

DOTS-PLUS FOR MULTIDRUG-RESISTANT TUBERCULOSIS PATIENTS IN SOUTH AFRICA
PATIENT CLINIC CARD Annexure 5

PATIENT PERSONAL DETAILS

First Name Surname

DOTS-Plus Number / Registration Date / /
 (ddmmyy)

Province

District Clinic/Hospital Treatment Point

Gender M F Race 1 2 3 4 9

Nationality RSA Other If Other, Specify

ID Number

Date of Birth (ddmmyy) / / Age yrs

Home Address
Postal Code

Tel: Code Number Fax: Code Number

PATIENT CONTACT DETAILS

MDR CENTRE DETAILS

Contact Person MDR Centre

Tel: Code Number Centre Address
 Fax: Code Number

Other information

Tel: Code Number

Fax: Code Number

Contact Person

Treatment Episode No Folder Number

MDR INFORMATION

Resistant to

Patient Classification

Site of Disease

- Isoniazid
- Rifampicin
- Ethambutol
- Other Drugs

- New MDR, Never Treated Before
- MDR, Treated For TB Before
- MDR, Treated For MDR Before

- Pulmonary
- Extra-pulmonary
- Both

Date MDR Diagnosis Confirmed (ddmmyy) / /

BACTERIOLOGY AND TREATMENT

Month	Weight (kg)	Date Sputum Taken	BACTERIOLOGY RESULTS		TREATMENT								
			Smear	Culture	Date	Ka/Am	Z	Et	Of/Ci	E	Te/Cy/	Other (specify)	
Pre-Rx													
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
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18													
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20													
21													
22													
23													
24													

Ka = Kanamycin Am = Amikacin Z = Pyrazinamide Et = Ethionamide Of = Ofloxacin Ci = Ciprofloxacin
 E = Ethambutol Te = Terizidone Cy = Cycloserine

MEDICAL HISTORY

HOUSEHOLD CONTACTS

Name	Age	Name	Age

DRUG ADVERSE EFFECT MONITORING

Adverse Effect (indicate grading*)	MONTH																							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Abdominal pain																								
Constipation																								
Decreased hearing																								
Depression																								
Diarrhoea																								
Dizziness																								
Fatigue																								
Fever																								
Headache																								
Joint pain																								
Nausea																								
Psychosis																								
Rash																								
Skin colourisation																								
Tinnitus																								
Tremors																								
Vision changes																								
Vomiting																								
Other (list)																								

Grading: 1 = mild: requiring no intervention
 2 = moderate: requiring palliative intervention (eg. pain killer)
 3 = severe: requiring change in treatment, REFER TO MDR CENTRE

TREATMENT OUTCOME

- Cured
- Treatment Completed
- Treatment Failure
- Defaulted
- Died
- Transferred
- Lost to Follow-up

Completed by

Signature

Date (ddmmyy)

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CLINICAL DETAILS

**DOTS-PLUS FOR MULTIDRUG-RESISTANT TUBERCULOSIS PATIENTS IN SOUTH AFRICA
SERIOUS ADVERSE DRUG EFFECT (ADE) REPORT**

Repeat this page as necessary

Serious ADE = Any untoward medical occurrence that at any drug dose results in death, is life-threatening, requires patient hospitalisation or prolonging of existing hospitalisation or results in persistent or significant disability/incapacity

Patient Name _____

MDR Centre _____

DOTS-Plus Registration Date / /

DOTS-Plus Number /

Date of ADE Onset (ddmmyy) / /

Duration : hours:minutes

Drug(s) Implicated:

Kanamycin/ Amikacin Ethionamide Ofloxacin/ Ciprofloxacin Cycloserine/Terizidone

Ethambutol Pyrazinamide Other, list _____

Action Taken:

Drug(s) Withdrawn Drug Sensitisation

Hospitalisation / Prolonged Hospitalisation Other: _____

Outcome of Event:

Complete Recovery Death

Ongoing Condition / Sequelae Unknown

Adverse Effect:

<input type="checkbox"/> Abdominal pain	<input type="checkbox"/> Fatigue	<input type="checkbox"/> Rash
<input type="checkbox"/> Constipation	<input type="checkbox"/> Fever	<input type="checkbox"/> Skin colourisation
<input type="checkbox"/> Decreased hearing	<input type="checkbox"/> Headache	<input type="checkbox"/> Tinnitus
<input type="checkbox"/> Depression	<input type="checkbox"/> Joint pain	<input type="checkbox"/> Tremors
<input type="checkbox"/> Diarrhoea	<input type="checkbox"/> Nausea	<input type="checkbox"/> Vision changes
<input type="checkbox"/> Dizziness	<input type="checkbox"/> Psychosis	<input type="checkbox"/> Vomiting

Other: list _____

Please prepare a comprehensive report on the serious ADE and its management and submit this to the National Coordinator **within five calendar days.**

Physician's Name _____

Signature _____

Date / /
(ddmmyy)

**DOTS-PLUS FOR MULTIDRUG-RESISTANT TUBERCULOSIS PATIENTS IN SOUTH AFRICA
DEATH REPORT**

Patient Name

Date of Birth / / (ddmmyy) Unknown

MDR Centre

DOTS-Plus Registration Date / /

DOTS-Plus Number /

Episode Treatment Start Date / /

Episode Number Not treated

Date of Death / / Month of Treatment

Death Certificate Issued Yes No Unknown

CAUSE OF DEATH AS ON DEATH CERTIFICATE OR BY VERBAL AUTOPSY

Primary Cause	<input type="checkbox"/> PT	Secondary Cause	<input type="checkbox"/> PT
	<input type="checkbox"/> UN		<input type="checkbox"/> UN
	<input type="checkbox"/> OC		<input type="checkbox"/> OC
	<input type="checkbox"/> NC		<input type="checkbox"/> NC
	<input type="checkbox"/> RD		<input type="checkbox"/> RD

Status at Time of Death Inpatient
 Outpatient
 Interrupted
 Transferred
 Treatment not started yet

Comments

Completed by

Designation

Date / / (ddmmyy)

FOLLOW-UP DETAILS

Date (ddmmyy) _____	Vital Status	Weight (kg)	TB Signs & Symptoms	Bacteriology	Date Sputum collected _____	Other Illnesses (List)
	Alive: Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>			No <input type="checkbox"/> Yes <input type="checkbox"/> If yes, list	Smear Pos <input type="checkbox"/> Culture <input type="checkbox"/> Pos Neg <input type="checkbox"/> <input type="checkbox"/> Neg Unknown <input type="checkbox"/> <input type="checkbox"/> Unknown MDR-TB confirmed <input type="checkbox"/> Yes <input type="checkbox"/> No	

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	Alive: Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>			No <input type="checkbox"/> Yes <input type="checkbox"/> If yes, list	Smear Pos <input type="checkbox"/> Culture <input type="checkbox"/> Pos Neg <input type="checkbox"/> Neg Unknown <input type="checkbox"/> Unknown MDR-TB confirmed <input type="checkbox"/> Yes <input type="checkbox"/> No	

Follow-up Outcome

Alive, Healthy

Alive, Recurrent TB

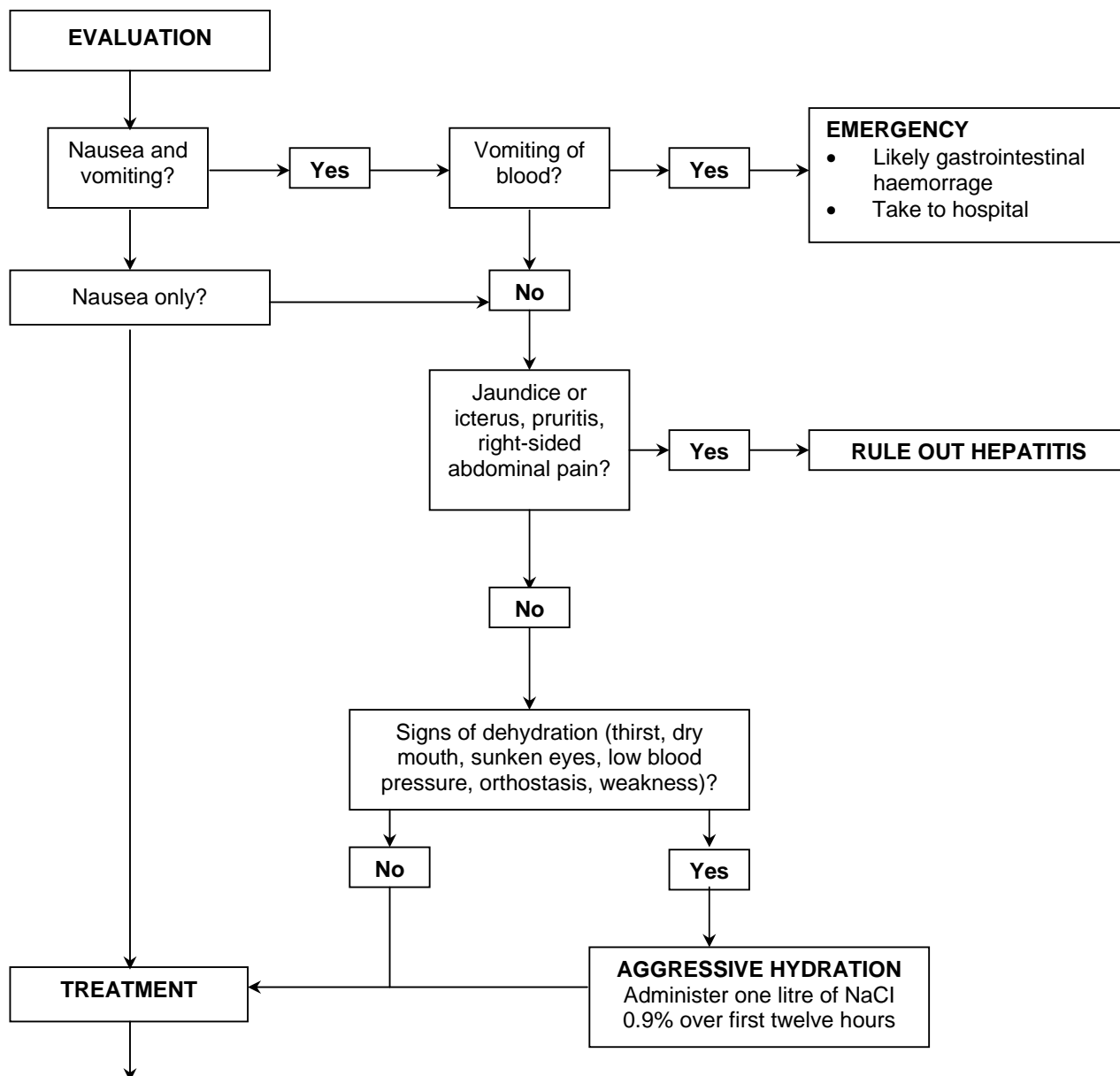
Alive, Recurrent MDR-TB

Alive, Other illnesses

Deceased

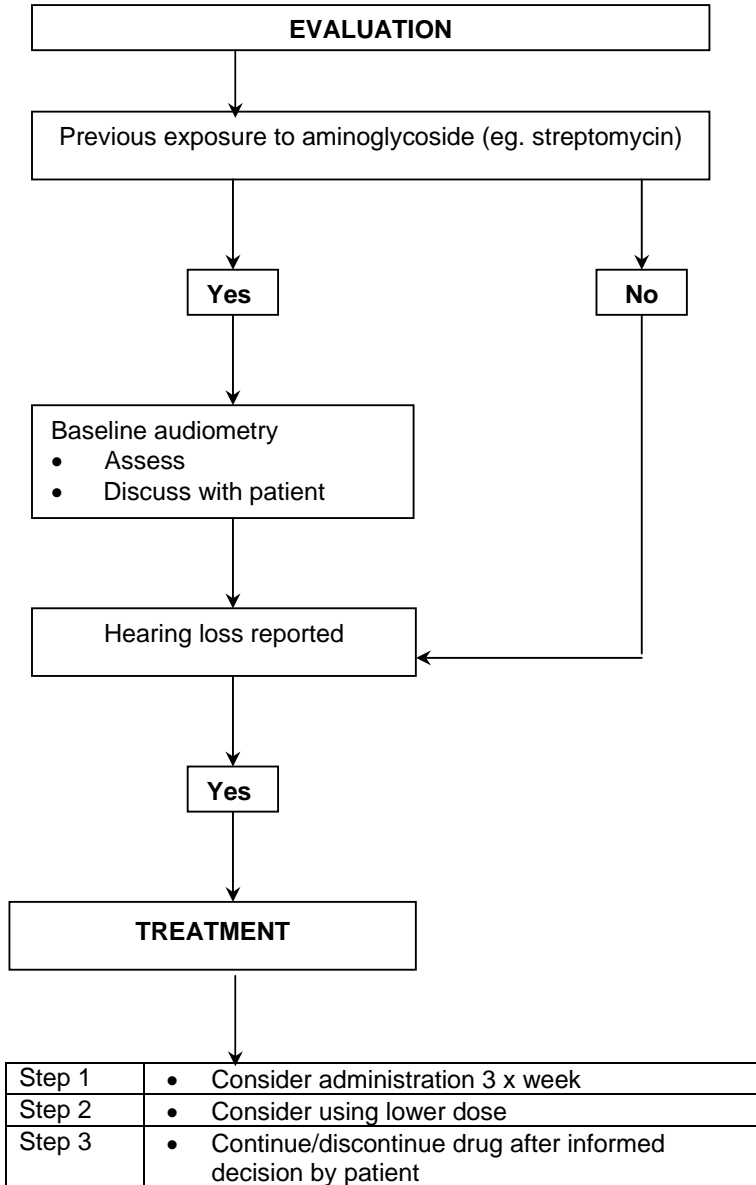
Lost to Follow-up

Management algorithm for nausea and vomiting



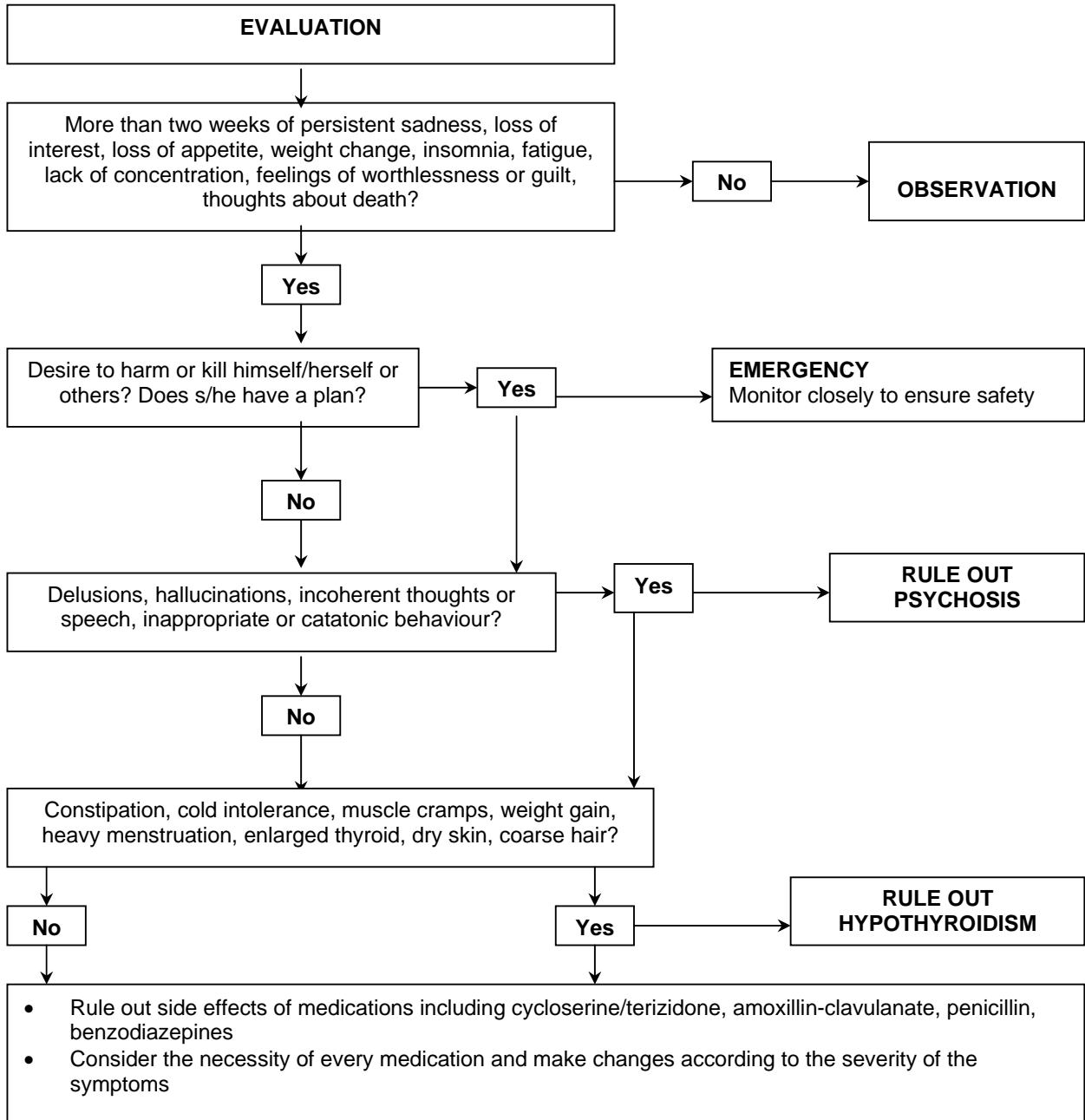
Step 1	<ul style="list-style-type: none"> • Check electrolytes and replete if necessary • Administer ethionamide in three separate doses or • Administer ethionamide at night with short-acting benzodiazepine
Step 2	<ul style="list-style-type: none"> • Administer anti-emetics, thirty minutes prior to taking anti-MDR tuberculosis medications (anti-emetics include: prochlorperazine, diphenhydramine, lorazepam, dimenhydranate, metoclopramide, phenergan, etc.) • Avoid metoclopramide and prochlorperazine if neurological problems • Use benzodiazepines if anxiety (avoid benzodiazepines in patients with tenuous respiratory status at risk of CO₂ retention)
Step 3	<ul style="list-style-type: none"> • Administer anti-emetics IV or IM as needed
Step 4	<ul style="list-style-type: none"> • Retry ethionamide at 750 mg/day

Management algorithm for hearing loss



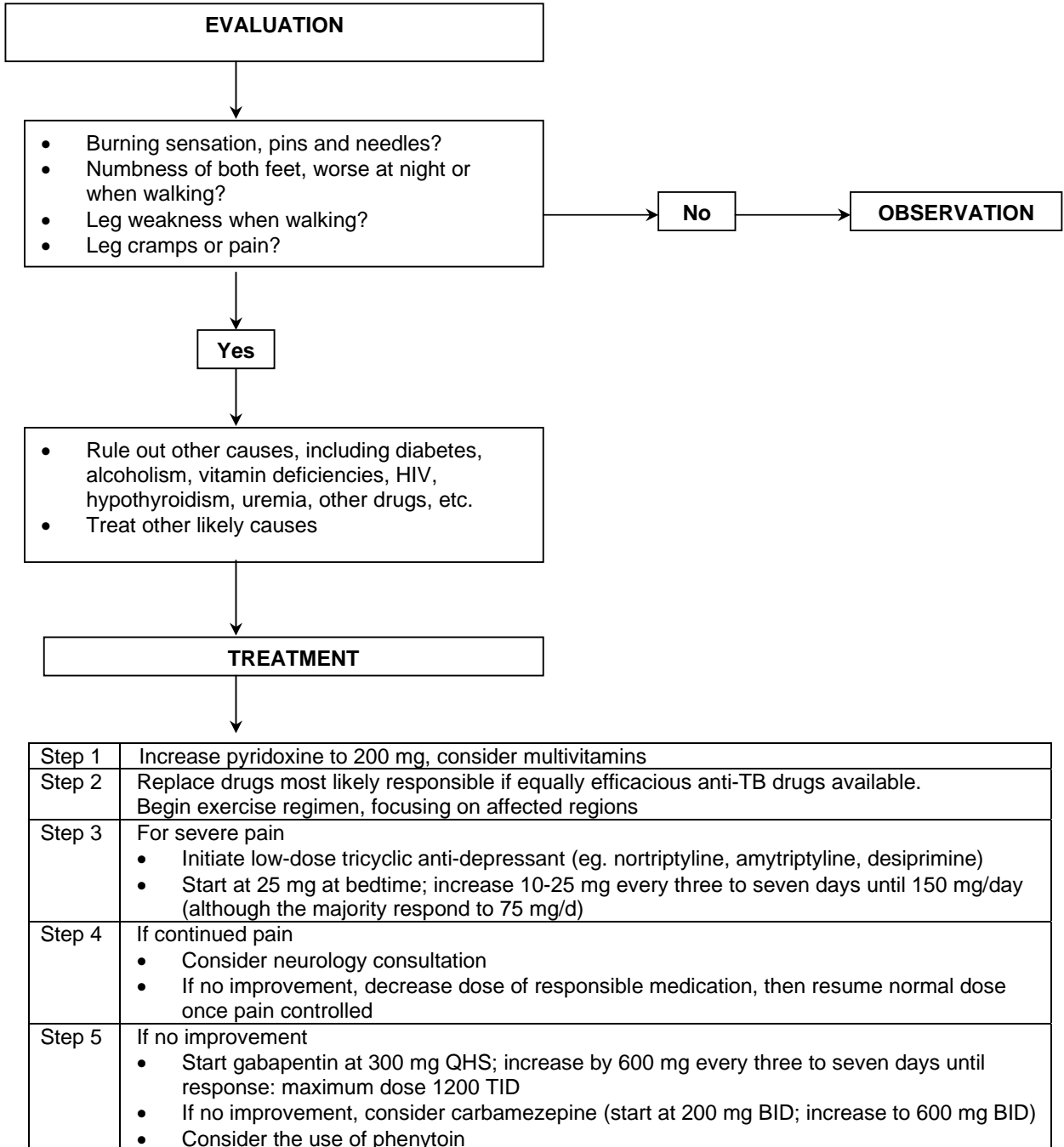
Step 1	• Consider administration 3 x week
Step 2	• Consider using lower dose
Step 3	• Continue/discontinue drug after informed decision by patient

Management algorithm for depression

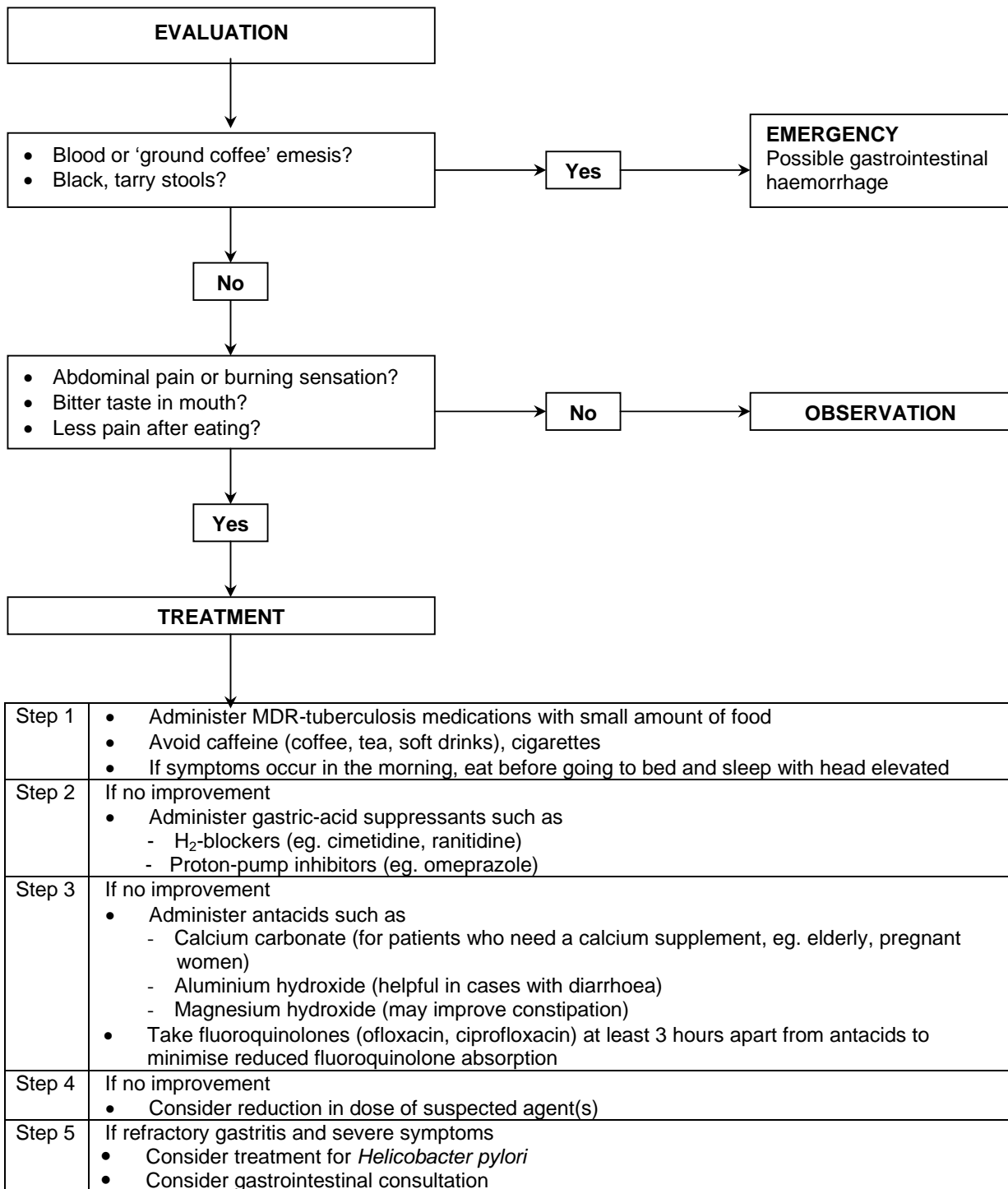


TREATMENT	
Step 1	<ul style="list-style-type: none"> • Intensive psychological therapy with counselling to patient and family • Emotional support from the family and health promoter aimed at resolution of causes of stress • Group therapy or informal support groups
Step 2	If no improvement in symptoms <ul style="list-style-type: none"> • Increase pyridoxine to 200 mg per day in patients receiving cycloserine/terizidone • Initiate antidepressant therapy (amitriptyline, nortriptyline, fluoxetine, sertraline, etc.) • Use antidepressants with caution in patients with a history of convulsions • Consider anti-psychotics and/or benzodiazepines according to the patient's condition • Consider psychiatric consultation

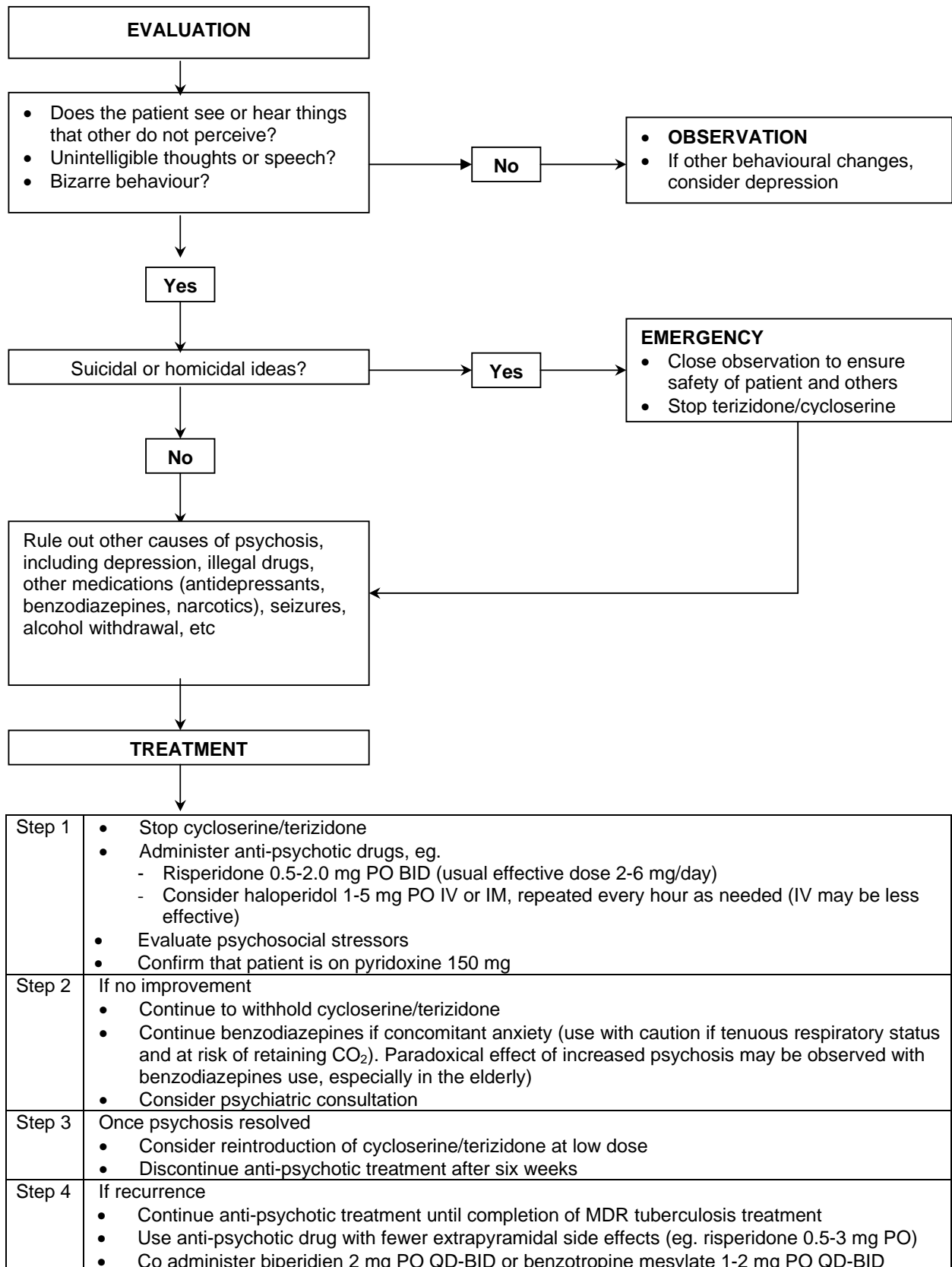
Management algorithm for peripheral neuropathy



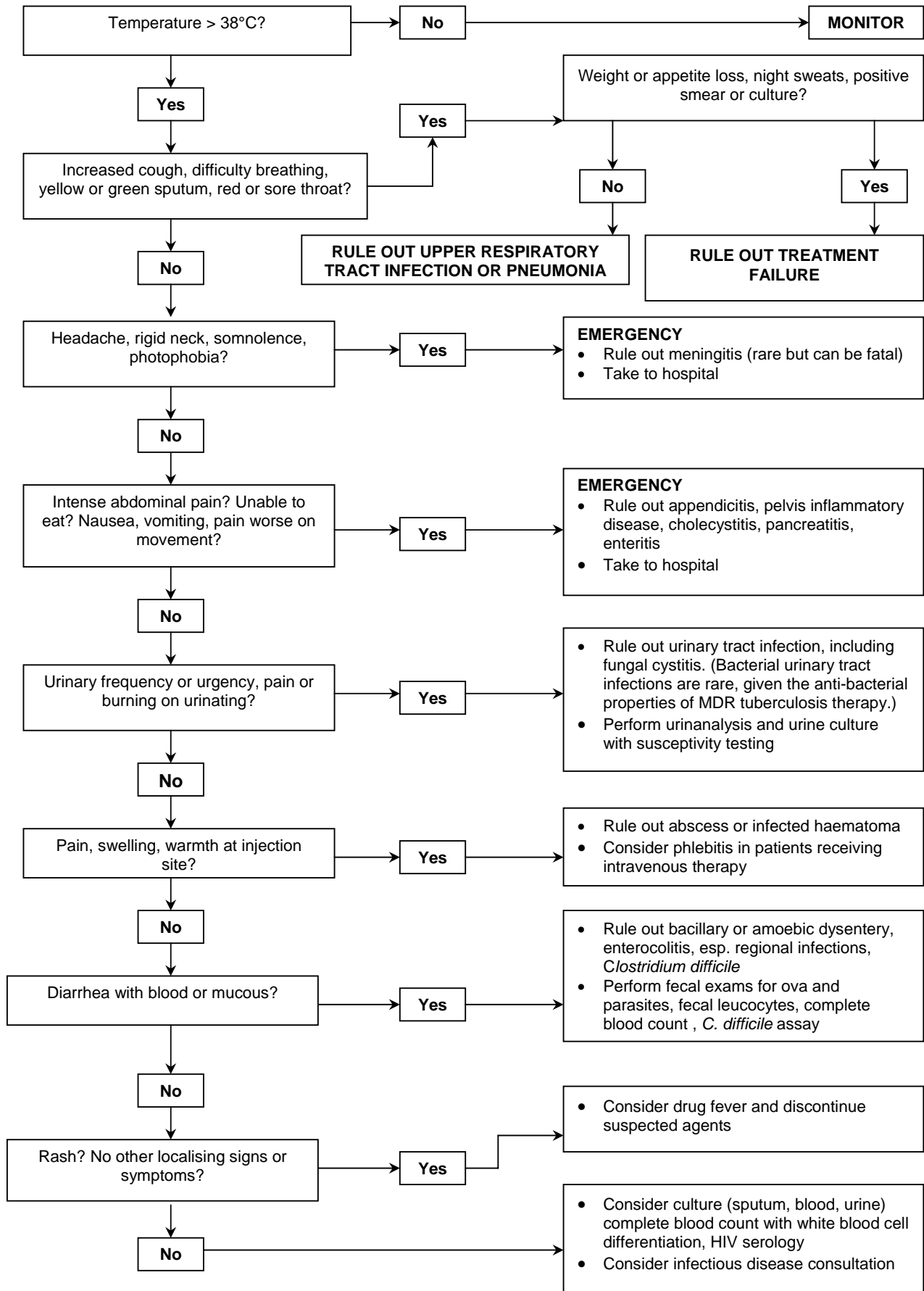
Management algorithm for gastritis



Management algorithm for psychosis



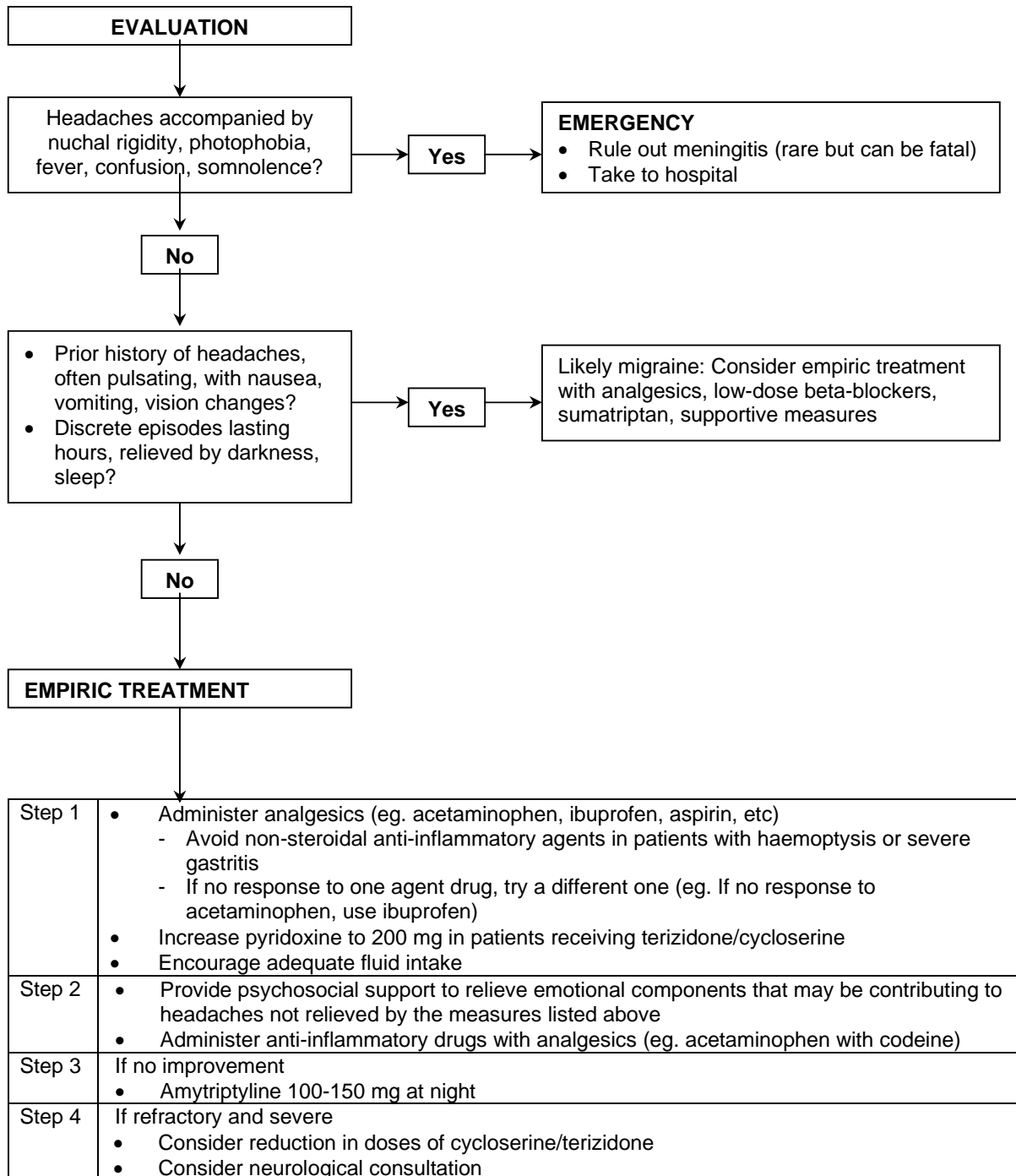
Management algorithm for fever: Part I



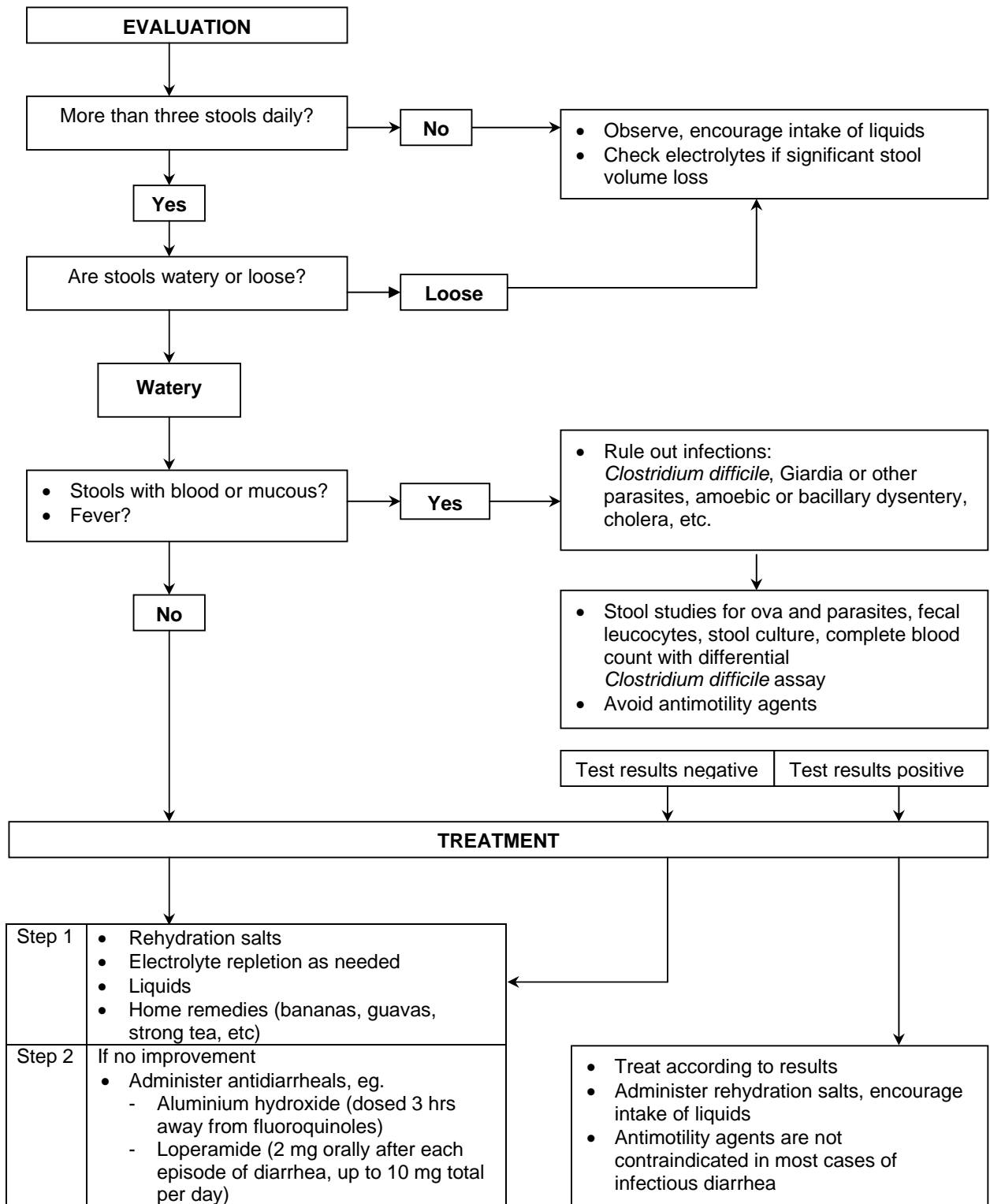
Management algorithm for fever: Part II

POSSIBLE CAUSE	PRESENTATION	TREATMENT
URINARY TRACT INFECTION		
Bacterial	<ul style="list-style-type: none"> • Urine leucocytes • Positive Gram stain • Positive urine culture 	<ul style="list-style-type: none"> • Treat according to susceptibility testing
Fungal	<ul style="list-style-type: none"> • Urine leucocytes • Positive Gram stain • Negative urine culture 	<ul style="list-style-type: none"> • Treat with fluconazole 200 mg QD first dose, then 100 mg QD for 4 days
ABSCCESS, HEMATOMA		
	Injection site: <ul style="list-style-type: none"> • Pain • Warmth • Swelling • Fluctuance 	<ul style="list-style-type: none"> • Aspirate with 18-gauge needle or incise and drain • If abscess, treat with difloxacin 500 mg 4 times a day (or other anti-staphylococcal therapy)
GASTROENTERITIS, ENTEROCOLITIS		
Viral	<ul style="list-style-type: none"> • Diarrhea, usually without mucous or blood • Negative fecal studies 	<ul style="list-style-type: none"> • Give rehydration salts
Bacterial/Parasitic	<ul style="list-style-type: none"> • Diarrhea, can be with mucus or blood • Positive fecal leucocytes • Possible <i>Clostridium difficile</i> if positive fecal leucocytes elevated white blood count, fever. Perform <i>Clostridium difficile</i> toxic assay if available 	<ul style="list-style-type: none"> • Give rehydration salts • Treat according for fecal study results • If <i>Clostridium difficile</i> suspected or confirmed, treat with metronidazole 500 mg TID for 10-14 days

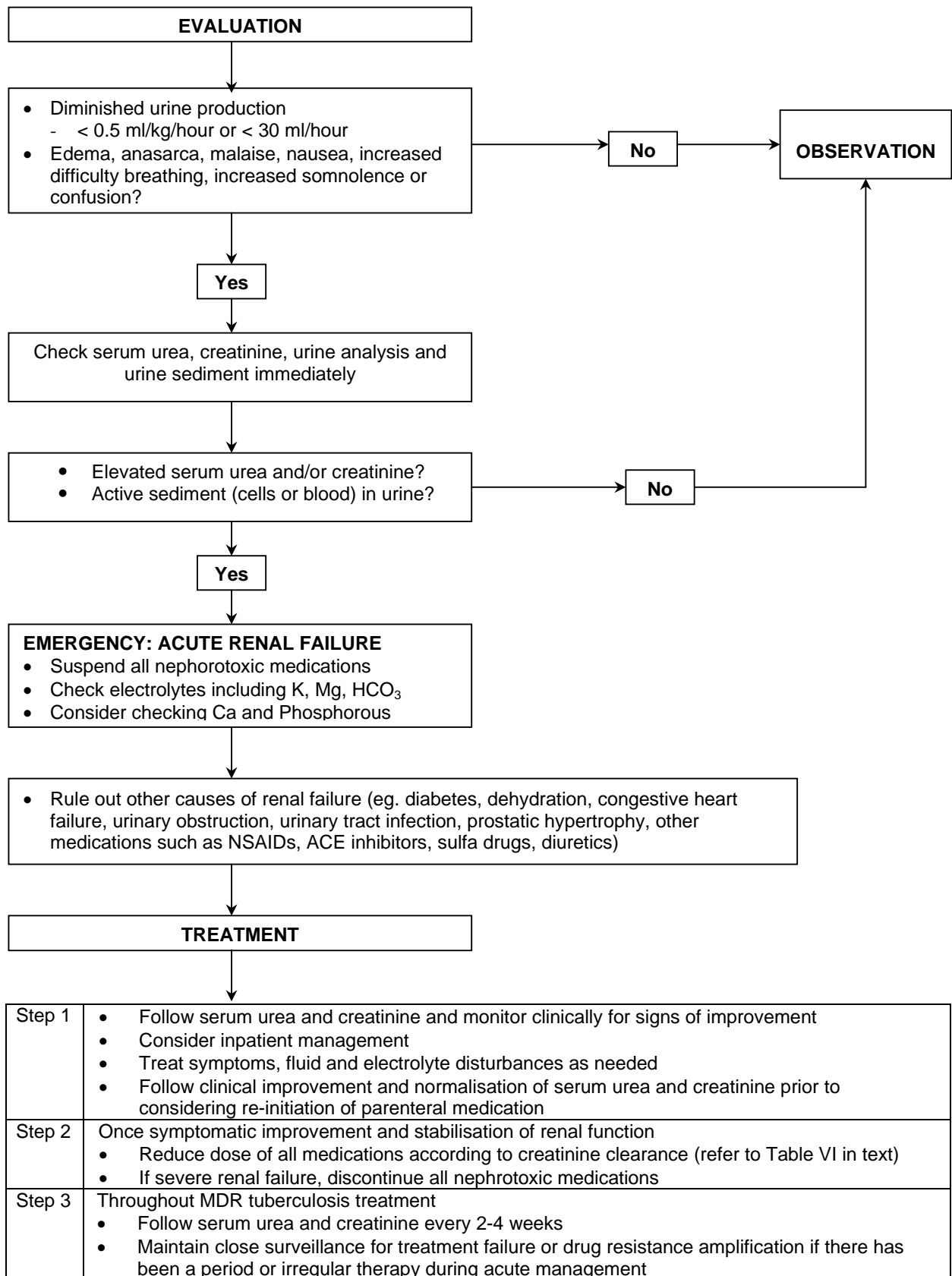
Management algorithm for headache



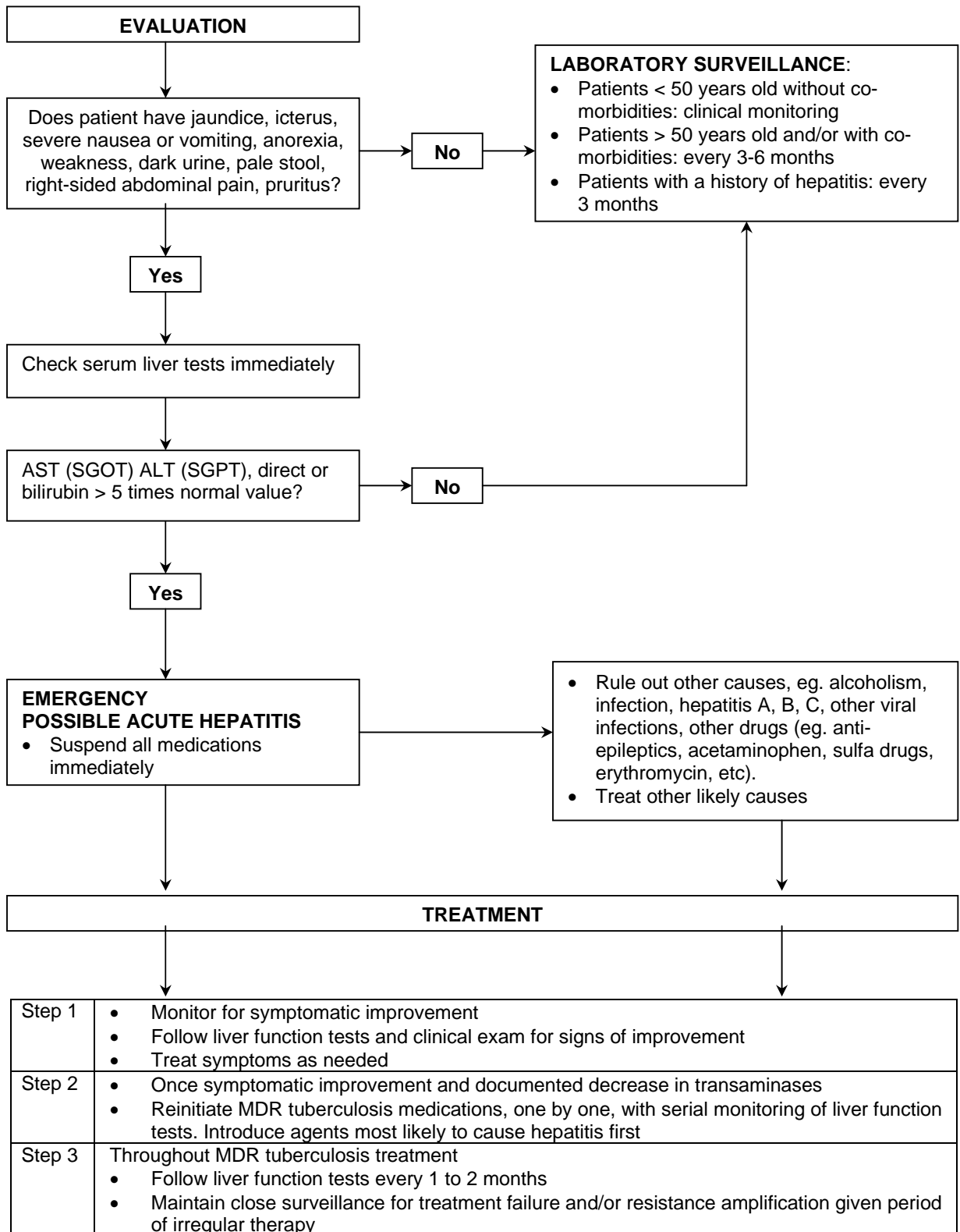
Management algorithm for diarrhoea



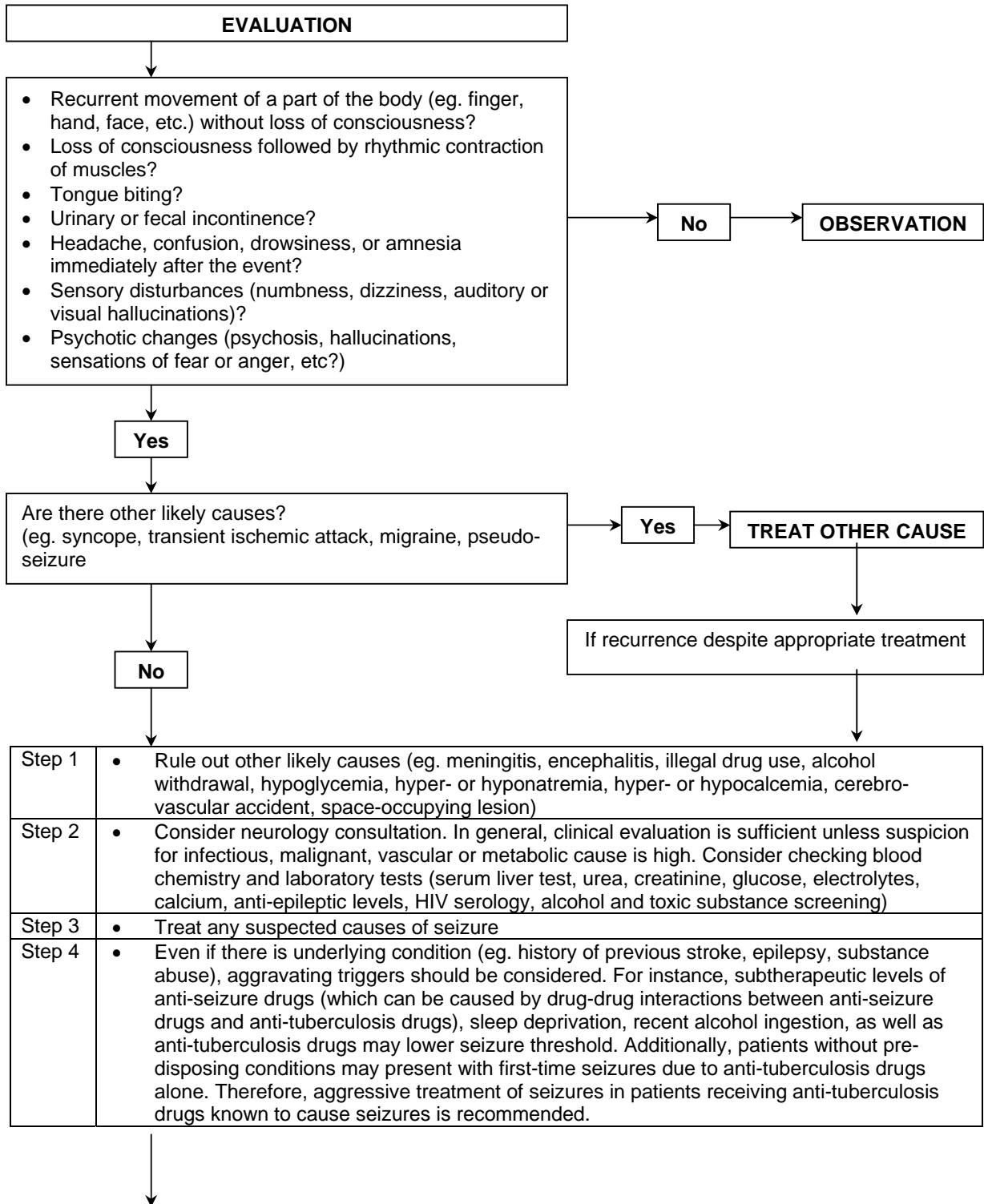
Management algorithm for nephrotoxicity and renal failure



Management algorithm for hepatitis

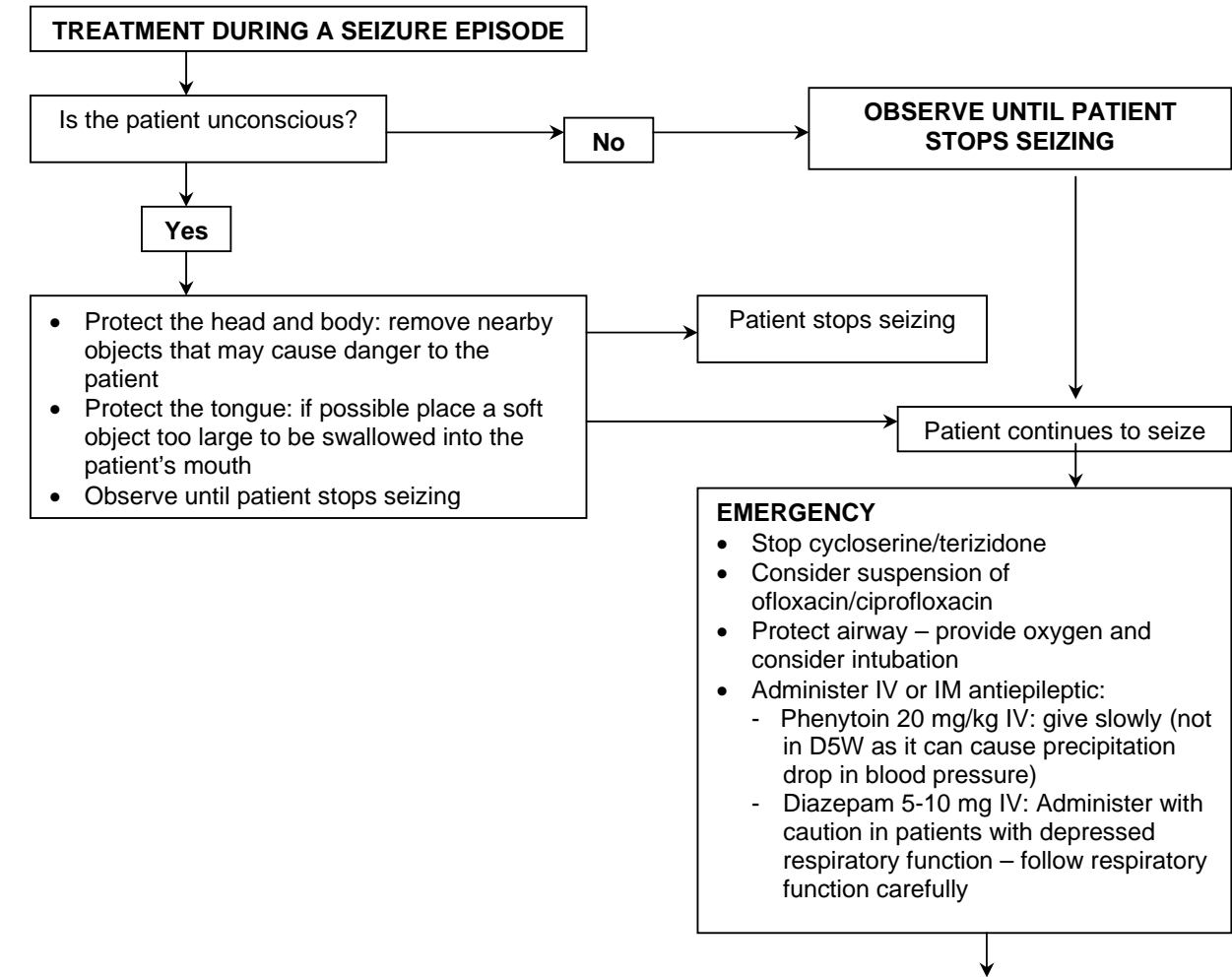


Management algorithm for seizure: Part I



Continued: Part II

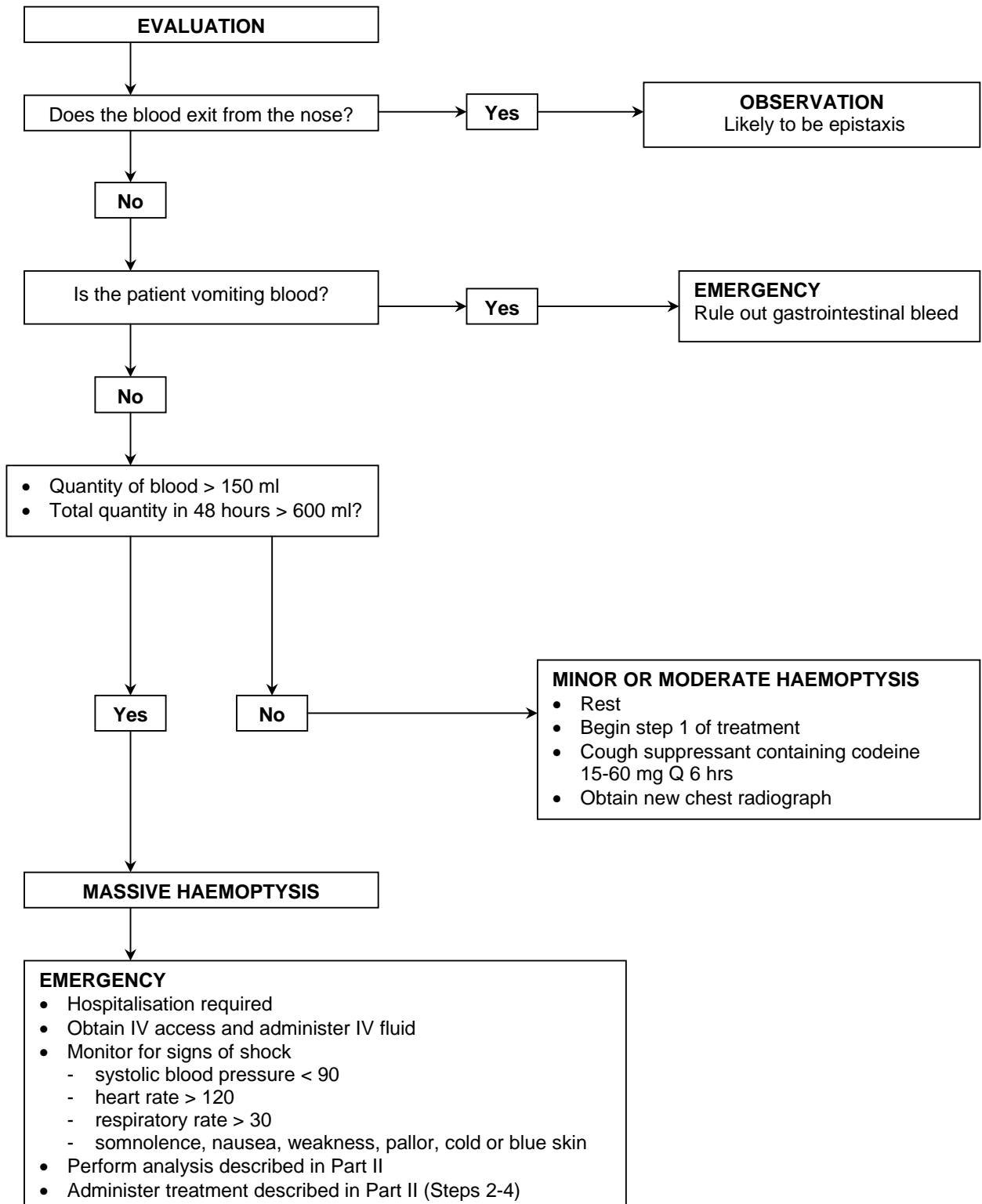
Management algorithm for seizure: Part II



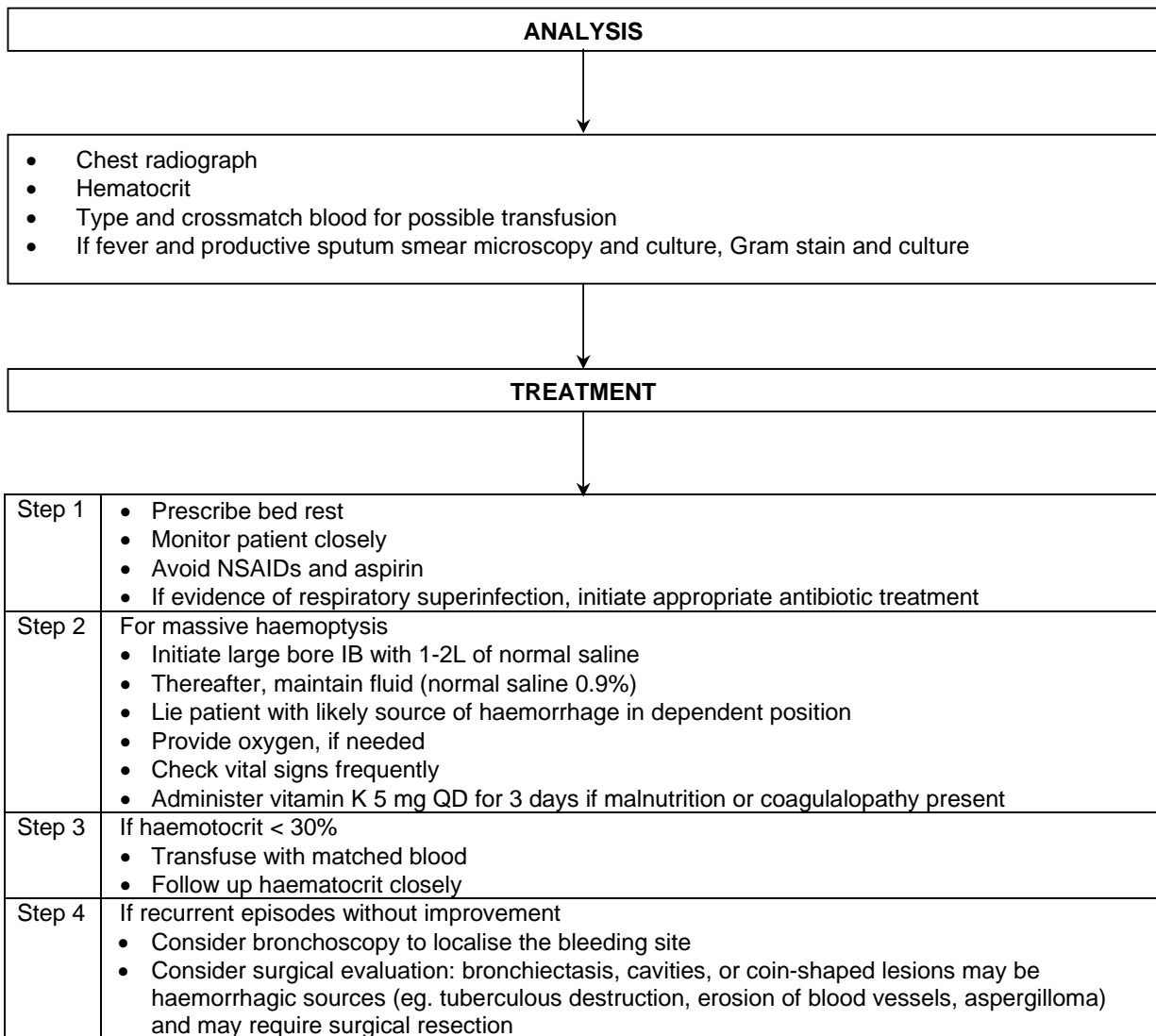
TREATMENT FOR PREVENTION OF FURTHER SEIZURES

Step 1	<p>Initiate antiepileptic treatment for the remainder of MDR-tuberculosis therapy:</p> <ul style="list-style-type: none"> Phenytoin (3-5 mg/kg/day) Potential adverse effects: ataxia, incoordination, confusion, skin rash, cerebellar dysfunction, hepatotoxicity, gingival hyperplasia, lymphadenopathy, hirsutism. Levels increased by fluoroquinolones Carbamazepine (600-1200 mg/day) Potential adverse effects: ataxia, dizziness, diplopia, vertigo, GI upset, hepatotoxicity; skin rash Phenobarbitol (60-120 mg/day) Potential adverse effects: sedation, ataxia, confusion, dizziness, decreased libido, depression, skin rash Valproic acid (750-1250 mg/day) Potential adverse effects: ataxia, sedation, tremor, hepatotoxicity, bone marrow suppression, GI upset, weight gain
Step 2	<p>Once stabilised</p> <ul style="list-style-type: none"> Consider reintroduction of suspected agent at lower dose
Step 3	<p>If no improvement</p> <ul style="list-style-type: none"> Check cycloserine/terizidone blood level and adjust if supra-therapeutic Decrease fluoroquinolone dose

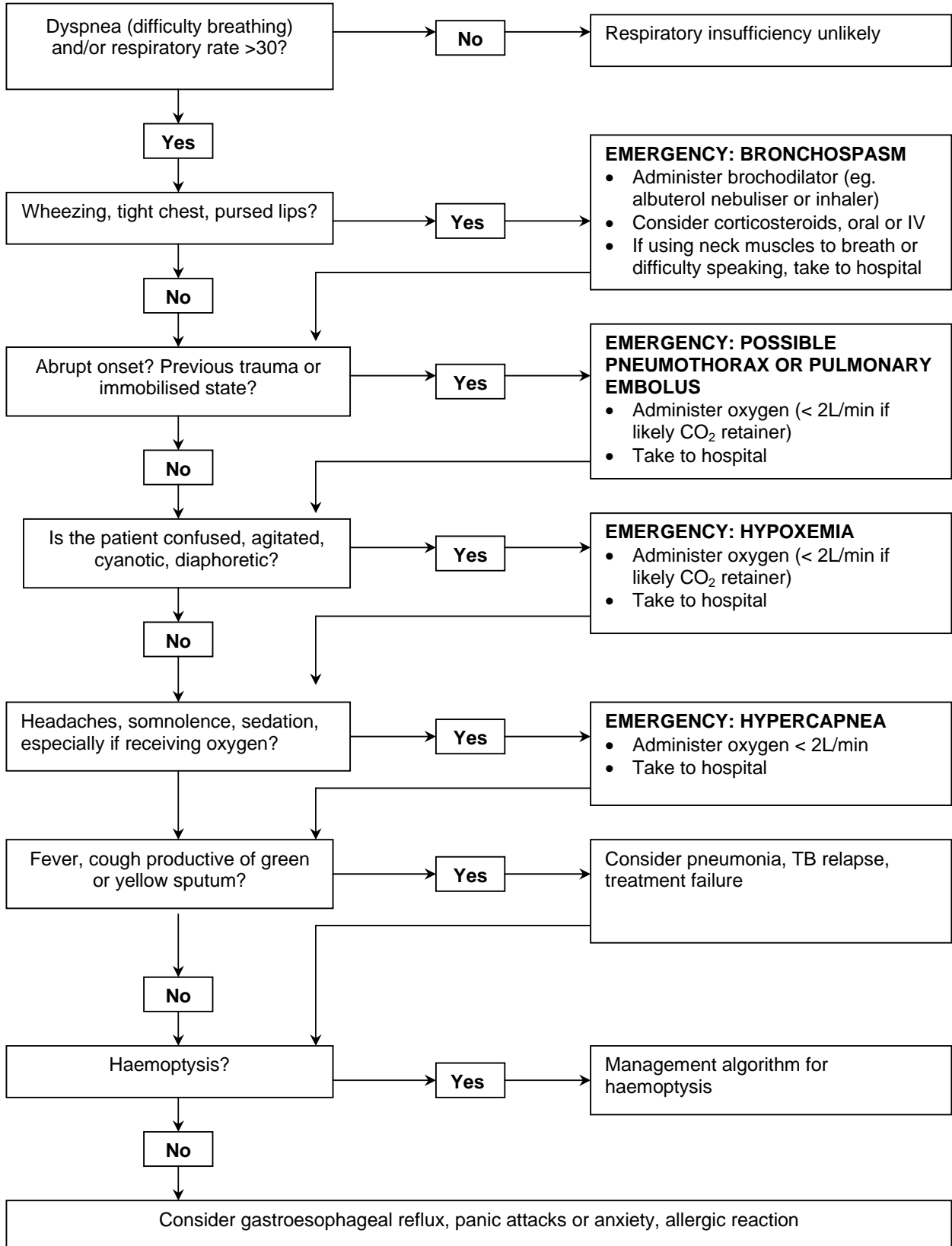
Management algorithm for haemoptysis: Part I



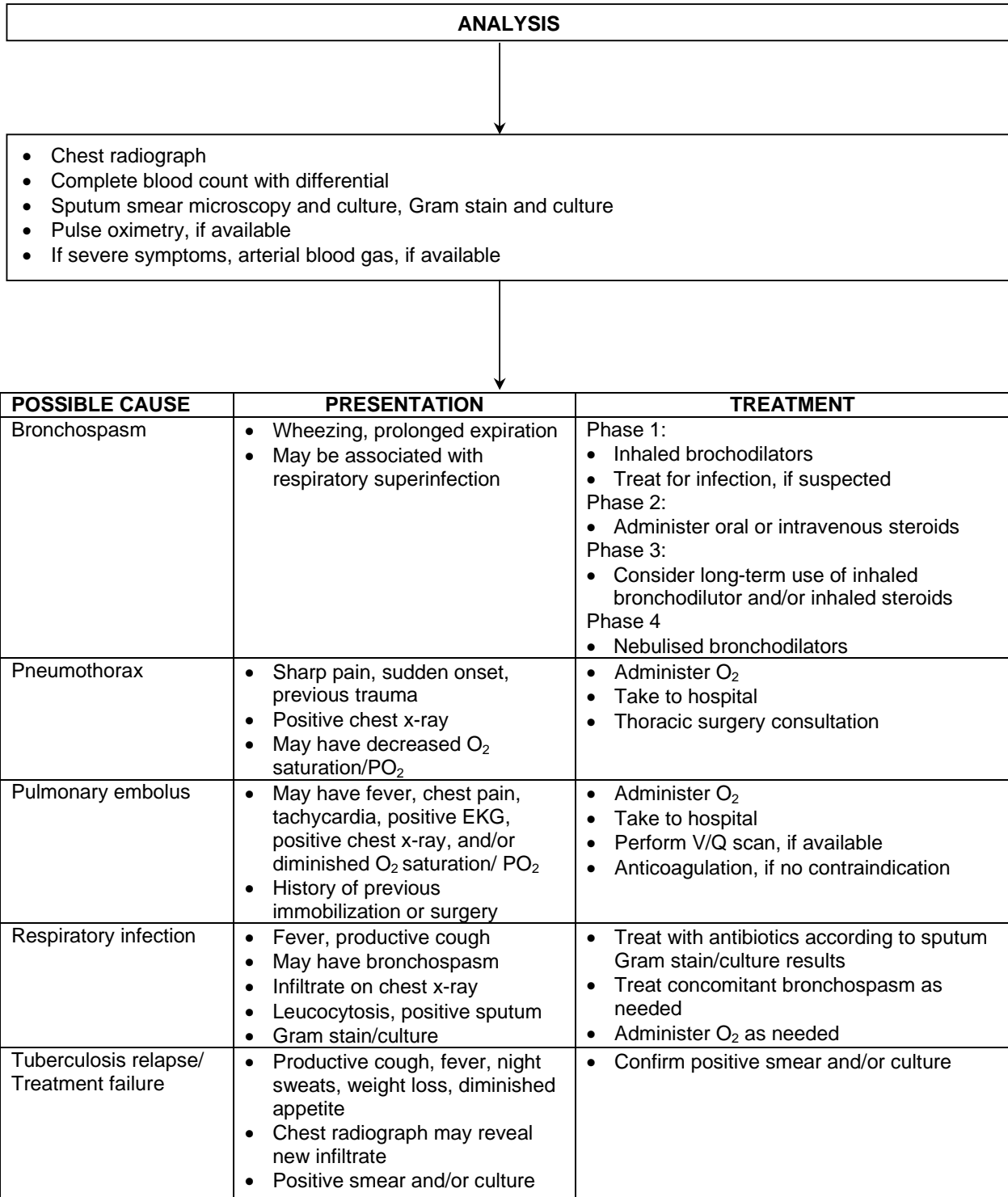
Management algorithm for haemoptysis: Part II



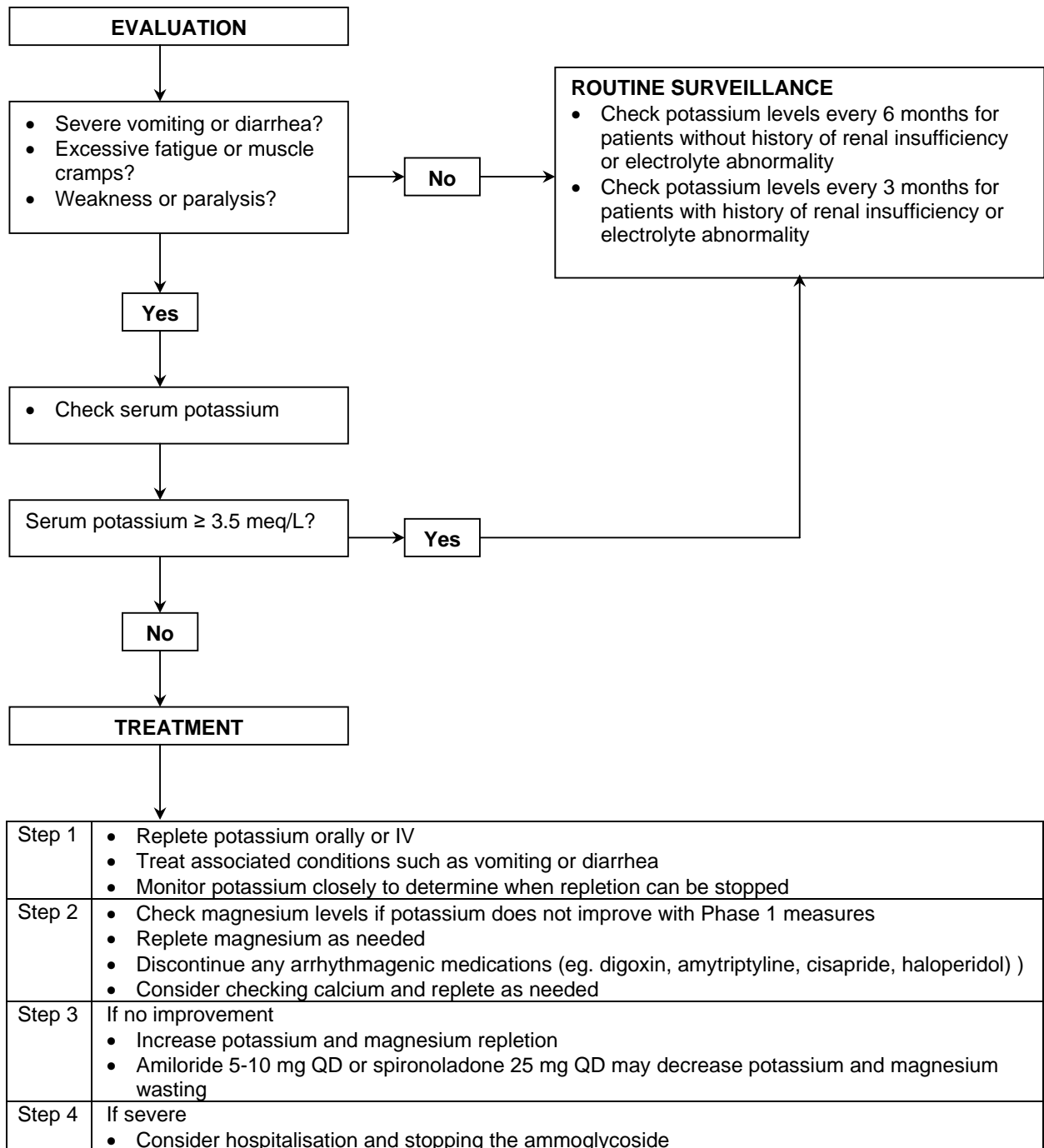
Management algorithm for respiratory Insufficiency: Part I



Management algorithm for respiratory Insufficiency: Part II



Management algorithm for hypokalemia



Management algorithm for anaphylaxis and allergic reactions

