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Ministry of Health and Family Welfare, Government of India

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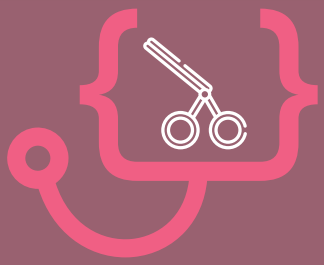


2022 Edition, Vol.III

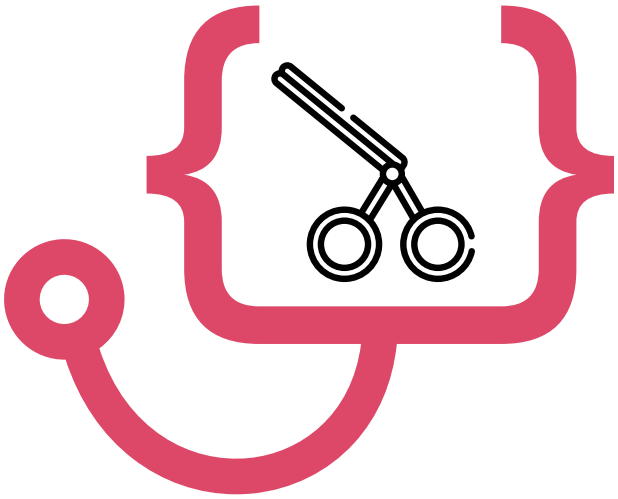
STANDARD TREATMENT WORKFLOWS

of India

PARTNERS

national health authority

World Health Organization India



STANDARD TREATMENT WORKFLOWS *of India*

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These STWs have been prepared by national experts of India with feasibility considerations for various levels of healthcare system in the country. These broad guidelines are advisory, and are based on expert opinions and available scientific evidence. There may be variations in the management of an individual patient based on his/her specific condition, as decided by the treating physician. There will be no indemnity for direct or indirect consequences. Kindly visit our web portal (**stw.icmr.org.in**) for more information.

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INTRODUCTION

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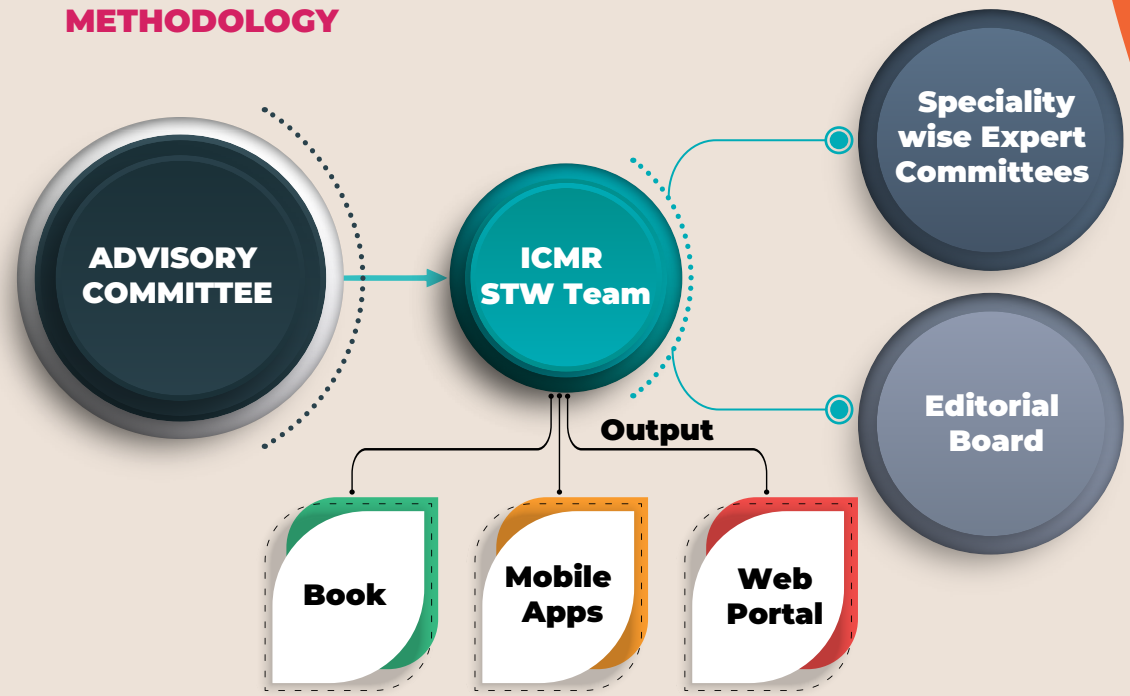
GOAL

To empower the primary, secondary and tertiary health care physicians/surgeons towards achieving the overall goal of Universal Health Coverage with disease management protocols and pre-defined referral mechanisms by decoding complex guidelines.

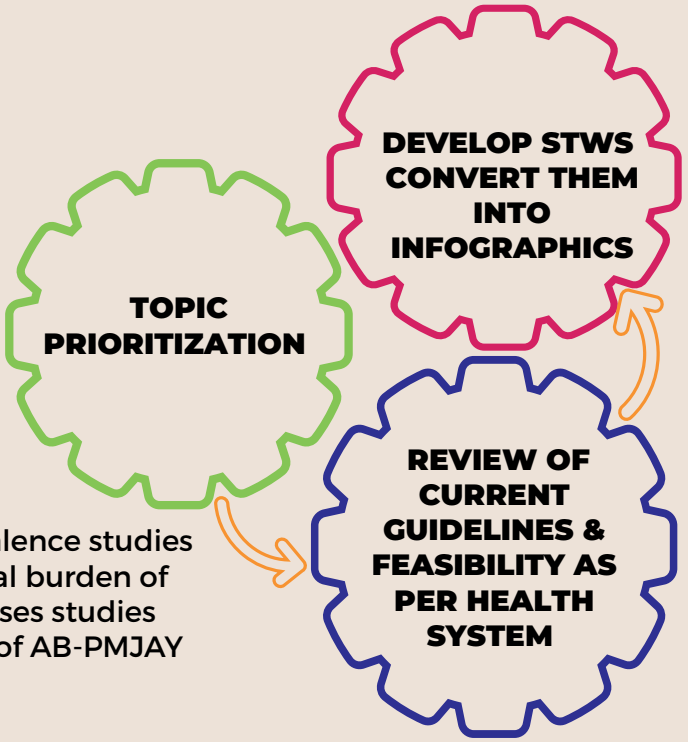
OBJECTIVES

To formulate treatment algorithms for common and serious medical & surgical conditions for both outdoor & indoor patient management at primary, secondary and tertiary levels of India's healthcare system that are scientific, robust and locally contextual.

METHODOLOGY



PROCESS OVERVIEW



- Participation also from Public Health Specialists Search Strategists Graphic Designers

- Prevalence studies
- Global burden of diseases studies
- HBP of AB-PMJAY

- Review by Editorial Board
- Approval by Advisory Committee

ENDOCRINOLOGY

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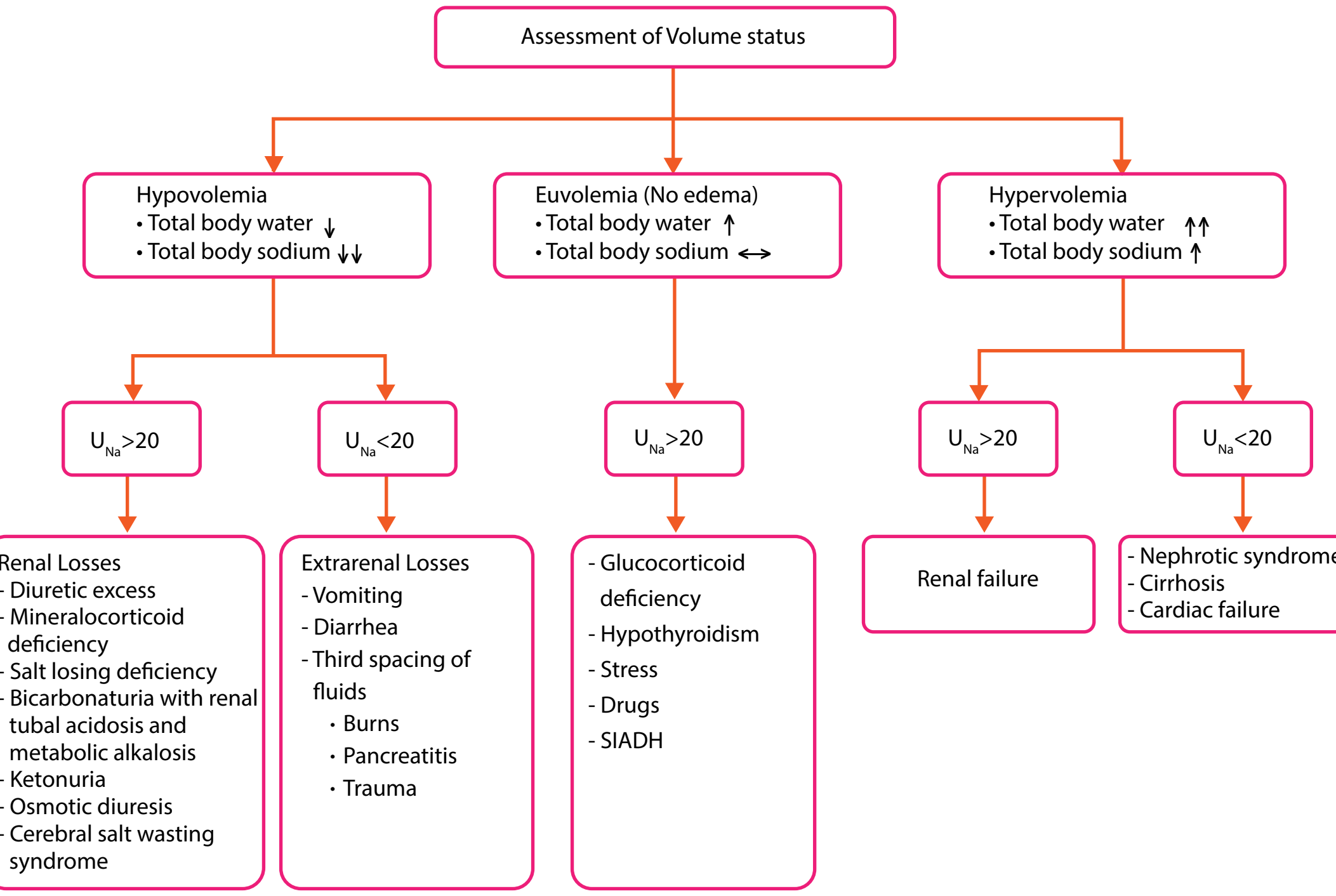
Standard Treatment Workflow (STW)

APPROACH TO HYPONATREMIA

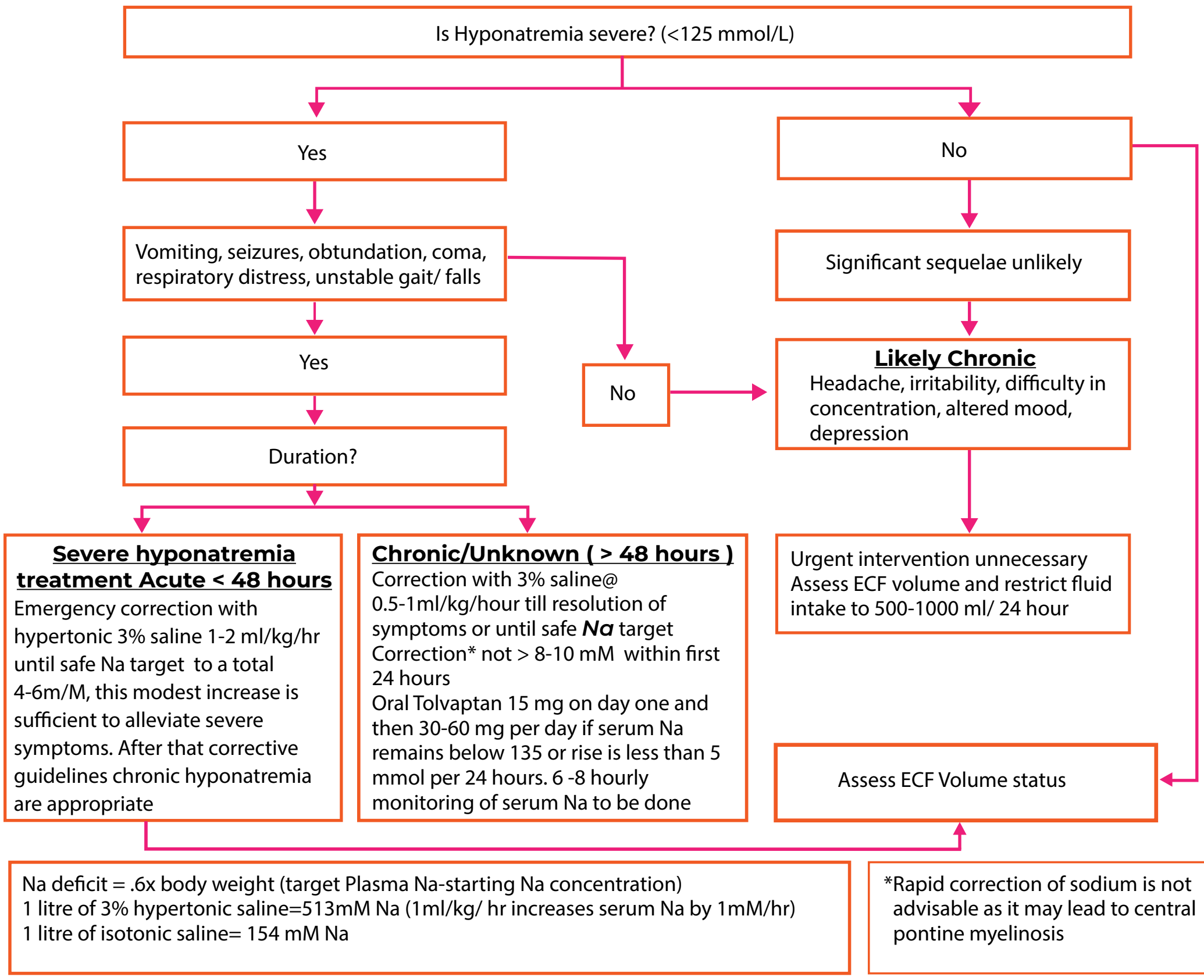
ICD-10-E87.1



TREATMENT

Intravenous hydration with isotonic normal saline in hypovolemic hyponatremia

Treatment of underlying disease in hypervolemic hyponatremia



ABBREVIATIONS

ECF: Extracellular fluid
Na: Sodium
SIADH: Syndrome of inappropriate antidiuretic hormone secretion
U_{Na}: Urinary sodium

KEEP A HIGH THRESHOLD FOR INVASIVE PROCEDURES

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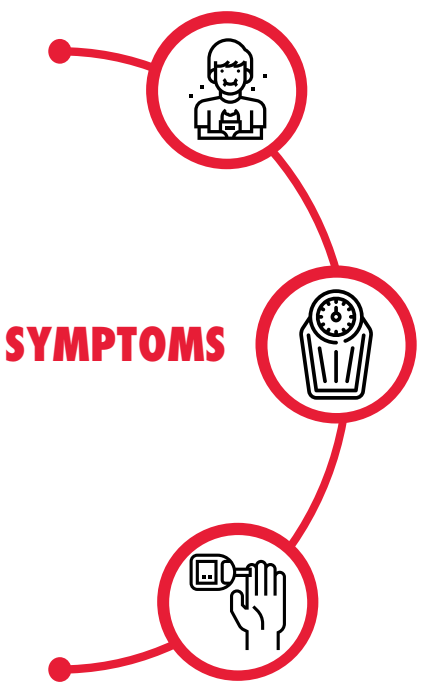
Standard Treatment Workflow (STW)

DIABETES MELLITUS TYPE 1

ICD-10-E10



- Polydipsia
- Polyuria / Nocturia
- Polyphagia
- Weight loss
- Short duration of complaints
- Diabetic ketoacidosis as first presentation

DIAGNOSIS

- Diagnosis of diabetes: Fasting plasma glucose ≥ 126 mg%; post-glucose ≥ 200 mg%; HbA1c ≥ 6.5% (all to be re-confirmed); random glucose ≥ 200 mg% with symptoms
- Characteristic of T1 diabetes; urine/blood ketones: moderate-large (in > 50%)
- Continuous requirement of insulin since diagnosis

INVESTIGATIONS

HbA1c, creatinine, hemoglobin, TSH, tTG (tissue transglutaminase) antibody, lipid profile

AMBULATORY MANAGEMENT

NUTRITION

- Calories should be appropriate to the expected body weight, pubertal status, activity
- Balanced diet including all food groups
- Simple sugars and excessive fats to be avoided
- Meals/snacks to be individualized and reflect insulin schedule (usually 3 meals, 2 snacks)

REGULAR EXERCISE

- Beneficial and should be encouraged

EDUCATION

- Emphasize diabetes related education to patient and caregivers

SMBG

- Check before each meal and at bedtime
- Should be checked more frequently in case A1c is not controlled, frequent hypoglycemia
- Glucose at midnight (12.00-2.00 am) occasionally to rule out nocturnal hypoglycemia
- Ketones should be checked if blood glucose is > 250 mg/dl

TARGET

- Pre-meal 80-130 mg%
- 2 hours post-meal: 120-180 mg%

INSULIN TREATMENT

Insulin administration (0.25 to 1.0U/kg depending on age and pubertal status)

Basal and bolus regimen

- Basal: glargine or detemir or NPH 40-50% of daily requirement
- Bolus: regular or rapid acting 50% of daily requirement/3 injections before each meal

Insulin doses can be adjusted depending upon
1. Pre-meal and post-meal glucose level
2. Carbohydrates in the meal
3. Excercise pattern

REASONS FOR REFERRAL TO HIGHER CENTRES

Uncontrolled hyperglycemia	For education of patient & family For insulin injection techniques/ SBGM/ identifying hypoglycemia s/s	Recurrent hypoglycemia	Severe diabetic ketoacidosis (altered sensorium, rapid breathing)	Chronic diabetes specific complications

MONITORING

AT EVERY VISIT

- Growth & pubertal development (for children and adolescents)
- Dietary and medication compliance
- BP, Weight monitoring
- Insulin site and injection technique
- Review SMBG record
- Hypoglycemia

EVERY THREE MONTHS

- Glycated hemoglobin (HbA1c)
- Target: <7% (should be individualized)

COMPLICATIONS & COMORBIDITIES (5 YEARS AFTER DIAGNOSIS, THEN ANNUALLY)

- Fundus examination (Retinopathy)
- Foot examination (Neuropathy)
- Urine albumin/creatinine ratio
- Other investigations (S-creatinine, TSH), lipid profile

SICK DAY RULES/DKA

IN CASE OF SICKNESS / INFECTION

- Measure glucose frequently, check for urine ketones if glucose >250 mg%
- Drink plenty of fluids, monitor urine output
- Eat small light meals 4-5 times/day
- In addition to usual insulin doses, take extra regular insulin s.c. every 6 hourly (10-15% of total daily insulin dose)
- If glucose not falling, excess vomiting, low urine output, high or rising ketone, admit the patient

DKA MANAGEMENT

- As per STW on Diabetic Ketoacidosis (DKA)

HYPOGLYCAEMIA

- **Symptoms and signs:** Sweating, hunger, tremors, irritability, weakness, drowsiness / seizures / unconsciousness (late stage)
- **Diagnosis:** Mild / moderate: glucose <70 mg% with or without symptoms
- **Severe hypoglycemia:** coma / seizures / inability to treat oneself
- **Treatment:** If glucose <70 mg% take 3 tsf glucose powder or sugar; if severe: caregiver should give inj. glucagon 1 mg s.c./ i.m. OTHERWISE IMMEDIATELY take to hospital for intravenous glucose injection (1-2 ml/kg of 25% dextrose)
- **Prevention:** Identify mismatch of food, exercise, insulin

ABBREVIATIONS

BP: Blood pressure
DKA: Diabetic ketoacidosis
SBMG: Self-monitoring of blood glucose
TSH: Thyroid-stimulating hormone
tTG: Tissue transglutaminase

REFERENCES

1. American Diabetes Association; Standards of Medical Care in Diabetes—2022 Abridged for Primary Care Providers. Clin Diabetes 1 January 2022; 40 (1): 10–38. https://doi.org/10.2337/cd22-as01

KEEP A HIGH THRESHOLD FOR INVASIVE PROCEDURES

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Standard Treatment Workflow (STW)

DIABETES MELLITUS TYPE 2

ICD-10-E11

SYMPTOMS

May be asymptomatic

- Osmotic symptoms ie., polyuria, polydipsia and polyphagia
- Recurrent infections
- Blurring of vision
- Weight loss
- Non healing wounds
- Paraesthesia

DIAGNOSIS

FPG ≥126 mg/dl (after 8hr fasting)	OR	2-h plasma glucose ≥200 mg/dl during OGTT	OR	HbA1C ≥ 6.5%	OR	Diabetes symptoms + random plasma glucose ≥ 200 mg/dl

PREDIABETES:

Impaired fasting glucose: FPG 100-125 mg/dL; Impaired glucose tolerance: 140-199 mg/dL; HbA1c 5.7-6.4%

ASSESS

CO-MORBIDITIES: Hypertension, Dyslipidaemia, CAD, CKD

EXAMINATION: BMI, waist circumference; BP; Peripheral pulses; Pin-prick sensation, monofilament test ,vibration, DTR; Skin, oral cavity, foot; Fundus (dilated) examination

INVESTIGATION

- HbA1c
- Creatinine
- K^+
- Fasting lipid profile
- Urine routine examination and spot albumin: creatinine ratio#
- LFT/ ALT, AST
- ECG
- Others like Echo, USG abdomen as indicated

#These may best be carried out after initial glycaemic control

TREATMENT

- Dietary modification
- Avoidance of tobacco and restriction/ avoidance of alcohol
- Physical activity
- Pharmacotherapy:
  - HbA1c < 8.5%: Monotherapy- Metformin
  - HbA1c 8.5-10%: Dual therapy- Metformin + SU's/TZD/ DPPIVi/SGLT2i /AGI/GLP-1RA
  - HbA1c > 10%: Basal Insulin+ Metformin + another OAD / triple OAD combination

METABOLIC TARGETS

- HbA1c </= 7 .0% (except elderly and those with significant comorbid conditions) where higher target may be acceptable
- Pre-prandial capillary plasma glucose: 80-130 mg/dl
- Post-prandial capillary plasma glucose: <180 mg/dl
- BP=140/90 (130/80 in CKD) LDL: < 100 mg/dl (< 70mg/dl in CAD)

MONITORING

- Blood glucose; FPG and 2 hours PPG once monthly more frequent as required including SMBG or CGM
- HbA1c every 6-12 months (3 monthly if uncontrolled)
- Annual monitoring : ECG, urine ACR (albumin creatinine ratio),dilated fundoscopy,foot examination

REFERRALS

- Endocrinology: for uncontrolled hyperglycemia
- Ophthalmology: at initial evaluation and every year
- Nephrology: for deranged renal function
- Cardiology: for CAD/HF/arrhythmia

SCREENING FOR DIABETES MELLITUS

IN AN APPARENTLY NORMAL ADULT

- In obese or overweight (BMI ≥ 27.5 or ≥ 23 kg/m^2) with any of the following risk factors
- First degree relative with diabetes
- History of cardiovascular disease
- BP (≥ 140/90 mmHg)
- Dyslipidemia (TG > 250 mg/dL, HDL <40 mg/dl in male, <50 mg/dl in female
- Physical inactivity
- Polycystic ovary syndrome (PCOS)
- Insulin resistance (acanthosis nigricans)
- Adults > 30 years of age
- Previous history of GDM

IN AN ADULT WITH ILLNESS

- In any adult/adolescent who presents with one of the following illness/complaints
- Osmotic symptoms (polyuria, polydipsia, polyphagia, nocturia)
- Unexplained weight loss
- Unexplained depression or dementia
- Acute coronary syndrome
- Deep seated infections (liver abscess, lower lobe pneumonia, tuberculosis, pyelonephritis, abscesses, septic arthritis, osteomyelitis)
- Recurrent infections (tinea, oral thrush, onychomycosis, cystitis-urinary tract infection, sinusitis, STI, cellulitis, carbuncle)
- Non-healing ulcers (foot ulcers-infected/neuropathic)
- Exogenous/iatrogenic Cushing's syndrome

IN PREGNANCY

- H/O GDM/Pre-existing diabetes
- All pregnant women to be screened in 1st trimester with FPG
- FPG ≥ 126 and/or HbA1c ≥ 6.5% to be considered pre-existing diabetes
- FPG between 92-125 to be considered as GDM
- All those women with normal screening in 1st trimester to get a 75 g-oral glucose tolerance test done at 24-28 weeks
- All GDM women to be tested 6 weeks post-partum and once every 3 years
- PREDIABETES: should be tested yearly

ABBREVIATIONS

ALT: Alanine transaminase
AST: Aspartate aminotransferase
BMI: Body mass index
BP: Blood pressure
CAD: Coronary artery disease
CGM: Continuous glucose monitor
CKD: Chronic kidney disease
DTR: Deep tendon reflex
ECG: Electrocardiogram
FPG: Fasting plasma glucose
GDM: Gestational diabetes mellitus
HDL: High-density lipoprotein
LDL: Low-density lipoprotein
LFT: Liver function test
OAD: Oral antidiabetic drug
OGTT: Oral glucose tolerance test
SMBG: Self-monitoring of blood glucose
TG: Triglyceride

KEEP LOW THRESHOLD FOR DIAGNOSIS. MAKE SURE TO FOLLOW UP TO MEET TARGETS

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Standard Treatment Workflow (STW)

DIABETIC KETOACIDOSIS

ICD-10-E11.10

May be the initial presentation in T1DM

Pain abdomen

Recurrent vomiting

Rapid/labored breathing

Altered sensorium

ASSESS

- Sensorium (GCS), pulse rate, blood pressure, respiratory rate, temperature
- Signs of dehydration (dry tongue, sunken eyes, skin turgor, urine output)

ASSESS SEVERITY OF DKA

	Mild	Moderate	Severe
pH	7.25-7.3	7.0-7.25	<7.0
HCO_3	15-18	10-15	<10
Level of Sensorium	Alert	Mild Drowsiness	Stupor/ Coma
Sever case: ICU Admission			

LOOK & ADDRESS FOR PRECIPITATING FACTORS

- Skipping/missing insulin doses
- Fever/cough/loose stools/burning micturition

INVESTIGATIONS

- Spot capillary blood glucose (venous blood preferable in case of shock)
- Serum ketone/urine ketone by dipstick)
- VBG (for pH, bicarbonate, anion gap)
- Na^+/K^+/BUN/Creatinine/ECG

MANAGEMENT

MONITORING

- Strict input/ output charting: every 1 hour
  - Report if urine output is <30ml/hour for 2 consecutive hours
  - One hour after starting the treatment: Till resolution of DKA
  - BP and vital signs: every 1 hour
  - Blood glucose every 1 hour
  - Venous pH, Na, K, HCO_3 : 2-4 hourly
  - Blood ketones (if available)/Urine for ketones: 12 hourly
- After resolution of DKA: Blood glucose monitoring every 4 hours

TREATMENT

- Replace fluids – 1 l of 0.9% saline over first hour followed by 250-500 ml/hour (10-20ml/kg/hour initially for children)
- Administer regular insulin – 0.1 IU/kg IV then 0.1 IU/kg/hour IV infusion
- Double infusion rate if less than 10% fall in blood glucose after 1 hour
- When blood glucose < 250 mg/dl, add 5% dextrose @ 50 ml/hour
- Supplement potassium before insulin if serum K^+ < 3.3 mEq/L (or ECG changes)
- Replace potassium @ 10-20 mEq/hour with insulin infusion if serum K+ < 5.5 mEq/L
- If pH < 7.0, add sodium bicarbonate; 50 mmol in 200 ml sterile water over 2 hour
- Bicarbonate should be given only: if pH is less than 6.9 or if pH is less than 7.1 along with hypotension or if hyperkalemia is present

WHEN TO STOP INSULIN INFUSION?

- Patient accepting orally, blood glucose consistently < 250 mg/dl, normalization of anion gap and correction of metabolic acidosis
- Administer SC dose of long/intermediate-acting & short acting insulin at least 30 mins before stopping insulin infusion. Shift to basal-bolus/pre-mixed insulin regimen

COMMON ERRORS/PITFALLS IN DKA DIAGNOSIS AND MANAGEMENT

- Initiating Insulin therapy before I/V fluid therapy
- Failure to review fluid replacement therapy particularly in elderly patients
- Failure to identify underlying cause
- Search for another cause of obtundation: If the osmolality is <than 320 mOsm/kg H_2O
- Potassium: may be normal despite depletion of body stores due to metabolic acidosis
- Elevated total leucocyte count does not suggest presence of infection until more than >15 X 109/l
- Monitor for cerebral edema especially in childern
- Body temperature cannot be used as a guide to presence of infection
- Hyperamylasemia: Cannot be used as a marker for diagnosis of pancreatitis
- Hypertriglycredemia: can cause pseudohyponatremia and when marked precipitates pancreatitis
- Ketosis may worsen paradoxically with successful treatment initially
- Stopping I/V insulin before S/C insulin given

ABBREVIATIONS

BUN: Blood urea nitrogen
DKA: Diabetic ketoacidosis
ECG: Electrocardiogram
GCS: Glasgow coma scale
I/V: Intravenous
ICU: Intensive care unit
SC: Subcutaneous
VBG: Venous blood gas

KEEP A LOW THRESHOLD FOR TIMELY DIAGNOSIS AND MANAGEMENT OF DKA

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Standard Treatment Workflow (STW)

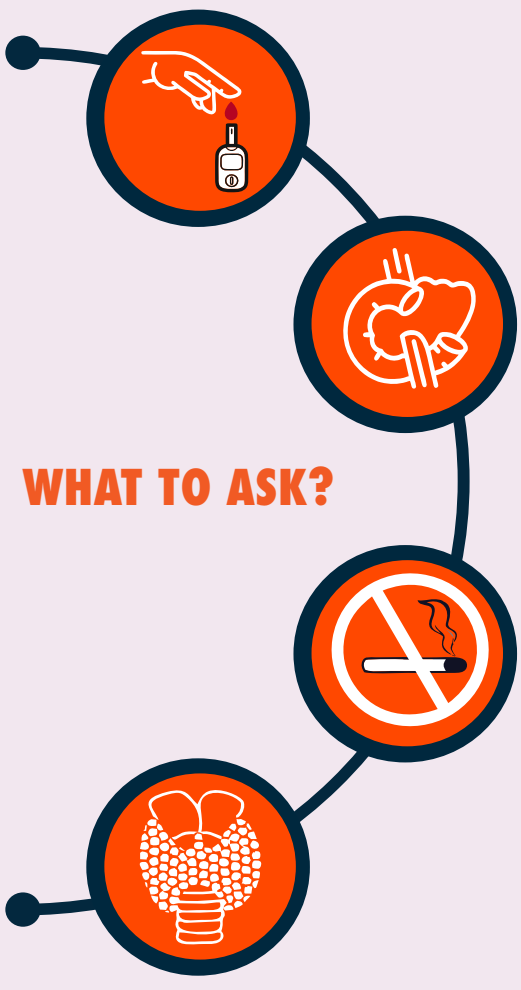
FRAGILITY FRACTURES

ICD-10-Z87.310

WHAT ARE FRAGILITY FRACTURES

- To be suspected in fractures resulting from trivial trauma or fall from a standing height or less
- For example fracture neck of femur, forearm fracture (Colle's), vertebral fracture

WHAT TO ASK?



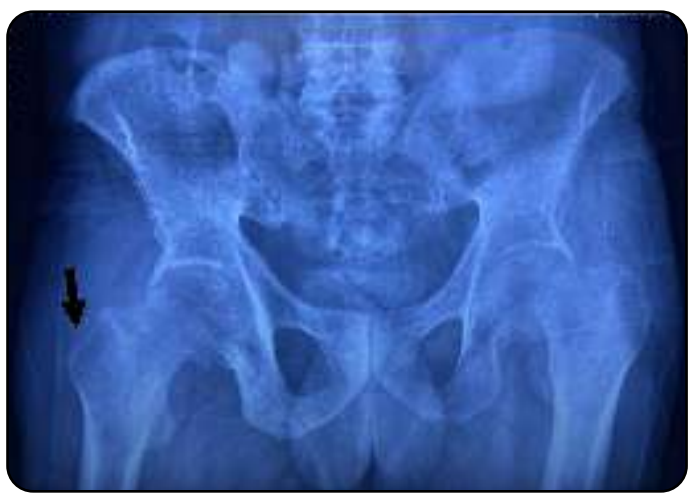
Postmenopausal females	Family history of fracture	Previous history of fracture
Renal stone disease	Pancreatitis	Steroid abuse or alternative medications or clinical stigma of cushing's
Premature ovarian failure (less than 40 years)	Diabetes	Chronic diarrhoea or bloating sensation
Use of antiepileptics like phenytoin etc Cushings with hypogonadism	Chronic systemic illnesses like rheumatoid arthritis	Smoking, chronic systemic diseases, CKD, CLD, Endocrine disorders, Thyroid disorders, Hypogonadism

INVESTIGATIONS

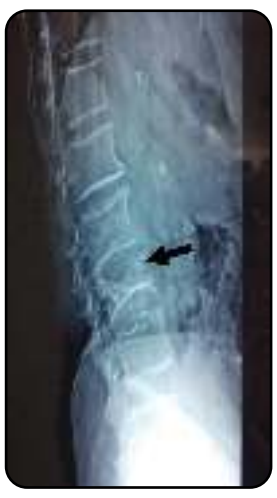
Biochemical:
Fasting serum calcium, phosphate, alkaline phosphate and albumin (if available) hemogram
myeloma-proteins in serum or urine
Fasting blood glucose PTH (parathyroid)
25 hydroxy Vitamin D, IgA tTg
Renal function tests, bone markers beta cross LAP

Bone imaging:
DXA scan osteoporosis T score-osteoporosis ≥ -2.5 severe osteoporosis= fracture or T score ≥ -3.0
X-ray of fracture site Use Z score for age less than 50 for men and premenopausal women
X-ray lumbar spine (Lateral), pelvis (AP), skull (lateral), both hands

Ultrasound abdomen, gall stones, renal stones and nephrocalcinosis, Ultrasound neck, enlarged parathyroid
Sestamibi scan for parathyroid enlargement



Fracture neck of the femur



L4 Osteoporotic fracture

Sestamibi Scan for parathyroid adenoma

HOW TO TREAT?

Resuscitate the patient if needed
Stabilize the fracture

WHEN AND WHERE TO REFER?

Refer to orthopaedician for fracture management surgical management

Refer to endocrinologist for evaluation and treatment of osteoporosis

TREATMENT

- Daily oral calcium 1-1.5 gm/day
- Vitamin D supplementation to maintain serum 25OHD levels of 30.0-50 ng/ml
- Stop smoking alcohol
- Inj Zoledronic acid 5mg I/V infusion OR
- Inj Denosumab 60mg S/C every 6 months OR
- Inj rPTH 20 µg S/C daily for maximum 2 years

ABBREVIATIONS

CKD: Chronic kidney disease
CLD: Chronic liver disease
rPTH: recombinant Parathyroid hormone

KEEP A HIGH THRESHOLD FOR INVASIVE PROCEDURES

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Standard Treatment Workflow (STW)

HYPOTHYROIDISM

ICD-10-E03.9

WHEN TO SUSPECT HYPOTHYROIDISM ON CLINICAL GROUNDS?

Primary hypothyroidism	Congenital hypothyroidism	Central (Secondary) hypothyroidism
Symptoms Fatigue / Weight gain with poor appetite / Dry skin and cold intolerance / Hair loss / Constipation / Hoarseness of voice / Dyspnea / Muscle weakness and cramps / Menorrhagia (later oligomenorrhea or amenorrhea) / Infertility / Difficulty concentration and poor memory / Paraesthesia / Impaired hearing **Signs** Dry coarse skin / Cool peripheral extremities / Puffy face, hands and feet (myxoedema) / Diffuse alopecia / Goitre / Bradycardia / Peripheral Oedema / Delayed tendon reflex relaxation / Carpel tunnel syndrome / Serous cavity effusions	New born screening (usually asymptomatic)Prolonged icterus / Edema of the eyelids, hands, and feet / Hypotonia / Inactivity / Gestation > 42 wk / Birth weight > 4 kg / Poor feeding / Hypothermia / Abdominal distention / Open posterior fontanelle (> 5 mm)	Mild-moderate symptoms of hypothyroidism / Signs and symptoms of other pituitary deficits / Manifestations of concomitant hypothalamic pituitary disease Clinical manifestation are less pronounced in secondary hypothyroidism as compared to primary hypothyroidism as there may be multiple pituitary hormone deficiencies which can mask the features of hypothyroidism

Billewicz scoring for diagnosis of Hypothyroidism

Symptoms	Score if present	Physical signs	Score if present
Hearing impairment	1	Slow movement	1
Diminished sweating	1	Periorbital puffiness	1
Constipation	1	Delayed ankle reflex	1
Paraesthesia	1	Coarse skin	1
Haorseness	1	Cold skin	1
Weight increase	1	Add 1 point for women younger than 55 years Total score:12	
Dry skin	1		

Hypothyroid ≥6 points **Intermediate 3-5 points** **Euthyroid ≤2 points**

HOW DOES ONE CONFIRM CLINICAL SUSPICION OF HYPOTHYROIDISM?

Primary hypothyroidism	Congenital hypothyroidism	Central (Secondary) hypothyroidism
Tests to be ordered TSH FT4 or Total T4 TPO antibodies (if available) **Interpretation** Overt hypothyroidism - TSH elevated with low FT4 or T4 levels Subclinical hypothyroidism - TSH elevated with normal FT4 or T4 levels	**Tests to be ordered after 72 hours** TSH FT4 or T4 USG neck, nuclear imaging (Not a must, Do not delay treatment) **Interpretation** Screening - TSH > 30 mU/ L; T4 < 10th centile Confirmatory - TSH > 9 mU/L; FT4 < 0.6 ng/ml	**Tests to be ordered** FT4 or T4 TSH Other pituitary profile Imaging of sella **Interpretation** TSH levels normal or low with low FT4 or T4 levels

INITIATING THERAPY

Primary hypothyroidism	Congenital hypothyroidism	Central (Secondary) hypothyroidism
Levothyroxine 1.6 to 1.8 mcg per kg per day Single dose, fasting status, no calorie intake for 1 hour thereafter Titrate based on TSH levels Elderly and CAD patients: Start with 12.5–25 mcg/d with 12.5 - 25mcg/d incremental dose every 3–4 wk Consider treating subclinical hypothyroidism in presence of - Large goitre / Positive TPO antibody / ASCVD / Heart failure / Dyslipidemia / Infertility / Depression / refractory anaemia / personal or family history of autoimmune disease	Levothyroxine therapy 10 to 15 mcg per kg per day Single daily dosing Given with breast milk in powdered form Titrate based on FT4 levels and TSH initially, later based on TSH levels	Levothyroxine 1.3 mcg per kg per day Treatment to be initiated only after treating co existing adrenal insufficiency with Hydrocortisone replacement as there is risk of precipitating adrenal crisis, Titrate based on FT4 or T4 levels

HOW SHOULD THE PATIENT BE FOLLOWED UP?

Primary hypothyroidism	Congenital hypothyroidism	Central (Secondary) hypothyroidism
Titrate based on TSH levels • Target TSH ‣ Young patient's 1–2.5 mU/L ‣ Middle-aged patients 1.5–3 ‣ Elderly patients ◦ < 60 y: > 4.5 mU/L ◦ 60–70 y: > 6.0 mU/L ◦ 70–80 y: > 7.0 to 8.0 mU/L • Once in 3 to 6 months initially, once stable dose is achieved, annual follow up	**Titrate based on FT4 or T4 levels and TSH** • Titrate based on FT4 or T4 levels and TSH • Target T4: 10 to 16 mcg/dl • Target FT4: 1.4 to 2.3 ng/dl • Target TSH: 0.5 to 2 mU/L • Initial follow up at 2 and 4 weeks • Every 1 to 2 months in first 6 months • Every 3 to 4 months from 6 months to 3 years of age • Every 6 to 12 months till growth is complete	**Titrate based on FT4 or T4 levels** • Target T4 or FT4 Young people - upper half of normal range • Elderly - mid normal range • Once in 3 to 6 months initially, once stable dose is achieved, annual follow up

ABBREVIATIONS

ASCVD: Atherosclerotic cardiovascular disease
CAD: Coronary Artery Disease
TPO: Thyroid peroxidase
TSH: Thyroid-stimulating hormone
USG: Ultrasound sonography

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KEEP A HIGH THRESHOLD FOR INVASIVE PROCEDURES

This STW has been prepared by national experts of India with feasibility considerations for various levels of healthcare system in the country. These broad guidelines are advisory, and are based on expert opinions and available scientific evidence. There may be variations in the management of an individual patient based on his/her specific condition, as decided by the treating physician. There will be no indemnity for direct or indirect consequences. Kindly visit the website of DHR for more information: (**stw.icmr.org.in**) for more information.

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