Rational Drug Bulletin

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Editorial

The Millennium Development Goals (MDGs) are eight international development goals, established following the Millennium Summit of the United Nations in 2000, and incorporated in the United Nations Millennium Declaration. India is one of the 189 UN Member States that committed themselves to help achieve the Goals by 2015.
The Goals are simple:

- To eradicate extreme poverty and hunger
- To achieve universal primary education
- To promote gender equality and empowering women
- To reduce child mortality rates
- To improve maternal health
- To combat HIV/AIDS, malaria, and other diseases
- To ensure environmental sustainability
- To develop a global partnership for development.

While three of the eight MDGs are directly related to health, all eight MDGs have considerable bearing on human health. India has achieved some success in universal primary education, gender equality in education, and in developing a global partnership for development. But there is slow progress in health as reflected in the health indicators related to mortality, morbidity, and in various environmental factors contributing to poor health of our citizens.

It is now admitted in the latest official MDG Report that India is likely to fall short of a majority of the targets and indicators with respect to Goal 1 (eradication of poverty and hunger), Goal 3 (gender equality), Goal 4 (child mortality reduction), Goal 5 (improving maternal health) and Goal 7 (environmental sustainability).

Even the partial successes achieved on targets and indicators with respect to goal 2 (universal primary education), Goal 6 (combating specific diseases) have a few caveats. The school enrollment rates are ahead of the targets, but the dropout rates are high, making the enrollment rates meaningless. The incidence of HIV/AIDS has come down, but it is increasing in states where it was hitherto low. There are also wide variations in the penetration of information and communication devices as agreed under Goal 8 (partnership for development). And, as the report indicates, the performance of the majority of states on many of the goals and targets is appalling, and the quality of achievements that have been made is far from satisfactory.
Will we be able to stand up and move quick, really quick, to achieve what we promised for our citizens?

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Hypertension

Case definition

A case of Hypertension: Hypertension in adults (>18 yrs) is defined as systolic blood pressure (SBP) of 140 mm of Hg or greater and/ or diastolic blood pressure (DBP) of 90 mm of Hg or greater, based on the average of two or more properly measured, seated BP readings on each of two or more visits.
Primary hypertension: When etiology is unknown, as in 90 to 95% of patients.
Secondary hypertension: Hypertension with an identifiable cause, secondary to which hypertension appears. Correction of primary cause is likely to improve hypertension.
Isolated systolic hypertension: A systolic pressure> 160, with Diastolic pressure <90 mm of Hg, most common in elderly patients, due to reduced vascular compliance.

Table 1. Classification of Blood Pressure [BP] for Adults

BP Classification	Systolic Blood Pressure	Diastolic Blood Pressure
Normal	<,120	and < 80
High Normal	120- 139	or 80 -89
Stage 1 hypertension	140 – 159	or 90-99
Stage2 hypertension	> 160	or > 100

Pointers to secondary hypertension

- Onset of hypertension before 30 years of age, or after age of 55 years.
- Abdominal bruit.
- Accelerated hypertension.
- Resistant hypertension.
- Decreased pressure in the lower extremities, delayed or absent femoral arterial pulses or asymmetry
- of upper limb pulses.
- Paroxysms of hypertension accompanied by headache, palpitations, pallor, and perspiration.
- Flash pulmonary edema.
- Abnormal urinalysis.

Epidemiology of the condition in our country
Prevalence: According to a recent review on "the global burden of Hypertension," estimated prevalence in India, in 2000 was about 21 %. (Indian Guidelines for management of Hypertension 2006)

Differential Diagnosis
Following are-the conditions where hypertension has an identifiable cause, unlike in primary hypertension.

Table 2. Identifiable causes of hypertension

Cause	Features
Chronic kidney disease	Elevated creatinine, abnormal urinalysis, renal ultrasonography
Coarctation of the aorta	Decreased pressure in the lower extremities or delayed or absent femoral arterial pulses.
Cushing syndrome and other glucocorticoid excess states	Truncal obesity, glucose intolerance, and purple striae
Pheochromocytoma	Lable hypertension, paroxysms of hypertension accompanied by headache, palpitations, pallor and perspiration
Primary aldosteronism a other niineralocortic'	Unprovoked hypokalemia
Cause	**Features**
Renovascular	Onset of hypertension

hypertension	before 30 years, or after 55 years of age Abdominal bruit Accelerat Resistan Flash pulmonary edema Renal failure of uncertain etiology
Sleep apnea	Obesity, snoring, day time somnolence, resistant hypertension
Thyroid	Goiter, features of dysthyroidism
Parathyroid disease	Hypercalcemia

Diagnostic, Criteria, Investigations, Treatment & Referral criteria

Clinical Diagnosis: An average of two or more properly measured, seated, BP readings on each of two or more visits, classifying as per table 1. A thorough general and systemic examination should be carried out to look for target organ involvement and to rule out secondary causes of hypertension.

Investigations: The diagnosis is mainly clinical. However complete haemogram, routine and microscopic examination of urine, blood urea, serum creatinine, fasting blood sugar,fasting lipid profile, ECG and chest X ray may be done outside or from level 3 care, as outlined below.

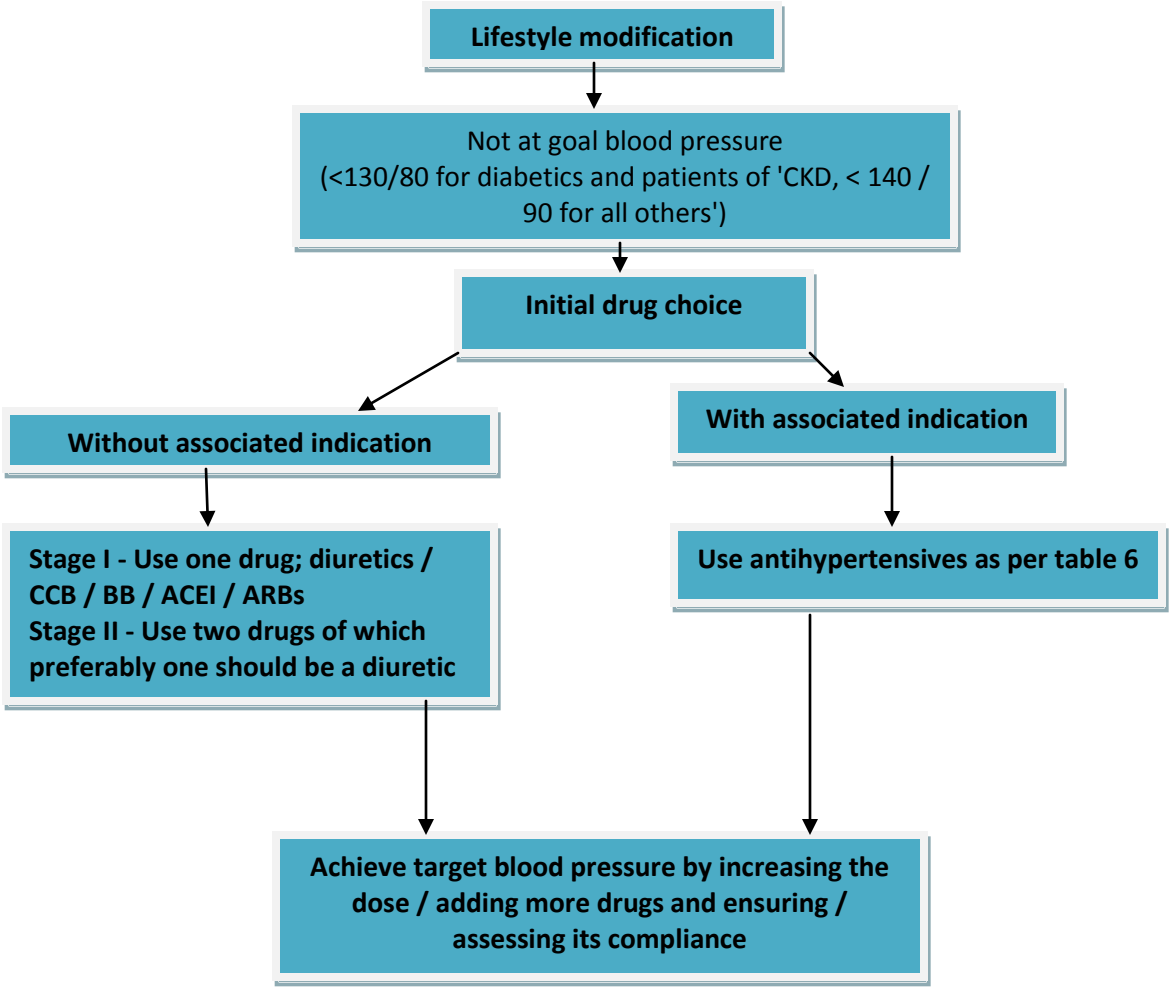
Treatment: Treatment comprises of lifestyle modification and pharmacological therapy with antihypertensive drugs. Patients with stage 1 hypertension without any other risk factors or target organ damage can be managed by instituting life-style modifications and reviewed after 3 months to decide whether they require antihypertensive therapy.

Goals of Therapy

To reduce SBP and DBP to < 140 and <90 mm of Hg. In hypertensive patients with diabetes or renal disease, the BP goal is < 130/80 mm Hg

Lifestyle Modifications

- Adoption of healthy lifestyles by all patients is an indispensable part of the management of all patients with hypertension and alone is sufficient for individuals with high normal blood pressure.
- Weight loss -As little as 10 Ibs (4.5 kg) reduces BP, although the ideal is to maintain normal body weight.
- Dietary Approach - Diet rich in fruits and vegetables, and low in fat, dairy products, cholesterol, saturated and total fat. Dietary sodium should be less than 100 mmol per day (2.4 g of sodium).
- Regular physical activity-brisk walking at least 30 minutes per day, most days of the week.
- Alcohol intake - (preferably avoided)
    - Men- not more than 1 oz (30 mL)ofethanol, the equivalent of two drinks per day
    - Women- not more than 0.5 oz of ethanol (one driJ1k) per day in women and lighter weight persons.
- Patients should be strongly counseled to quit smoking



Oral Antihypertensive Drugs

Class	Drug	Usual dose range, mg/d	Usual daily frequency
Thiazide diuretics	Hydrochlorothiazide	12.5 - 50	1
	Indapamide	1.25 – 2.5	1
Beta blockers (BBs)	Atenolol	25 – 100	1
	Metoprolol	50 – 100	1 – 2
	Propranolol	40 – 160	2
Angiotensin II-antagonists (ACE inhibitors)	Ramipril	2. 5 – 20	1
	Envas	2.5 – 20	2
Angioten in receptor blockers	Losartan	25 – 100	1 – 2
	Valsartan	80 – 320	1 – 2

Class	Drug	Usual dose range, mg/d	Usual daily frequency
Calcium channel blockers (CCBs)-Non-dihydropyridines	Diltiazem extended Release	180 – 420	1
CCBs –Dihydrdpyridines	Nifedipine (long-acting) Amlodipine	30 -60 2.5 – 10	1 1
Central α2 agonists and other centrally acting drugs	Clonidine Methydopa	0.1 – 0.8 250 – 3000	2 2
Alpha blockers	Prazosin	2.5 – 10	1

Referral criteria:

- All patients detected to have hypertension for the first time
- Those with target organ damage, for further evaluation
- Those with features suggestive of secondary hypertension, requiring further evaluation

Level 2: At 6-10 Bedded Primary Health Centre
Clinical diagnosis: Same as level 1 (including for a fresh case, reporting directly).
Investigations:
Same as Level 1 (including for a fresh case, reporting directly).
Treatment

- Same as Level 1

Referral criteria
Same as level 1
Patients requiring those investigations that are available only at the next level of health care.
Refractory hypertension- suboptimal control of blood pressure in spite of appropriate antihypertensive drugs in maximal doses (o e ofthese drugs should be a diuretic)

Level 3: At 30-100 Bedded Community Health Centre
Clinical Diagnosis: Same as level 1 (including for a fresh case, reporting directly). Evaluate for cardiovascular risk factors as pertable4. Look for target organ damage.

TABLE 4. Cardiovascular Risk Factors

Age (older than 55 yrs for men, 65yrs for women)
Diabetes mellitus
Elevated LDL [or total] cholesterol or low HDL cholesterol
Estimated GFR < 60 mL/ min
Family history of premature cardiovascular disease (men aged <55 or Women aged <65)
Microalbuminuria
Obesity (body mass index ≥ 30 kg / m^2)
Physical inactivity
Tobacco usage, particularly cigarettes

Investigations:

Same as Level 2, including for a fresh case reporting directly. Evaluate the target organ damage as per table 5. Evaluate judiciously for identifiable causes of hypertension (secondary hypertension) as per table 2. Routine laboratory tests for all patients

- 12-lead ECG
- Hematocrit
- Urinalysis
- Blood glucose
- Serum electrolytes
- Serum creatinine (calculate GFR from the modified Cockcroft and Gault equation) . Serum Calcium
- Lipid profile (after 9- to 12-hour fast)
- Urinary albumin excretion or albumin I creatinine ratio (ACR) for those with diabetes or kidney disease.

More extensive testing for identifiable causes is indicated in the following conditions

- BP control is not achieved
- Clinical and routine laboratory evaluation strongly suggests an identifiable secondary cause

Table 5.Target organ damage

Organ	Features	Evaluation history	Examination	Investigation
Heart	Heart failure	Exertional breathlessness, PND, Orthopnea, edema	Pedal edema, JVP, diffuse apical impulse, S3, S4, chest examination for pulmonary edema	X-ray chest, ECG Echocardiography
	Coronary artery disease	History of angina, prior myocardial infarction, prior coronary revascularization		In addition to above, TMT and Coronary angiography if indicated.
	Left ventricular hypertrophy		Forceful sustained apical impulse	ECG, Echocardiography.
Brain	Stroke or transient ischemic attack	History of sudden Onset, transient / persistent neurological deficit	neurological deficit	
	Dementia		MMSE, neurological examination	NCCT / MRI brain

Chronic kidney disease		Uremic complaints, urine out-put, dyspnea	Pallor, edema, peripheral, sensorium and orientation, asterexis, electrolytes, uremic odour and clinically for dialysis	Urine analysis, BUN, creatinine, heamoglobin electrolytes, Ca^{2+}, PO4-, ECG, X-Ray chest, sonography for kidney
Peripheral arterial disease		H/O claudication	Assess peripheral pulses, look for arterial bruits	Doppler studies
Retinopathy				Fundoscopy

Treatment: Same as Level 2. Additionally, look for compelling indications to modify the medications.

Table 6. Preferred indications for Individual drug classes

Compelling indication	Recommended					
	Diuretic	BB	ACEI	APB	CCB	Aldostereone Antagonisit
Heart failure	•	•	•	•		•
Post-myocardial infarction		•	•			•
High coronary disease risk	•	•	•		•	
Diabetes	•	•	•	•	•	
Chronic kidney disease			•	•		
Recurrent stroke prevention	•		•			

Important contraindications, for e.g. raised serum creatinine-more than 3 mg% while prescribing ACE inhibitors or while prescribing 13 blockers in patients with heart failure having NYHA class III symptoms, should be kept in mind.

Evaluation of refractory hypertension

Evaluation of remediable causes in refractory hypertension-

- Excess salt intake
- Inadequate diuretic therapy
- Non-adherence
- Inadequate doses and inappropriate combination
- Other medication use such as non steroidal anti inflammatory drugs, cocaine, amphetamine. sympathomimetics, corticosteroids, cyclosporine etc.

- Associated conditions like obesity, excess alcohol use, obstructive sleep apnea.
- Identifiable causes of hypertension

Referral criteria:

- Refractory Hypertension
- Definitive management of secondary hypertension
- Definitive management of complications of hypertension

Level4: At 100 or More Bedded District Hospital

Clinical Diagnosis: Same as level 3.Usually a patient requiring the referral to level 4 would have either complications of hypertension not manageable at level 3 or a secondary hypertension manageable only at level 4.
Investigations: Same as level 3. Other investigations, including hormonal, imaging (CT/MRI). renal, coronary and other angiographies if indicated, and not available at level 3, including those mentioned in table 5 and 7.
Treatment: Hormonal therapy, surgery and non-surgical interventional management etc can be offered at this level of care in secondary hypertension and complications of hypertension.

Table 7. Common management offered for various identifiable causes of hypertension

Diagnosis	Diagnostic test	Management
Coarctation of the aorta	CT angiography	Surgical correction
Cushing syndrome and other glucocorticoid excess states including chronic steroid therapy	History/dexamethasone suppression test, serum cortisol	Resection of tumour, tapering of corticosteroids if possible
Pheochromocytoma	24-hour curinary metanephrine and normetanephrine	Surgical resection
Primary aldosteronism and other mineralocorticoid excess states	Doppler flow study; magnetic resonance angiography	Stenting / surgical revascularization
Sleep apnea	Sleep study with O_2 saturation	Continuous positive airway pressure
Thyroid/parathyroid disease	TSH, serum PTH	Anti thyroid drugs, radio iodine, surgical resection, replacement in the case of hypothyrodism

Source

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Acute Respiratory Tract Infection [ARI]

Introduction

- Recommendation for case management has been made in Govt. of India – **ARI Control Program,** subsequently incorporated in CSSM Programme,at present in RCH programme (a WHO project)
- In 2000, Government of India constituted a task force comprising pediatricians and other health professionals to review the subject and to recommend (WHO - sponsored).

Presentation in this section is the updated recommendations on some selected areas. Details taken from the monogram: Guidelines for Management of ARI in Children 2nd Task Force, Ministry of Health and Family Welfare, Government of India

- Nose block: Clear by N. saline drop + moist wick. No medicated nasal drop usually needed, may be harmful.
- Paracetamol for fever

Fever with Cough and Cold (Acute Nasopharyngitis)

- No random antibiotics (majority - viral).
- Commercial cough formula usually not needed.
- With exhausting cough associated with severe vomiting: simple cough syrup (codein-free) - e.g. dextromethorphan may help.
- In cough with bronchospasm: salbutamol should be given..
- Normal feeding: Extra fluid.
- LOOK FOR SIGNS OF PNEUMONIA OR SEVERE PNEUMONIA / DISEASE - educate mother.

Children aged 2 months to 5 years with cough or difficult breathing:
Clinical classification to facilitate treatment decisions:

Clinical category	Essential features	Treatment strategy
Very severe pneumonia	• Central cyanosis, • Lethargy, unconsciousness, Convulsion • Not able to drink or feed, • Head nodding (severe respiratory distress)	• In patient care. • IV / IM Chloramphenicol / Ampicillin / Benzyl Penicillin + Gentamicin. • Give oxygen.
Severe pneumonia	• Lower chest indrawing or nasal flaring.	• In patient care. • IM/IV Benzyl penicillin or

	• No sign of very severe pneumonia..	Ampicillin
Pneumonia	Fast breathing: **Age** **Resp. rate / min.** 2 months > 60 2 months to 12 months > 50 12months to 5yrs. >40 No sign of severe or very severe pneumonia.	Home care. Oral Co-trimoxazole or Amoxycillin.
No pneumonia	Only cough and cold with or without fever	Paracetamol for fever. No antibiotic.

Signs indicating need for admission in children who have pneumonia

- Central cyanosis
- Not able to drink or breast feed
- History of convulsions
- Lethargy or unconsciousness
- Severe respiratory distress (e.g. head nodding)
- Lower chest indrawing
- Nasal flaring
- Stridor in a calm child
- Severe dehydration or shock
- Severe malnutrition or severe anemia: visible severe wasting, severe palmar pallor or edema of both feet.

Domiciliary treatment of non-severe pneumonia in children aged 2 months to 5 years

- Cough and fast breathing and no features of severe or very severe pneumonia:
  Cotrimoxazole* for 5 days
  Treat wheezing, if present

[* Alternative drugs include ampicillin or amoxycillin or procaine penicillin]

↓

- Reassess in 2 days:
  - Developed features of severe pneumonia, Treat as for severe pneumonia.
  - Improved, continue cotrimoxazole for a total of 5 days.
  - Not improved but no indicators of severe pneumonia. Reassess on day 5 If not improved, change cotrimoxazole to amoxycillin or ampicillin or IM procaine penicillin.

Dosage of antibiotics suitable for domiciliary treatment of non-severe pneumonia

Drug	Route of administration	Each dose per kg body weight	Frequency of dosing
Cotrimoxazole [trimethoprim(TMP) + sulphamethoxale(SM)]	Oral	4 mg of trimethoprim	Every 12 hours
Amoxicillin	Oral	15 mg	Every 8 hours
Ampicillin	Oral	25 mg	Every 6 hours
Procaine Penicillin	IM	50,000 units	Once daily

Dosage of cotrimoxazole & amoxicillin by age or weight categories

Age or weight	Cotrimoxazole Adult tablet single strength [80 mg TMP + 400 mg SM]	Cotrimoxazole Pediatric tablet [20 mg TMP+ 100 mg SM]	Cotrimoxazole Suspension [40 mg TMP+ 200 mg SM per 5 mL]	Amoxicillin Tablet 250 mg	Amoxicillin Suspension 125 mg in 5 mL
2 months to 12 months [6-9 kg body weight]	½	2	5 mL	½	5 mL
12 months to 5 years [10 – 19 kg body weight]	1	3	7.5 ml.	1	10 mL

TMP: Trimethoprim, SM: Sulphamethoxazole

Cotrimoxazole: two times daily for 5 days, Amoxicillin: three times daily for 5 days.

Treatment of severe pneumonia (2 months - 5 years of age)

Antibiotic	Dose	Interval	Route
A First 48 hours:			
Benzyl Penicillin OR	50,000 IU / kg/dose	6 hours	IV / IM
Ampicillin OR	50 mg / Kg / Dose	6 hours	IV / IM
Chloramphenicol	25 mg / Kg / Dose	8 hours	IV / IM
B. Re-access at 48 hours			
B.1. If condition improves, then for next 3 days, or 3 days after the child is well; Give:			
Procaine penicillin	50,000 IU / kg/dose	Once	IM
Amoxicillin	15 mg / Kg / Dose	8 hours	Oral
Chloramphenicol	25 mg / Kg / Dose	8 hours	Oral

Condition does not improve(by 48 hours), change antibiotics

- Chloramphenicol used, change to cloxacillin 25 - 50 mg / kg / dose 1M / IV 6hourly + Gentamicin 7.5 mgm/kg/dose once daily
- If ampicillin used, change to chloramphenicol IV /IM.

- If after 48 hours condition improves, continue treatment orally.

Antibiotic algorithms for very severe and severe pneumonia

- Very severe pneumonia:

Central cyanosis, or not able to drink or breast feed, or convulsions, or lethargic or unconscious, or severe respiratory distress, e.g. head nodding

↓

IM or IV chloramphenicol (IM or IV Benzylpenicillin plus gentamicin if chloramphenicol is not available)

↓

If child improves: continue orally for a total course of 10 days.
If no improvement within 48 hours, switch to gentamicin plus cloxacillin and when child improves continue cloxacillin orally for a total course of 3 week.

- Severe pneumonia:
  [Lower chest indrawing, or nasal flaring, and No features of very severe pneumonia]

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IM or IV Benzyl Penicillin

If child improves: continue for another day and then switch to oral amoxycillin for a total course of 5 days.
If no improvement within 48 hours, switch to chloramphenicol and when the child improves continue orally for a total course of 10 days.

Clinical classification of sick young infants aged 0 to 2 months

(a) Possible serious bacterial infection - pneumonia, septicemia or meningitis

Presence of any of the following in a young infant thought to be sick by the mother

- Convulsions
- Many or severe skin pustules
- Umbilical redness extending to the skin
- Fast breathing (respiratory rate >= 60 per minute)
- Severe chest indrawing
- Nasal flaring
- Respiratory grunting
- .
- Bulging fontanelle
- Lethargic or unconscious
- Less than normal movement
- Fever (axillary temperature> 37.5.C) or low body temperature (axillary temperature < 35.5.C)
- Cough and severe undernutrition (weight < 2.0 kg in the first month, <2.5 kg in the second month, or presence of visible severe wasting)
- Not able to feed at all, or no attachment with breast at all, or no sucking at all

(b) Local bacteial infection:

- Red umbilicus or umbilicus draining pus, or
- Skin pustules.

Steps of treatment of possible serious bacterial infection In infants less than 2 months of age:

A. Give Ampicillin - 50mg/kg/dose - 6 hourly IV / IM

or

Benzyl penicillin - 50,000 IU/kg/dose - 6 hourly IV / IM (12 hourly if < 1 wk of age)
+ Gentamicin - 7.5 mg/kg/dose – once daily IV / IM.

B. Reassess after 48 hours:

B1 -If good response:

- Continue therapy for 4 days after child is well
- Switch over to oral amoxycillin (15 mg/kg - 8 hourly) + IM gentamicin, when the baby takes orally.

B2 - If no response after 48 hours / deterioration

Add chloramphenicol [25 mg/kg/dose x 8 hourly IV/1M] (except in 1st wk of life and prematures)
Alternatively - Cefotaxime -50 mg/kg/dose - 6 hourly IV / IM + Ampicillin 50 mg/kg/dose x 6 hourly

C - If staphylococcal infection is suspected
Cloxacillin - 50 mg/kg/dose - 6 hourly IV/IM + Gentamicin - 7.5 mg/kg/dose – once daily - IV/IM

D - If meningitis is suspected- Ampicillin + Gentamicin is more effective than Penicillin +Gentamicin. Alternatively, Ampicillin + Chloramphenicol (except in prematures & 1st week of life) may be used. Treat for 14 days or until baby is well for 4 days ,whichever is longer.

Doses of ampicillin, benzyl penicillin, gentamicin and cefotaxime for young infants aged less than 2 months

Antibiotic route of administration	**Dose / frequency [for each dose, not total daily dose**	**Preparation**	**Amount per dose in mL for 3-5 kg young infants**
Ampicillin IM or IV	50 mg / Kg every 6 hours	From a vial of 250 mg mixed with 3 ml sterile water	2.5
Benzyl-Penicillin IM or IV (Penicillin G)	50 mg/kg every 6 hours	From a vial of 600 mg (1 000 000 units) mixed with 2 ml sterile water	0.35
Gentamicin IM or IV	7.5 mg/kg once daily	From a vial containing 20 mg (2 ml at 10 *mg/ml)* Undiluted*	3.0
		From a vial containing 80 mg (2 ml at 40 *mg/ml)* with 6 ml sterile water*	3.0
Cefotaxime		From a 250 mg vial mix with 5 ml	5.0

Management of a child with stridor:

A. Severe croup

*Admit to hospital

*Give Chloramphenicol IV/IM.

*Keep tracheostomy set ready. Continue close & careful observation & consult surgeon.

If signs of obstruction i.e. air-hunger, cyanosis ,minimum air-entry, severe chest in-drawing etc.-Perform Tracheostomy.

No role of cold steam ,cough syrup or mucolytic agent.

B. Mild croup

Treat at home. No antibiotic (mostly viral)

If with measles - hospitalize.

Croup / stridor due to diphtheria:

- Admit in hospital.
- Give Procaine Penicillin 50,000 IU per kg intramuscularly daily for 7 days.
- Give Diphtheria antitoxin - 40,000 unit – IV / IM immediately.
- Tracheostomy - for severe obstruction.
- Supportive care.

Bronchial asthma

Bronchial asthma is manifested by difficulty in breathing due to bronchoconstriction (increased airway resistance) as a sequel of infection, immunological reaction or familial reason as the case may be. Rarely drugs (aspirin) and environmental toxins could be the stimulating factor of the disease.

Salient clinical features:
Symptoms of asthma consist of a triad comprising of dyspnoea, cough and wheeze. Commonly asthma is an episode.
Diagnosis of asthma is established by demonstrating reversible airway obstruction. Reversibility is traditionally defined as 15% or greater increase in FEV1 after 2 puffs of Beta adrenergic agonist.

Treatment:
Non-pharmacological:
Regular breathing exercise
Avoid triggering factors like smoke, dust, fumes, pollens, etc.

Treatment and follow-up depend on the severity of the attack and the patient's response:
Mild to moderate attack
– Reassure the patient; place him in a 1/2 sitting position.
– Administer:
• Salbutamol (aerosol): 2 to 4 puffs every 20 to 30 minutes, up to 10 puffs if necessary during the first hour. In children, use a spacer to ease administration (use face mask in children under 3 years). Single puffs should be given one at a time, let the child breathe 4 to 5 times from the spacer before repeating the procedure.
• Prednisolone PO: one dose of 1 to 2 mg/kg
– If the attack is completely resolved: observe the patient for 1 hour (4 hours if he lives far from the health centre), then give outpatient treatment: salbutamol for 24 to 48 hours (2 to 4 puffs every 4 to 6 hours depending on clinical evolution) and prednisolone PO (1 to 2 mg/kg once daily) to complete 3 days of treatment.
– If the attack is only partially resolved: continue with 2 to 4 puffs of salbutamol every 3 to 4 hours if the attack is mild; 6 puffs every 1 to 2 hours if the attack is moderate, until symptoms subside, then when the attack is completely resolved, proceed as above.
– If symptoms worsen or do not improve, treat as severe attack.

Acute Severe Asthma:
- IV. drip + IV hydrocortisone (10 ml) 2 vials stat - repeated 8- 12 hourly – then switch over to oral steroid.
- Nebulization with short acting sympathomimetics like Salbutamol can be given every 20 minutes.
- If the patient fails to respond after 1 hour, slow IV injection of Aminophylline (250 mg) diluted with dextrose solution (under cardiovascular supervision) should be advocated.
- Oxygen inhalation with mask delivering 50% to 60% oxygen.
- Routine use of steroid - oral or Parentral. Inj. Hydrocortisone 200 mg IV stat and 100 mg TDS, then oral steroids.
- Amoxycillin (500 mg) 1 cap 3 times a day for 7 days, if there is chest infection.

Chronic asthma:

Long-term treatment of asthma according to severity

Categories	Treatment
Intermittent asthma – Intermittent symptoms (< once/week) – Night time symptoms < twice/month – Normal physical activity	No long term treatment Inhaled **salbutamol** when symptomatic
Mild persistent asthma – Symptoms > once/week, but < once/day – Night time symptoms > twice/month – Symptoms may affect activity	Continuous treatment with inhaled **beclometasone** + Inhaled **salbutamol** when symptomatic
Moderate persistent asthma – Daily symptoms – Symptoms affect activity – Night time symptoms > once/week – Daily use of salbutamol	Continuous treatment with inhaled **beclometasone** + Inhaled **salbutamol** (1 puff 4 times/day)
Severe persistent asthma – Daily symptoms – Frequent night time symptoms – Physical activity limited by symptoms	Continuous treatment with inhaled **beclometasone** + Inhaled **salbutamol** (1-2 puff/s 4 to 6 times/day)

Referral criteria

All acute asthmatic patients should be managed at the primary care centers up to maximum of 2 to 3 hours. If symptoms and distress still persist in spite of medication patient should be shifted to higher centers for altered sensorium, silent chest, carbon - di - oxide narcosis, hypotension, etc.

Chronic Obstructive Pulmonary Diseases (COPD)

COPD is a group of slowly progressive respiratory diseases characterized by reduced maximal expiratory flow during expiration due to airway obstruction and bronchial hyperactivities. It pathologically comprises of emphysema and chronic bronchitis.

Diagnosis is confirmed by history and supported by clinical examination, X-Ray and pulmonary function testing.

Non-pharmacological :

- Cessation of smoking, avoidance of smokes and fumes, physiotherapy to facilitate expectoration.

Management of Severe exacerbation:

- Salbutamol 100 microgram/puff may be given every 20 minutes
- Amoxycillin (500 mg) 1 capsules 3 times/day for 7 to 10 days.

- Prednisolone (40 mg) 1 to 3 times/day
- Theophylline SR (200 mg) 1 to 2 tabs/day.

Indication for referral:

- Impaired consciousness,
- Cyanosis,
- Respiratory rate more than 30 per minute,
- Paradoxical abdominal breathing.

Patients must be shifted for ventilatory support.

News & Views

Central labs under CDSCO report 118 cases of substandard drugs in 11 months

Joseph Alexander, New Delhi, Friday, October 11, 2013, 08:00 Hrs [IST], Pharmabiz.com

The different drug testing laboratories under the Central Drugs Standard Control Organisation (CDSCO) have so far reported 118 cases as sub-standard in the last 11 months, since the authorities launched the drug alert system to alert the public about those drugs, devices and cosmetics which have failed to clear the tests.

After the system was introduced in November last year, the CDSCO laboratories reported 10 cases in the two months of 2012 and 108 cases were reported this year. Most of the samples were substandard, mainly due to assay dissolution and assay description.

During the month of September, as many as 14 cases were reported. Out of these, nine cases were reported by CDL, Kolkota while three were from the laboratory at Guwahati. V-Dox tablets (B.No. VD-2012) manufactured by Vardhaman Parma of Haryana was found spurious while ABD-400 tablets (B.No. T-1206147) from GS Pharmaceuticals of Haridwar failed the test in uniformity of weight in the tests done at RDTL, Guwahati. Genta Injections (B. No. GT-2012) from Vardhaman also failed the test, after the sample was sent by Tripura Drug Control Department.

Metronidazole tablets IP from Jackson Laboratories with batch no. T-3474 and Crystal Pharmaceuticals with batch number of M-313 failed the assay tests at regional drug testing lab at Chandigarh after the samples were collected and sent by the North Zone (Ghaziabad) of CDSCO.

Ronac Injection (diclofenac sodium injection IP 3ml) with batch number of LI-346 from Om Biomedic Pvt Ltd of Haridwar, Mono 20 (isosorbide mononitrate tables IP) with batch number of DB-2115007 from Biochem Industries Ltd, Daman and Bupivacaine Hydrochloride Injection IP (B.No. 0956L1101 from Unijules Lifesciences of Nagpur were reported as substandard by Kolkota Lab.

Nitrocontin 6.4 (controlled release tablets of nitroglycerine) (B.No F00912) from TC Healthcare Ltd from Ghaziabad, Clavam DT (amoxycillin and Potassium clavunate dispersible tablets) (B.No. 1161969) from Alkem Laboratories of Daman, Klavmox 1200 mg (amoxicillin & potassium clavulanate injection) (B.No. 2312026) by Kilitch Drugs of Thane and Quinine Dihydrochloride Injection IP (B.No- 3915) from Vulan Laboratories of Kolkota also failed the tests at CDL, Kolkota. Quinine Dihydrochloride Injection (B.No 22)

manufactured by Superb Drugs of Kolkota also was found sub-standard. The central lab also reported Dicyclomin HCL Injection USP (B.No. DE 1102 by Modern Laboratories, Indore, as substandard after the tests.

An overview of marketing of generics

Interlink Knowledge Cell

Thursday, November 28, 2013, 08:00 Hrs [IST], Pharmabiz.com

Indian pharmaceutical companies and their subsidiaries have successfully spread their presence in the global generic markets and have entrenched themselves in all the three types of markets, viz., matured generic markets (eg. USA, UK, Germany), early generics markets (Eg. Italy, Spain, France, Japan) & emerging generics markets (eg. Brazil, China, Turkey, Hungary). The Indian companies have received 178 Abbreviated New Drug Applications (ANDAs) approvals from US Food & Drug Administration (FDA) as compared to 144 in the previous year despite stringent approval norms. The US FDA granted a total of 476 ANDAs approvals during the year 2012 as against 431 approvals in the previous year. Of these total US FDA approvals, Indian companies grabbed 37.4 per cent approvals in 2012 as against 33.4 per cent in the last year.

The generic opportunity is not without its own share of challenges. High competition from local companies, competition from the innovator brand, low pricing, quality issues, shrinking profit margins and at times regulatory hassles are some of the main challenges faced by the generics industry.

To overcome these challenges, many generic manufacturers have adopted different strategies. Companies have used new technology platforms, new components and new configurations to provide better patient compliance and increase patient's quality of life. Super generics, biosimilars, bio-superiors, NDDS and value added formulations are some of the new product alternatives that have emerged. Thus, competition is being tackled with enhanced value proposition and product differentiation.

The pulse of Indian companies in this dynamic generics scenario was explored by Interlink Knowledge Cell which conducted a brief survey of five leading pharma experts for their opinion on the above. Findings of this exclusive survey are discussed below.

Markets catered to Indian companies are mainly catering to the generic markets in the regulated markets such as USA, UK and emerging markets such as Brazil, South Africa, China, Turkey etc. Our experts opined that while registration in non-regulated markets is relatively simpler, that in regulated markets is very challenging. Each ANDA application does involve a lot of time, effort and expense for the applicant organisation to bear. So, in regulated markets the number of players is comparatively lesser than in un-regulated markets. The easier the registration process, the stronger is the level of generic competition.

The decision on which markets to enter ultimately rests with the organisation, based on resources available. Typically, the top 50 companies focus on regulated markets while the rest find it easier to enter the non-regulated markets.

Type of products offered
Unanimously all the five experts concurred that India specialises mainly in offering the identical generic version of the original product, particularly of antibiotics, cardio-vascular drugs, etc.

Developing a NDDS version of the original product is not 'everybody's cup of tea' as it involves a high degree of scientific competence of the R&D team. Offering generics that are difficult to develop (eg. Patches, Pulmonary devices, special topical forms, etc) are also not common from Indian companies. A few top Indian companies are working on biosimilars.

Challenges faced in generic marketing
The most important challenges in generic marketing were the tough competition from the innovator brand followed by the low pricing and low margins. Competition from other brands was not rated as a major challenge. As regards regulations, experts cited that, 'getting approvals from the regulatory bodies' is also a difficult issue that they face, particularly in the regulated markets and in China. Other challenges faced include patent battles with the innovator brand with its long drawn legal proceedings and at times, rejection due to quality issues.

Steps to take for meeting these challenges
Indian companies are taking multiple steps towards tackling these challenges. These steps are on the following fronts; management mindset from average volume, high margin to above average volume and meagre volume where quantum of margin would be higher. Upgrading Manufacturing plants to standards of US FDA, upgrading the registration department and documentation processes, hiring / training competency of people in these areas, implementing strict QA / QC norms are some of the important steps that organizations can take. Conduct BE / BA studies for all exported generics.

One of our experts also felt that the industry must take onus of ensuring quality checks periodically of exported generics from the country, by creating a new independent monitoring mechanism.

Difficulties faced when implementing these solutions
It was expressed that, while the top companies have adequate financial resources to implement the above mentioned steps, the smaller Indian companies face this constraint and do get caught up in a difficult situation. The entire industry gets a bad image if the quality of even a few Indian-made generics is poor. Monitoring the quality is a major issue. In developing countries, the government is often the major purchaser due to shrinking availability of funds for healthcare and due to ageing population. Getting orders from these governments is getting very difficult.

In conclusion, Indian companies do have a challenging time in choosing the path ahead for their generic business, particularly with regards to the markets they choose and the resources they can make available to enter the more mature western markets.

List of Substandard Drugs 2013

Name of Manufacturer	Name of Drug	Batch No.
AD Life Sciences, 5-67/1, Pedda Amberpet, R.R.Dist, Hyderabad-A.P	PEEZOLE-D (Pantoprazole & Domperidone Tablets)	RPA-12076
A. K. Biotech Pvt. Ltd., Export Promotional Industrial Park, Kartholi, Jammu-181133	Calcium Carbonate Tablets (MARYCAL-500)	MMT-657
Aaryak Absorbent Cotton Industries, Plot no-M-230, Phase IV, Behind Lokmat, MIDC, Akola. M.S.	Absorbent Cotton Wool I.P.	578
Abbott Healthcare Pvt Ltd, Village:- Bhatauli Khurd, Baddi, Solan HP 173205	Phensedyl New Cough Linctus	PHB 1163
Accent Laboratories, Baddi, HP	Triprolidine & Pseudoephedrine Tablets (Acticof)	AT-116
	Triprolidine & Pseudoephedrine Tablets (Rectified)	AT-116
Accent Pharma, Plot No- B-159, 22nd Cross, PIPDIC Ind.Est., Methupalayam, Pundicherry-605009	Gluconorm -G 4 Forte Tablets	A120364
Acme Surgicals, 53, Umesh Vihar, Traspostnagar, Meerut-2, UP	Pro-Fine Cotton Crepe Bandage	1620
Adcon Labs, 50B, Khandelwal Compound, Nemawar, Hyderabad-500073	Nycin Cream	52
Affy Parentrals, Vill, Gullerwala, P.O. Baddi, Dist- Solan,(H.P.) 173205	Voglimit-0.2 Tablet	PGT-1386
Aegle Healthcare, Plot No.. 127-128, EPIP, Phase-I, Jharmajri, Baddi, Distt. Solan (HP)	Ciprofloxacin Tab IP (Terocip-500 Tab)	AHT-012
Aerodeep Remedies Pvt Ltd, 161 Bhadrapur Saini Post-Dualtpur, Haridwar (UK)	Inj. Arteenate (Combipack-Containing Artesunate for Inj. 60 mg, Sodium bicaronate Inj. & Sodium Chloride Inj.)	AD-111013
Agam and Gem Laboratories Pvt.Ltd, Plot no-5, Daman Industrial Estate Daman-396215	Multi Life Plus Tablets	BYP/101/R
Agron Remedies Pvt. Ltd., Sarverkhera, Moradabad Road, Kashipur-244713	Alprazolam Tab IP 0.5 mg	FAT-14
	Strobact-OZ Suspension (Ofloxacin & Ornidazole Suspension)	SSZ-01

Name of Manufacturer	Name of Drug	Batch No.
Ahlcon Parenterals (I) Ltd, SP-918, Phase III, Ind Area, Bhiwadi	Dextrose Inj IP (10 % w/v)	A-11205
Akola Surgicals Pvt Ltd, Gram Gorva, Dist-Akola	SPANCOT Absorbent Cotton Wool I.P.	SK110, SK135
Akpash Pharmaceuticals Pvt Ltd, 275, Sector-E, Sanwar Road, Indore	Ciprofloxacin Tab IP (Ciprodot-250)	HT-094
Akums Drugs & Pharmaceuticals Ltd. 19,20,21, Sector 6 A, IIE, SIDCUL, Ranipur, Haridwar- 249403	Hytide RD 20	HWCJ10
	Lupisera – D Tablets IP	005E1ABY
	Lupome (Omeprazole Capsules IP)	002A2AJS
Aldoc Pharmaceuticals, B-17, Road No. 02, IPIA, Kota-5 (Raj)	Cefpodoxime Proxetil Tab IP 200 mg	CPX-01
Alive Healthcare , 123, HPSIDC, Industrial Area, Baddi	Efizyme Syrup (Syrup of Diastase and Pepsin)	120317
Alkem Laboratories, Survey No. 333/1, Kachigam, Daman 396210	Clavam DT (Amoxycillin & Potassium Clavunate Dispersible Tablets)	1161969
Allkind Healthcare, Plot no. 88-B, Export Promotion, Ind. Park, Phase II Vill. Thana, Baddi, Solan-173205	RABOZEN-20 Tablets	AKT3187
Alps Life Sciences Pvt. Ltd., 1692 HSIDC-Rai- 131029	Triprolidine & Pseudoephedrine Hydrochloride Tablets USP (VEVCOLD - T)	AT-116
	Triprolidine & Pseudoephedrine Hydrochloride Tablets USP (VEVCOLD - T)	AT-118, AT-120
Alps Pharmaceuticals (P) Ltd, Ind Estate, Patal Devi, Almora-263601 (UK)	Ciprofloxacin Tab IP (CIPOX-250)	AL 12009
Affine Formulations Pvt. Ltd, 1947/3, Village Bhatia, Tehsil, Nalagarh, Dist- Solan, (H.P.)	Pantoprazole and Domperidone Tablets. (Paron D)	13030
Akhere Pharmaceuticals, Plot No-20, Prasanthi Nagar, Kukatpally, Hyderabad-72	Prednisolone-10 (Prednisolone tablets I.P)'	AKRS002
Johnson & Smith Co, B-48, III Stage, Peenya Industrial Estate, Bangalore	PACIN-BRU Tablets (Paracetamol and Ibuprofen Tablets)	21307
K. S. Surgical, Village:-Ekladi, Post:-Ladpur, Bulandshahar	Optika Plus Cotton Crepe Bandage BP	CB-12
Kanak Pharmaceuticals, 3, Pal Colony, Assandh Road, Panopat- 1232003	Subofer syrup	RP-528

Name of Manufacturer	Name of Drug	Batch No.
Kaizen Pharmaceuticals, Vill. Katha, Baddi-173205 Dist. Solan	Pepticare DSR (Pantoprazole & Domperidone Sustained Release Caps)	BZC13K12
Kanha Biogenetic Laboratories, IB EPIP, Phase-I, Jharmajri, Baddi, Solan-174103	Remit-20 (Rabeprazole Tab IP)	1204002
Karnani Pharmaceuticals (P) Ltd., Factory: 38, Pharma City, Selaqui, Dehradun, U K, 248 197	K - Phyllin (Etofylline and Theophylline Tablets IP 100mg)	T-4026
Karnataka Antibiotic and Pharmaceuticals Limited, 14, 2nd Phase, Peenya Ind.Area, Bangalore-58	Amoxicillin and Potassium Clavulanate Injection	3400812
	Paracetamol Tab IP 500	KJ 358T
Kay Ess Biotech Pvt. Ltd., D-1651, DIC Industrial Estate, Phase III, Haridwar	Cetirizine & Pseudoephedrine tablets (Cetra-Z)	T-885
Kayyee Aeropharm (P) Ltd, Plot no-8,9,10 Lucky Industrial Estate, Opp. GIDC Bus stand, Kadi-382715 (NG)	Klinic Spirit (Isopropyl Rubbing Alcohol U.S.P.)	1811012
Kerala State Drugs and Pharmaceuticals Ltd., Alappuzha, Pin 688522	Azithromycin Tabs IP 250mg	DB 1002, DB 1003, DC 1002
	Paracetamol Tab IP	D8-1745
	Salbutamol Sulphate Tabs IP 40mg	J6 1167
Kilitch Drugs (India) Ltd., C-30/2, TTC INdl. Area, Pawane, Thane-400705	Klavmox 1200 mg (Amoxycillin & Potassium Clavulanate Injection IP)	2312026
Kirti Pharmachem, D-83, MIDC, Malegaon, Sinnar-422113	Pfpra-OZ (Ofloxacin & Ornidazole Tab)	KT13A02
Komal Healthcare Pvt. Ltd, Zenium House, Satya Sai Ind.Estate, Fatak Road, Bhayander (E), Mumbai-401105	Bandage Cloth	BC1-09
Kon Test Chemicals Ltd., Mambapur, Village, Jinnaram Mandal, Medak District – 502131, Andhra Pradesh	Rabikon–D (Rabeprazole & Domperidone Capsules)	RBD 101
Kriti Life Sciences Ltd., Annanad P O, Kerala	CENTRAL (Levocetrizine Dihydorcholoride Tab IP)	CL 108

Name of Manufacturer	Name of Drug	Batch No.
L.V.Life Sciences, VPO Gurumajra, Tehsil-Nalagarh Dist. Solan (H.P.)	Zymazym +Syrup (Pepsin & Fungal Diastase Syrup)	LV12F-101
Laborate Pharmaceuticals India Ltd., 51, Industrial Area, Paonta Sahib, Himachal Pradesh	Betamethasone Valerate and Neomycin Skin Cream (Valerate-N)	VNH-050, VNH-053
	Dexalab Injection	PDIHI-004
	Flucolab Tab (Fluconazole Tab IP)	FCIT-001
	Ifa Plus Tablets	IPHT-003
	Nflox-TZ	NCNTT
	OROCEPH-500 Capsule	OC5-7033
	Vibeltone Tablets	VTHT-001
Lark Laboratories (I) Ltd, SP-1192 E, Phase-IV, RIICO Indl Area, Bhiwadi (Raj)	Betamethasone Valerate Oint IP 01% w/w	13
	Larkin (Paracetamol Tablets IP)	E-7183
	Metronidazole & Norfloxacin Tab (Largyl-N)	LN-7109, LN-7110
Lark Laboratories (India) Ltd, Post Bag No: 23, Delhi: 110020	Oroceph-500 Caps	OC5 – 7033
Legen Healthcare, Plot No. 20, Sector-5, Parwanoo-173220, Dist. Solan (HP)	Koldonil-Plus Tablets	TX-697
	Mefenamic Acid & Dicyclomine HCl Tab (Spam-M)	TX-848
Life Vision Healthcare, 140, EPIP, Phase-1, Jharmajri, Baddi, (H.P.)	Drones-M Tab	LVT-1314
	Oflosar-ORD	LVS-1073
	OXILCOPE - L	LVT 1315
Lifewin Remedies Ltd, 147, Mauza Sansiwala, P. O. Baritiwala Teh. Kasauli Dist. Solan	Cifiglo-200	AGX-0112
	Penmed-D Tab	AGT-431
Logos Pharma, Village Maissa Tibba, Tehsil Nalagarh District Solan	Laurepan-D	LCO3641
Lucent Biotech Ltd, 165/3, Nalhera, Anantpur, Roorkee, Haridwar, Uttarakhand	Ethambutol Tab IP (Ethamtroy-800)	LTT-019/12, LTT-022/12

Source: http://www.drugscontrol.org/substandard_drugs2013.htm

WHO declares antibiotic-resistant bacteria 'a major global threat'

Kounteya Sinha,TNN | Apr 30, 2014, 07.31 PM IST

LONDON: The most comprehensive picture of antibiotic resistance, with data from 114 countries has revealed that resistance to the last-resort treatment for life-threatening infections caused by common intestinal bacteria Klebsiella pneumonia — carbapenem antibiotics — has spread to all regions of the world.

K pneumoniae is a major cause of hospital-acquired infections such as pneumonia, bloodstream infections, infections in new borns and intensive-care unit patients. In some countries, because of resistance, carbapenem antibiotics would not work in more than half of people treated for K pneumoniae infections.Resistance to antibiotics was on Wednesday declared a "major global threat" to public health by the World Health Organization (WHO).

The report brought out by the WHO has also revealed high levels of E coli resistance to third generation cephalosporins and fluoroquinolones — two important and commonly used types of antibacterial medicine in Southeast Asia region, which is home to a quarter of the world's population. In more bad news, in some parts of the region, more than one quarter of Staphylococcus aureus infections are reported to be methicillin-resistant (MRSA), meaning that treatment with standard antibiotics does not work.

The report, "Antimicrobial resistance: global report on surveillance" published on Wednesday, has revealed that resistance is occurring across many different infectious agents specially in seven different bacteria responsible for common, serious diseases such as bloodstream infections (sepsis), diarrhoea, pneumonia, urinary tract infections and gonorrhoea.

The results are cause for high concern, documenting resistance to antibiotics, especially "last resort" antibiotics, in all regions of the world.Resistance to one of the most widely used antibacterial medicines for the treatment of urinary tract infections caused by E coli — fluoroquinolones — is very widespread.

In the 1980s, when these drugs were first introduced, resistance was virtually zero. Today, there are countries in many parts of the world where this treatment is now ineffective in more than half of patients.

Treatment failure to the last resort of treatment for gonorrhoea — third generation cephalosporins — has been confirmed in Austria, Australia, Canada, France, Japan, Norway, Slovenia, South Africa, Sweden and the United Kingdom. More than 1 million people are infected with gonorrhoea around the world every day.

Antibiotic resistance causes people to be sick for longer and increases the risk of death. For example, people with MRSA (methicillin-resistant Staphylococcus aureus) are estimated to be 64% more likely to die than people with a non-resistant form of the infection. Resistance also increases the cost of health care with lengthier stays in hospital and more intensive care required.

"Without urgent, coordinated action, the world is headed for a post-antibiotic era, in which common infections and minor injuries which have been treatable for decades can once again kill," says Dr Keiji Fukuda, WHO's assistant director general for health security.

"Effective antibiotics have been one of the pillars allowing us to live longer, live healthier, and benefit from modern medicine. Unless we take significant actions to improve efforts to prevent infections and also change how we produce, prescribe and use antibiotics, the world will lose more and more of these global public health goods and the implications will be devastating."

Antibiotic resistance — when bacteria change so antibiotics no longer work in people who need them to treat infections — is now a major threat to public health.

The report reveals high levels of resistance to third generation cephalosporins in K pneumoniae throughout the WHO European Region. In some settings, as many as 60% of Staphylococcus aureus infections are reported to be methicillin-resistant (MRSA), meaning that treatment with standard antibiotics does not work.

What is CDMU?

- **CDMU is a non-profit organization**
- **CDMU's aim is ensuring rational use of medicine**
- **CDMU ensure quality generic medicine at affordable price**

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