were fraught with risk of infection. All this changed with the use of antibiotics. But this miracle seems to be short-lived. Irresponsible and erratic use of these life-saving drugs has resulted in development of drug resistance in many organisms and death due to hospital-acquired infections is on the rise. It appears that our complacency is leading us into bigger problems in the present millennium.

Various studies conducted in developed as well as developing countries during the last few years show that irrational drug use is a global phenomenon.

WHY DO DOCTORS OVERPRESCRIBE ANTIBIOTICS?

Uncertainty of diagnosis and lack of confidence are two major reasons for irrational use of antibiotics. Faulty training of medical students, lack of effective continued medical education, and poor communication between doctors and patients have compounded the problem of irrational therapy. Many doctors succumb to peer pressure and parental pressure. Ineffective drug regulation and aggressive pharmaceutical marketing practices have contributed to increasing irrationality of drug prescriptions. "Mixed" infections with bacteria and ameba are not known to occur and this "mixing" is done by drug industry to sell two drugs where none may be indicated. Fear of legal suit makes doctors overreact to patient's need of drugs because of firm belief that error of commission is acceptable but not error of omission. Even, irrational drug prescription can be a bone of contention in courts, more so, if it results in side effects. It is the negligence that is punished and not mistakes, especially if they are within realm of expected competence and scientific limitations.

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RATIONAL DRUG THERAPY: RATIONAL PRESCRIBER A PRIORITY!

Although rational drug therapy is a joint responsibility of policy makers, drug manufacturers, healthcare professionals as well as patients, doctors provide final decision of use of drugs. Hence, rational prescriber is a priority to success of rational drug therapy. Rationality should ensure safety at all costs and should try to confine to the limits of acceptable standards. Rationality may have a changing concept. Paracetamol is considered to be an antipyretic of choice but even ibuprofen or mefenamic acid is an acceptable alternative. Oral rehydration solutions (ORSs) have undergone modifications and have been the mainstay of treatment of diarrhea. However, it is well known that not all children suffering from diarrhea accept ORS. It is now proved that those children who do not accept ORS lose much less electrolytes in stool. So rationality demands to hydrate a child suffering from diarrhea with suitable modification but within limits. Knowing that asthma is a chronic inflammatory disease, inhaled steroids have emerged frontline drug for its treatment. Thus, rational prescriber has to learn, unlearn, and relearn to keep pace with changing concept.

HOW TO PREVENT MISUSE OF ANTIBIOTICS?

It is vital to arrive at provisional working diagnosis based on clinical analysis of detailed history and focused physical examination. If doctors learn to document provisional diagnosis, drug prescription is likely to be rational. Every doctor is expected to follow standard, national or organizational guidelines and document actions taken with justifications including instructions to parents or patients. Such documentation is a proof of honesty, transparency, and responsibility on the part of the doctor. This alone increases confidence in rational therapy. Restricted hospital drug formulary would inculcate ideal therapeutic practice among doctors. Education has a role but may not ensure rational behavior of doctors. There is a need for group audit but best would be self-audit. Drug regulatory authority must ban irrational drugs. Drug controller in the United States of America (USA) banned commonly used cold and cough remedies few years ago.

In view of misuse and overuse of antibiotics, council for appropriate and rational antibiotic therapy (CARAT) was formed in USA to guide rational antibiotic therapy.

In summary, rational drug therapy and, in particular rational antibiotic therapy is the need of the hour. Empirical antibiotic therapy has a place in routine practice, but only with rational approach. It includes assessing risk of waiting, clinically evaluating probable etiology of disease, supported by relevant laboratory tests, repeated observation to monitor progress, selecting appropriate empirical drug, and reassessment in case of poor response. With indiscriminate antibiotic use, there has been increasing drug resistance and time has come to change this trend lest we are defeated by simple infections.

KEY POINTS

- Right drug for right indication, in adequate dose for optimum duration that delivers safe and appropriate benefit to the clinical needs of the patient at the lowest cost.
- Selected drug must be relevant to treatment of concerned disease. Such a drug could be either specific curative drug such as antibiotic or merely a symptomatic reliever.
- Improper antibiotic use is a threat to the community and also to an individual patient.
- In absence of risk factors in a febrile child, it is rational to wait and observe progress without antibiotic therapy.
- Uncertainty of diagnosis and lack of confidence are two major reasons for irrational use of antibiotics.
- It is vital to arrive at provisional working diagnosis based on clinical analysis of detailed history and focused physical examination.

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