1. Hypertension

Approximately 30% of JMSMCO's patient population is hypertensive. It is not uncommon in the JMSMCO MCO population to see patients with end-organ disease in multiple body systems. The most common organs of damage are eyes, heart, kidneys and brain. The effects of uncontrolled hypertension are devastating and irreversible, but preventable with healthy living and early detection and treatment. JMSMCO's primary care providers utilize the protocol below in order to aid in the prevention, early detection and proper management of hypertension and its known sequelae.

Based on recommendations of the JNC 7, the classification of BP (expressed in mm Hg) for adults aged 18 years or older is as follows:

Classification	**Systolic**	**Diastolic**	**Follow-up**
Normal	**<120**	**<80**	**2 years**
Pre-hypertension	**120-139**	**80-89**	**1 year**
Hypertension			
Stage 1	**140-159**	**90-99**	**2 months**
Stage 2	**≥160**	**≥100**	**Assess and treat immediately**

The classification above is based on the average of 2 or more readings taken at each of 2 or more visits after initial screening. javascript:showrefcontent('refrenceslayer');Normal BP with respect to cardiovascular risk is less than 120/80 mm Hg. However, unusually low readings should be evaluated for clinical significance.

The natural history of essential hypertension evolves from occasional to established hypertension. After a long invariable asymptomatic period, persistent hypertension develops into complicated hypertension, in which end-organ damage to the aorta and small arteries, heart, kidneys, retina, and central nervous system is evident.

The progression of essential hypertension is as follows:

1. Prehypertension in persons aged 10-30 years (by increased cardiac output)
2. Early hypertension in persons aged 20-40 years (in which increased peripheral resistance is prominent)
3. Established hypertension in persons aged 30-50 years
4. Complicated hypertension in persons aged 40-60 years

Cochrane Authors' Conclusions: First-line low-dose thiazides reduce all morbidity and mortality outcomes. ACE inhibitors and calcium channel blockers may be similarly

effective, but the evidence is less robust. First-line high-dose thiazides and beta blockers are inferior to first-line low-dose thiazides.

In comparing the effects of thiazide diuretics, beta blockers, angiotensin-converting enzyme (ACE) inhibitors, and calcium channel blockers (CCBs) with placebo, thiazide diuretics lowered mortality and morbidity from stroke, heart attack, and heart failure more than beta blockers. ACE inhibitors and CCBs reduced mortality and morbidity as much as thiazide diuretics, but the evidence is less robust. Thiazide diuretics are a more favorable first-line choice in patients who do not have contraindications for their use.

The JNC 7 calls for routine blood pressure measurement at least once every 2 years for adults with a systolic blood pressure below 120 mm Hg and a diastolic blood pressure below 80 mm Hg, and every year for systolic blood pressure 120-139 and diastolic blood pressure 80-89 mm Hg.

I. Evaluation

A. Objectives:
1. Identify known causes of hypertension
2. Assess target organ damage and cardiovascular disease
3. Assess response to therapy
4. Identify cardiovascular risk factors and other diseases which may guide treatment

B. Methods:
Clinical history should contain, at minimum, the following data:
1. Known duration and previous B.P. readings
2. Presence or absence of cardiac, neurologic, renal, and peripheral vascular disease, diabetes, gout, dyslipidemia by previous knowledge or by presence of specific symptoms
3. Recent changes in weight, physical activity, sexual function, tobacco use, diet (including salt intake), alcohol consumption, fat intake, and caffeine
4. List all prescribed and OTC medication, adverse effects, including illicit and herbal therapy
5. Family history of hypertension, diabetes, CVA, CHD, and renal disease
6. Social history should include education level, marital status, and employment status.

C. Complete Physical Examination:
1. Initial lab data:
CBC, U/A, chemistry profile, lipid profile, 12 lead E.K.G., TSH, funduscopic exam, CXR
2. Work up for secondary hypertension if:
   a. History, physical, and initial lab data indicates
   b. B.P. responds poorly to drug treatment
   c. Previously well controlled pressure becomes uncontrolled
   d. Sudden onset of symptomatic or labile hypertension

3. Cause of secondary hypertension
    a. Pheochromocytoma
    b. Cushings Syndrome
    c. Primary Aldosterionism
    d. Hyperparathyroidism
    e. Renal Syndrome
    f. Sleep Apnea
    g. Substance Abuse
    h. Thyroid Disease
    i. Medications – OCPs, steroids, licorice, NSAIDS (COX-2), Epo, cyclosporine
    j. Coarctation of aorta
    k. Polycythemia vera (↑Hct)

D. Risk Evaluation:
    1. Major risk factors for development of clinical cardiovascular disease (CCD) and target organ damage (TOD)
        a. Smoking
        b. Dyslipidemia
        c. Diabetes
        d. Age over 60
        e. Menopause
        f. Family history of cardiovascular disease
        g. Obesity, BMI >30
    2. Target organ damage
    3. Heart--left ventricular hypertrophy, CAD, heart failure
    4. Neurovascular- TIA, CVA
    5. Renal--nephropathy
    6. Peripheral vascular disease
    7. Retinopathy

All patients with diabetes and one or more of TOD or CCD should receive drug therapy.

II. Drug Treatment of Hypertension

A. Treatment can be divided into:
    1. Initiation
    2. Individualism
    3. Modification
    4. Step down therapy
    Please note that previously used step-up therapy is not used anymore

B. Initiation: Treatment goal is BP <140/90 mmHg (BP<130/80 mmHg in patients with diabetes or chronic kidney disease. Most patients will need two medications to reach goal.
    1. Lifestyle Modifications (each ↓SBP ~5mmHg)
        a. Weight loss: BMI 18-24.9
        b. Exercise: ≥30min/d for ≥5d/wk
        c. Diet: ↑fruits & vegetables; ↓sat. and total fat (DASH Diet)

d. Na restriction ≤2.6g/d or lower

If patient does not reach BP goal then:

2. Initial Drug Choices
   a. Without Compelling Indications
      Stage 1 Hypertension (Systolic BP 140-159 mmHg or diastolic BP 90-99 mmHg)
      Thiazide-type diuretics for most. May consider ACEI, ARB, BB, CCB, or combination
      Stage 2 Hypertension (Systolic BP ≥160 mmHg or diastolic MP ≥100 mmHg)
      2-drug combination for most (usually thiazide-type diuretic and ACEI, ARB, BB, or CCB).
   b. With Compelling Indications
      Medications for the compelling indications (see Section 6) and other antihypertensive drugs (diuretics, ACEI, ARB, BB, CCB) as needed.
3. If Not at Goal Blood Pressure
   Optimize dosages or add additional drugs until goal BP is achieved. Consider consultation with hypertension specialist.

C. Individualism (cost factors, dosing frequency): Plasma renin profile may be helpful.
   Renin low to medium – HCTZ best
   Renin medium to high – capropril best (dlt and clonidine efficiency was independent of renin level)

III. Modification

A. When another disease process compels use of a specific agent

1. Type 1 diabetes with proteinuria	Ace inhibitor
2. Heart failure	Ace inhibitor + diuretic
3. Myocardial infraction	Beta blocker + ace inhibitor

IV. Favorable Effect on Comorbid Condition

A. Angina	Beta blocker, CCB
B. Atrial tachycardia and fibrillation	Beta blocker, non DHP CCB
C. Cyclosporine infused hypertension	CCB
D. Diabetes both 1 & 2 with proteinuria	ACEI, CCB
E. Type 2 DM	Low dose diuretic
F. Dyslipidemia	Alpha blocker
G. Essential tremor	Beta blocker
H. CHF	ACEI/ARB, Beta blocker, Aldo antagonist
I. Migraine	Beta blocker, CCB (non DHA)
J. Osteoporosis	Thiazide
K. Pre-operative hypertension	Beta blocker
L. Prostatism	Alpha blocker
M. Post- MI	Beta Blocker, ACEI
N. Chronic Kidney Disease	ACEI/ARB, Diuretics

V. Unfavorable Effects

A. Asthma	Beta blocker
B. Depression	Beta blocker, central alpha agonist reserpine
C. Diabetes	Beta blocker, high dose diuretic
D. Gout	Diuretic
E. Pregnancy	Ace, ARB

VI. Patient Education

A. Disease process and ways patients can manage their own care; Low sodium diet, weight reduction, decrease stress etc.
   1. Importance of follow-up visits; and
   2. Need for compliance with regimen to prevent unnecessary sequelae.

B. Specific dietary interventions:
   1. Soy protein may reduce both systolic and diastolic blood pressure
   2. Avoid black licorice
   3. K+ Supplementation (especially effective in African Americans)

VII. Follow-up:

A. Provider visit every three to six months or earlier if indicated.

B. Lab Work
   1. Urine test every 12 months;
   2. EKG every 12 months;
   3. Chest X-Ray for those patients over the age of 40 with lung cancer risk factors, i.e.: cigarette smoking, positive family history; and
   4. If HTN patient is taking diuretic medication, electrolytes are tested every 3-6 months or earlier as determined by the primary care provider. Potassium supplemented as necessary.

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Karmachandra Nair, M.D., Internal Medicine
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2. Low Back Pain

Low back pain (LBP) afflicts up to 80% of American adults during their lives. Low back pain is one of the most common complaints among JMSMCO's patients, accounting for 17.3% of the most frequent diagnoses listed in the CQI report. Back pain is the most frequent cause of activity limitation in people younger than 45 yrs, the second most common reason for patient visits, the fifth ranking reason for hospitalizations, and the third most common reason for surgical procedures. The causes of low back pain are developmental, infection, inflammatory, traumatic, metabolic, neoplastic and degenerative.

The process utilized by JMSMCO's primary care providers is as follows. A complaint of LBP is elicited during the history and risk factors are ascertained. After the appropriate musculoskeletal and neurologic examinations, medical treatment, including physical therapy if necessary, is initiated. In addition, the practitioner works with the patient to modify the home and work environment. The following is a more detailed protocol outlining this process:

1. At the initial visit, a complete history and physical exam are performed, including a neurological examination.

2. Appropriate diagnostic testing is obtained (the treating provider must evaluate the necessity of diagnostic exams , such as x-ray, before ordering)
    a. CBC, blood chemistry profile, ESR, urinalysis
    b. X-rays, such as lumbar spine, lumbosacral spine
    c. MRI
    d. CT scan if MRI is contraindicated (patients with implanted pacemaker or vascular metal chips, etc.)
    e. Myelography
    f. Bone scan
    g. Electrodiagnostic studies (EMG/NCU)

3. Specific diagnosis is established.

4. Treatment plan is formulated based on history, physical exam and diagnostic testing results. Typical treatment plans include treatments such as:

    a. Medications
        i. NSAIDS, like Ibuprofen, Naproxen
        ii. Muscle relaxants like Flexeril
        iii. Narcotic analgesic like codeine derivations (Percocet, Tylox, etc.) for short term use only

    b. Physical Therapy
        i. Hydroculator packs
        ii. Ultrasound

iii. Electrical stimulation (TENS)
iv. Massage
v. Therapeutic exercise
vi. Yoga
vii. Spinal manipulation B chiropractic care

c. Referral to appropriate sources, as needed, such as a Neurosurgeon or an Orthopedist.

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3. Depression/Anxiety

Approximately 25% of JMSMCO's patient population has some form of mental illness. Of this number, in a State-performed CQI report, 13.5% of these patients have some form of depression and 6% suffer from anxiety. Combined these numbers indicate that 19.5% of the medically-under served population of Maryland suffers from depression or anxiety. In response to this, the following protocol has been developed to treat depression and anxiety.

I. At the initial visit, a complete history and physical exam are performed, including laboratory evaluation and mental health screening.
   A. PHQ-2
   B. PHQ-9

II. A specific diagnosis of Depression is established using the following symptoms, in the absence of substance abuse, manic diagnosis, and/or recent death of a loved one and it must include at least 5 of the following symptoms during the same 2 week period and represent a change in previous functioning:
   A. Depressed Mood
   B. Markedly diminished interest or pleasure in activities most of the time
   C. Significant change in appetite or weight–5% change without dieting, or change in appetite.
   D. Alterations in sleep pattern (insomnia or hypersomnia)
   E. Psychomotor agitation or retardation
   F. Fatigue or loss of energy
   G. Feelings of worthlessness, excessive or inappropriate guilt
   H. Lack of concentration/ Indecisiveness
   I. Thoughts of death, dying or suicide

III. Differential includes: general medical conditions, mood incongruent delusions or hallucinations

IV. Symptoms should not be due to drug abuse, medication side effects, or general medical conditions

V. Initial Evaluations should aim to screen for other concurrent diseases and establish baseline testing
   A. Medical History
   B. Laboratory Data
      1. CBC
      2. Hemoglobin/Hematocrit
      3. Renal/Liver/Thyroid Function
      4. Electrolytes and Blood Sugar
      5. If medically indicated screen for cancer and/or infectious etiologies

VI. A treatment plan is decided upon with the patient, and initiated. Typical treatment plans include components such as:
   A. Counseling by the primary care provider

B. Consultation by psychologist or psychiatrist and/or with notification sent to ValueOptions.
C. Trial of anti-depressant medication, initiated by primary care provider
    1. Tricyclic agents (TCAs)
    2. Selective Serotonin Re-uptake Inhibitors (SSRIs)
    3. Others
D. Continual follow-up by both primary care provider and/or psychiatrists or psychologists
E. Monitor appropriate blood levels of therapeutic agents.

VII. Follow Up
A. Within the month after starting medical therapy
B. Every 4-8 weeks there after
C. Monitor appropriate blood levels of therapeutic agents

VII. Generalized Anxiety Disorder
A. Diagnosis
    1. Excessive or difficult to control worry about a number of events or activities
    2. Difficulty controlling worry
    3. Worry is associated with 3 physical symptoms that are present most of the time:
        - Restlessness or feeling on the edge
        - Easily fatigued
        - Irritability
        - Muscle tension
        - Sleep decrease
        - Decreased concentration or mind going blank
B. Symptoms cause significant distress or impairment in social occupational or other areas of functioning
C. Rule out substance abuse, medication side effect or general medical conditions
D. Treatment and Follow Up
    1. Major approaches include: cognitive –behavioral, supportive, insight oriented and pharmacotherapy
    2. Pharmacotherapy should rarely be initiated on the first visit
    May include Benzodiazepines, Buspirone, Venlafaxine, SSRI's

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4. High Risk for HIV Infection Protocol

I. The Centers for Disease Control (CDC) recommend screening for everyone 13 to 64 years of age (USPSTF recommends screening ages 15-65, Grade A).
   A. Obtain informed consent for:
      1. ELISA for HIV-1 Ab
      2. Western Blot – Confirmatory test for positive ELISA
      3. RNA PCR – useful if acute infection suspected
   B. Rapid preliminary tests: 4Ab tests uses saliva, plasma, blood (requires confirmation)
   C. If testing negative after potential exposure, retest 3 months after exposure

II. At the initial patient visit, a complete history and physical examination are performed.
   A. Review all meds
   B. Evidence of opportunistic infections, malignancies, STDs

III. Patient education is focused on safer sex practices, proper condom use, proper needle cleaning and disposal technique, information about available needle exchange programs, and substance abuse treatment, as needed.

IV. PEP (Post-Exposure Prophylaxis)
   A. If significant exposure, Initiate ≥3 drug regimen ASAP, for 4 weeks
   B. Preferred regimens by exposure type (see guidelines for alternative regimens):
      1. Occupational: raltegravir 400mg BID + tenofovir/emtricitobine QD
      2. Nonoccupational:
         - NRTI based -> efavirenz + (lamivudine or emtricitabine) + (zidovudine or Tenofovir)
         - PI based -> lopinavir/ritonavir (co-formulated as Kaletra) plus (lamivudine or emtricitabine) plus zidovudine
   C. Consider expert consultation, but do not delay treatment
   D. Recommended follow-up:
      1. HIV testing at baseline and at 6 weeks, 12 weeks, and 6 months after exposure; alternatively, if the clinician is certain that a fourth-generation combination HIV p24 antigen–HIV antibody test is being utilized, then HIV testing could be performed at baseline, 6 weeks after exposure, and 4 months after exposure.
      2. Complete blood counts and renal and hepatic function tests (at baseline and 2 weeks after exposure; further testing may be indicated if abnormalities are detected).
      3. Additional testing recommended for non-occupational exposures, where there is concern for other transmissible diseases (see referenced guideline #7).

   E. National Clinicians' Post-Exposure Prophylaxis Hotline at telephone number 888-448-4911 and website http://www.nccc.ucsf.edu/about_nccc/pepline/

V. PrEP (Pre-Exposure Prophylaxis)
   A. Only in those with very high risk of contracting HIV through sex or injection drug use.

B. Tenofovir plus emtricitabine (TDF/FTC or Truvada) is FDA approved for use as PrEP among sexually active adults at risk for HIV infection.
C. Eligibility criteria: Negative test for HIV, CrCl must be >60, persistent/ongoing risk
D. Monitoring:
    1. Q2-3 months with HIV testing, reassessing risk, counseling risk reduction
    2. Screen for STD's Q6mon
    3. Monitor BUN/Cr Q3mon for first year, annually thereafter
    4. Check b-HCG in women of reproductive age pre and periodically during Tx.

CDC Interim Guidance on HIV Pre-Exposure Prophylaxis

Before initiating PrEP

Determine eligibility:

- Document negative HIV antibody test immediately before starting PrEP medication.
- Test for acute HIV infection if patient has symptoms consistent with acute HIV infection or reports unprotected sex with an HIV-positive person in the preceding month.
- Determine if women are planning to become pregnant, are currently pregnant, or are breastfeeding.
- Confirm that patient is at ongoing, very high risk for acquiring HIV infection.
- If any sexual partner is known to be HIV-infected, determine whether receiving antiretroviral therapy; assist with linkage to care if not in care or not receiving antiretroviral therapy.
- Confirm that calculated creatinine clearance is ≥60 mL per minute (Cockcroft-Gault formula).

Other recommended actions:

- Screen for hepatitis B infection; vaccinate against hepatitis B if susceptible, or treat if active infection exists, regardless of decision regarding prescribing PrEP.
- Screen and treat as needed for sexually transmitted infections (STIs).
- Disclose to women that safety for infants exposed during pregnancy is not fully assessed but no harm has been reported.
- Do not prescribe PrEP to women who are breastfeeding.

Beginning PrEP medication regimen:

- Prescribe tenofovir disoproxil fumarate 300 mg (TDF) plus emtricitabine 200 mg (FTC) (i.e., one Truvada [Gilead Sciences] tablet) daily.
- In general, prescribe no more than a 90-day supply, renewable only after HIV testing confirms that patient remains HIV-uninfected. For women, ensure that pregnancy test is negative or, if pregnant, that the patient has been informed about use during pregnancy.
- If active hepatitis B infection is diagnosed, consider using TDF/FTC, which may serve as both treatment of active hepatitis B infection and HIV prevention.
- Provide risk-reduction and PrEP medication-adherence counseling and condoms.

Follow-up while PrEP medication is being taken:

- Every 2–3 months, perform an HIV antibody test (or fourth generation antibody/antigen test) and document negative result.
- At each follow-up visit for women, conduct a pregnancy test and document results; if pregnant, discuss continued use of PrEP with patient and prenatal-care provider.
- Evaluate and support PrEP medication adherence at each follow-up visit, more often if inconsistent adherence is identified.
- Every 2–3 months, assess risk behaviors and provide risk-reduction counseling and condoms. Assess STI symptoms and, if present, test and treat for STIs as needed.
- Every 6 months, test for bacterial STIs even if asymptomatic, and treat as needed.
- Three months after initiation, then every six months while on PrEP medication, check serum creatinine and calculate creatinine clearance.

On discontinuing PrEP (at patient request, for safety concerns, or if HIV infection is acquired):

- Perform HIV test(s) to confirm whether HIV infection has occurred.
- If HIV positive, order and document results of resistance testing, establish linkage to HIV care.
- If HIV negative, establish linkage to risk reduction support services as indicated.
- If active hepatitis B is diagnosed at initiation of PrEP, consider appropriate medication for continued treatment of hepatitis B infection.
- If pregnant, inform prenatal-care provider of TDF/FTC use in early pregnancy and coordinate care to maintain HIV prevention during pregnancy and breastfeeding.

Recommendations in black apply to both adult MSM and heterosexually-active men and women; items in blue are specific to heterosexual women.

http://www.cdc.gov/hiv/prep/pdf/PrEPfactsheet.pdf

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5. Women's Health Protocol

I. At the initial visit, a complete history and physical exam are performed, including a detailed gynecologic, contraceptive, and pregnancy history.

II. The components of the annual women's health preventative services:
   A. Blood pressure, weight checks and body mass index
   B. Blood glucose and cholesterol levels if risk factors for development of Diabetes and/or Heart Disease are present (Heart Disease remain #1 killer of women)
   C. Breast exam
   D. Pelvic exam including Pap smear, after age 21 (frequency to be determined according to patient risk levels), and STD screen
   E. Colon Cancer screening beginning at age 50 or earlier depending on risk
   F. Tobacco screening and counseling

III. The health care provider will review patients' contraceptive methods and ensure patients' satisfaction with their method of choice. The importance of practicing safe sex at every encounter should be stressed. The most commonly used types of contraceptive methods are:
   A. Oral contraceptive pill
   B. Depo-Provera
   C. Condom
   D. Diaphragm
   E. IUD
   F. Tubal ligation
   G. Ortho Evra
   H. Implantable contraception (Implanon)

IV. If the patient desires to become pregnant, counseling should emphasize the importance of early prenatal care, proper diet, use of vitamins and folic acid, and avoidance of alcohol, tobacco, and other drugs.

V. Monthly self breast exams should be reinforced and correct techniques reviewed. A clinical breast exam should be performed yearly.

VI. Women should receive regular mammogram screening appropriate for their age group and risk profile.

VII. Women who are menopausal should be counseled regarding latest recommendations regarding hormone replacement therapy. Treatment should be based on the delicate balance between benefit versus risk.

VIII. The importance of exercise at every age should be stressed and the significance of a balanced diet with calcium supplementation at an early age in the prevention of osteoporosis should be reviewed. A low fat and reduced carbohydrate diet should be reinforced and the risks of obesity discussed.

IX. Women with high risk factors should be screened for substance abuse and receive appropriate counseling and rehabilitation.

X. Risk reduction education and HIV testing should be offered to sexually active individuals.

XI. A safety assessment to screen for domestic violence and a mental health assessment to screen for depression and other disorders should be performed regularly.

XII. The need for immunizations should be evaluated including:
- A. Td booster every 10 years; administer a dose of Tdap if not previously received
- B. Influenza vaccine annually
- C. Pneumococcal vaccine for the elderly/high risk individuals
- D. Hepatitis B vaccines in high risk persons
- E. Varicella vaccines in susceptible individuals
- F. HPV vaccines to 26 years of age
- G. Herpes Zoster vaccine at age 60 or older.

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6. Children with Special Health Care Needs

I. Complete history and physical on initial visit with particular emphasis on:

A. Prenatal exposures including medications and drugs
B. Prenatal infections
C. Family history
D. Prior pregnancy history
E. Child's medical history and neurodevelopmental status including a history of prematurity or chromosomal disorders (e.g. Down's Syndrome, Fragile X, Tuberous Sclerosis)
F. Features of genetic syndromes (e.g.: Brushfield spots, webbed neck, coarse facial features, hepatosplenomegaly, dysmorphic features, macro or microcephaly)
G. Neurological findings (e.g.: cranial nerve function, hyper/hypotonicity)

II. Laboratory studies & other screening tools:

A. Blood and/or urine tests
B. Developmental Screening Test
C. Additional studies as appropriate:

1. Chest x-ray
2. EKG
3. Metabolic screening
4. Hormone levels, etc.
5. Cytogenetic studies
6. Imaging studies, e.g. MRI
7. EEG

III. Establish a diagnosis(es) based on above information. Refer to genetic, neurological developmental specialists, audiology and ophthalmology, if indicated.

IV. Develop a chronic condition management plan. Administer medical treatment in accordance to the plan. Refer the patient to case management, using a JMS referral form. If the patient qualifies, please enroll in REM.

V. Refer for early intervention and necessary therapies such as speech, occupational and physical therapies.

VI. Establish a medical home to include the provision of culturally effective, coordinated, and comprehensive care for children with special health care needs.

VII. Address the child's needs for appropriate educational services and access to adequate community services. Screen for co-existing conditions such as ADHD, anxiety and mood disorders and refer as needed to mental health/ behavioral specialists.

VIII. Review care plan at least annually to address any changes in the patient's general health.

IX. Assure accessibility to necessary durable medical equipment.

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Frances Bird, M.D., Staff Pediatrician

Sources:

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3. Persistence and Impact of Multiple Childhood Chronic Illness, 1994.
4. Institute of Medicine: Disability in America: Toward a National Agenda for Prevention, 1991.
5. National Institute for Health and Clinical Excellence (NICE). Autism. Recognition, referral and diagnosis of children and young people on the autism spectrum. London (UK): (NICE); 2011 Sep.51p; (clinical guideline; no. 128)

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7. Individuals with a Physical Disability

I. Principles and Goals

A. Comprehensive effort that incorporates physical, emotional and social parameters in the process of care.
B. Team effort that is multi-disciplinary in membership and interdisciplinary in process.
C. Not to be a limited intervention.
D. Frequently involving a plan of care that is continuing and intended for long-term follow-up.
E. Primarily focused on functional abilities of patient

1. Function that has been lost and may be restored.
2. Remaining function that needs to be protected and strengthened to accommodate disabilities resulting from lost functions unable to be restored.

II. Complete History and Physical Exam on initial visit to differentiate

A. Acquired causes of disability (e.g.: stroke, cancer, trauma, etc.).
B. Congenital causes of disability (e.g.: club feet, shortened or missing limb, birth trauma, etc.).

III. Diagnostic studies

A. Blood work profiles
B. Mini Mental Status
C. Radiology

1. X-rays
2. CT Scan
3. MRI
4. EMG

D. Nerve Conduction Studies
E. Vascular Studies
F. Other special labs or tests particular to the disability

IV. Assess Activity Capacity

A. Assess Functional Residual Capacity
B. Assess ability to perform Activities of Daily Living (ADLs) (e.g.: brush teeth, use toilet independently, dress self, bathe)
C. Assess ability to perform Instrumental Activities of Daily Living (e.g.: make a phone call, write a check, access transportation)
D. Collaborate with Home Health Agency, as needed.

V. Assess for Mental Illness secondary to physical disability.

VI. Treat Symptoms or Underlying Condition, if able

A. Medication

1. NSAID's
2. Narcotics
3. Muscle relaxants
4. Blood thinning agents
5. Bone-building agents
6. Other, as needed

B. Referral to specialty services, as needed

VII. Acquire Durable Medical Supplies, as needed

A. Assistive devices (e.g.: canes, walkers, crutches, shower stools, orthotics)
B. Home monitoring equipment (e.g.: glucometers)
C. Supportive devices (e.g.: braces, splints)
D. Personal needs equipment (e.g.: colostomy care products)

VIII. Ensure transportation to and from PCPs office.

IX. Assess patient's housing situation.

A. Work with Housing Authority to obtain necessary requirements, such as:

1. Ground floor
2. Elevator
3. Handicapped parking
4. No carpet
5. Well-lit hallways
6. Stall shower.

B. Advise patient to maximize available properties of current home and ensure safety factors:

1. Clear pathways through home
2. Wear slippers
3. Remove throw rugs, etc.

X. Facilitate changing insurance plans, as needed, according to disability level and permanence

A. Attempt to return patient to work force
B. Social service referral if potentially out of work for extended time
C. Perform disability determinations.

XI. Perform long-term monitoring and follow-up care

XII. Evaluate for intermediate or long-term care facility.

Written by:
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Aye Lwin, M.D., Assistant Medical Director
Sources:
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2. National Guideline Clearinghouse: Fitness for Duty, http://www.guideline.gov/summary/summary.aspx?doc_id=10419&nbr=005465&string=disability+AND+physical
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8. Individuals with a Developmental Disability

I. Definition of Developmental Disability:

Group of chronic, nonprogressive neurologic disorders with an onset from prenatal period through childhood and which continues into adulthood

II. Complete history and physical should be performed on the initial visit with particular emphasis on:

A. Family/Genetic history
B. Pregnancy history including exposures, toxins, and infections
C. Perinatal history
D. Developmental history
E. Educational history including adaptive, communication, and self care functioning
F. Social history
G. Complete Neurological Exam

III. Laboratory tests are indicated by the findings and history and may include:
A. Chromosomal analysis
B. Appropriate test for inborn errors of metabolism
C. Brain imaging studies (CT scan, MRI)

IV. The comprehensive assessment also includes standardized intelligence and psychoeducational testing. Prior assessment results should be reviewed and additional testing requested when indicated.

V. Establish a diagnosis based on the above information:

A. Mental retardation
B. Motor skills disorders
C. Speech disorders
D. Learning disorders
E. Mood disorders
F. Pervasive developmental disorders/Autism spectrum disorders
G. ADHD and disruptive behavior disorders
H. Medical/neurological primary diagnoses, e.g., fetal alcohol syndrome, prenatal substance abuse, fragile X syndrome

VI. An Individualized Care Plan (ICP) should be developed and the patient should be referred to case management.

VII. The management of persons with developmental disabilities is typically multidisciplinary. Early intervention should be instituted including educational and ancillary therapies such as physical, occupational, language, and family support.

VIII. Medical and psychological treatment should be administered in accordance with ICP goals. Referrals to specialists based on those goals should be done using approved network providers whenever possible.

XIII. The patient should have access to medically necessary equipment

XIV. The patient's progress should be monitored and the ICP should be reviewed/updated at least annually to address any changes in the patient's health needs.

XV. The medical needs of the whole person, not just the disability should be addressed. A healthy lifestyle should be promoted including proper nutrition and physical activity as tolerated. Clinical preventive services should be recommended.

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Sources:

1. *American Academy of Pediatrics: Screening infant and young children for developmental disabilities, 1994.*
2. *Perrin JM., Development of Children with Chronic Illness, 1994*
3. *Developmental and Behavioral Pediatrics: A Handbook for Primary Care, 1994.*
4. *J Am Acad Child Adolescent Psychiatry, 1999*
5. *National Guideline Clearinghouse: MA Department of Mental Retardation Health Screening Recommendation, http://www.guideline.gov/summary/summary.aspx?ss=15&doc_id=13696&nbr=7030*
6. *Disability & Health – CDC (ncbddd/disabilityandhealth/index.html)*
7. *US Dept of Health and Human Services, Surgeon General's call to action to improve the health and wellness of persons with disabilities. Washington (DC): Office of the Surgeon General; 2005*
8. *American Family Physician: Medical Care of Adults with Mental Retardation, 2006; 73:2175-83, 2184*

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9. Pregnant & Postpartum Women

(It is important that all pregnant women are seen for prenatal care as early as possible during their pregnancy, preferably during the first trimester of pregnancy or within 42 days of enrollment with Jai Medical Systems Managed Care Organization, Inc. – per HEDIS quality assurance standards.)

Note: For PCP's who see a patient for initial diagnosis or confirmation of pregnancy, but will not be providing subsequent global OB care, the Jai MCO's requirements for the visit include:

A. E/M code 99201-99205 or 99211-99215 as appropriate
B. Order an obstetric prenatal lab panel
C. Document LMP or EDD and obstetric history
D. Document counseling and education
E. Diagnosis of pregnancy with V22, V23, or V28 code on bill
F. Refer patient to OB case management, using appropriate form

Note: Though not a listed requirement, Rx of a prenatal vitamin is also appropriate.

I. Identification & Health History of Patient

A. Confirm Pregnancy
   1. Physical Exam
   2. Urine
   3. Blood

B. Complete the Maryland Prenatal Risk Assessment Form

C. History of patient, with focus on:
   1. Presenting pregnancy
      a. Calculate Estimated Date of Confinement (EDC)
         i. Nägele's Rule, based on LMP
         ii. Uterine size by palpation as well as in centimeters
            - at 8wks, pubic symphysis
            - at 12wks, slightly above pubic symphysis
            - at 15wks, midway between pubic symphysis and umbilicus
            - at 20wks, umbilicus
      b. Common signs & symptoms of pregnancy patient is currently experiencing
      c. Care to date
         i. Begun vitamins?
         ii. Adjusted eating habits to pregnancy requirements?

D. Previous pregnancy history, if any
   1. Length of gestation
   2. Birth weight
   3. Fetal outcome
   4. Length of labor
   5. Fetal presentation

6. Type of delivery
7. Complications

E. Medical history, with focus on:
   1. Chronic diseases, such as:
      a. Hypertension
      b. Diabetes
      a. Sickle Cell Trait/Anemia
      b. Hepatitis (all types)
      c. HIV
      d. Thyroid Dysfunction
      e. Tuberculosis
   2. Drug allergies
   3. History of blood transfusions
   4. History of cancer
   5. History of sexually transmitted diseases (STD)
   6. Potential risk of current STD
   7. History of (or current) Substance Abuse
   8. Current mental illness

F. Surgical history, with focus on:
   1. GYN surgery
   2. Induced abortions
   3. Previous Caesarean delivery and reason

G. Family history, with focus on:
   1. Diabetes, gestational or otherwise
   2. Pregnancy difficulties, including large babies
   3. Hypertension, during pregnancy or otherwise
   4. Stillbirths
   5. Multiple pregnancy
   6. Cancer
   7. Other inheritable diseases

II. Physical Exam

A. Complete physical exam, head to toe, including vital signs

B. Complete pelvic exam
   1. Pap smear – only if due to be done by standard screening guidelines.
   2. Cervical cultures for STDs (at initial exam and at 36^{th} week)
      a. Gonorrhea
      b. Chlamydia
      c. β-Strep (35-37 weeks only)
      d. Others

   3. Examination of pelvic soft tissue for masses or other unusual qualities
   4. Examination of the bony pelvis

C. TB skin test – if otherwise indicated

III. Lab Work

A. Basic blood screening
   1. Complete blood count with differentiation
   2. Blood group type
   3. Rh factor
   4. Blood group antigen antibodies (at initial exam and at 28wks if unsensitized Rh neg.)
   5. RPR (at initial exam and 28 wks)
   6. Rubella titer
   7. Varicella titer
   8. Hepatitis diagnostic profile
   9. HIV (with pre- and post-test counseling)

B. Urine screening (UA with microscopic & culture) to look for:
   1. Infection
   2. Protein
   3. Glucose

C. Pregnancy specific screening
   1. Sonogram:
      - To improve dating accuracy if uncertain LMP
      - Anatomy scan at 18-22wk
      - For other concerns
   2. Aneuploidy screen 1st and/or 2nd trimester labs +/-US
   3. Neural tube defect screen - Maternal serum AFP +/- US @15-20wks
   4. Chorionic villus sampling (CVS) – if indicated, after 10wks
   5. Amniocentisis (if indicated) - done at 16wks
   6. Glucose tolerance test - done at 26-28wks
   7. Group β-strep culture of lower vagina - done between 35-37wks

D. Immunizations
   1. Rh vaccine – if Rh negative, Rh immune globulin done at 28 wks,w/in 72 hr of delivery, and whenever there is risk of fetomaternal hemorrhage
   2. Influenza vaccine (inactivated) recommended
   3. TDaP – done at 27-36wk of each pregnancy

IV. General Prenatal Care Concepts for healthy, singleton pregnancy

A. Ideal frequency of visits
   1. Initial exam - up to 30 wks gestation - visit every four weeks
   2. 30 wks - 36 wks gestation - visit every two weeks
   3. 36 wks - delivery - every week

B. Details to note at each exam:
   1. Maternal weight gain or loss
   2. Maternal blood pressure
   3. Fundal height
   4. Abdominal exam findings
   5. Normal fetal heart tones
   6. Maternal urine
   7. Protein
   8. Glucose
   9. Screen for depression and domestic violence
   10. Screen for ongoing substance abuse

C. Encourage mother to enroll and participate in educational programs
   1. Newborn care
   2. Childbirth experience
   3. Nutrition during pregnancy

D. Recommend:
   1. Multivitamin supplementation
   2. Preventative dental services
   3. Regular mild to moderate exercise
   4. Appropriate weight gain per IOM 2009 guidelines, by pre-pregnancy BMI
   - BMI <18.5 kg/m^2 (underweight) — weight gain 28 to 40 lbs (12.5 to 18.0 kg)
   - BMI 18.5 to 24.9 kg/m^2 (normal weight) — weight gain 25 to 35 lbs (11.5 to 16.0 kg)
   - BMI 25.0 to 29.9 kg/m^2 (overweight) — weight gain 15 to 25 lbs (7.0 to 11.5 kg)
   - BMI ≥30.0 kg/m^2 (obese) — weight gain 11 to 20 lbs (5 to 9.0 kg)

E. Send copy of prenatal records to hospital at 34-36 wks, in preparation for labor and delivery; weekly copies after

V. Some Common Complaints & Their Treatments (if any)

A. Urinary frequency
   1. No treatment if urine is negative.
   2. Asymptomatic bacteria should be treated, do to risk of pyelonephritis

B. Back and/or pelvis pain
   1. Wear maternity girdle
   2. Rest frequently
   3. Local heat and back/message rubs

C. Varicose Veins
   1. Elastic stockings
   2. Elevation of legs
   3. Frequent rest
   4. Monitor for signs & symptoms of deep vein thrombosis

D. Lower limb edema
   Elevate legs

E. Breast Tenderness
   1. Wear good-fitting bra 24hrs/day
   2. Decrease caffeine products

F. Nausea & Vomiting
   1. Small frequent meals, solids and liquids separately
   2. Decrease caffeine products
   3. Anti-histamines
   4. Vitamin B_6

G. Sexually transmitted diseases
   1. Syphilis
      a. Penicillin
      b. Erythromycin
      c. Ceftriaxone (Category B)
   2. Chlamydia
      a. Zithromax (Category B)
      b. Erythromycin
   3. Gonorrhea
      Ceftriaxone
   4. Herpes Simplex
      a. Acyclovir prophylaxis from 36wk if symptomatic during pregnancy
      b. Cesarean delivery, if active when in labor

H. Other vaginal irritations
   1. Trichomoniasis
      a. Oral Flagyl (only after 1st trimester) (Category C)
      b. Vaginal Metrogel (any time)
      c. Clindamycin, vaginally

   2. Candidiasis
      a. Terazol (2nd and 3rd trimesters only) (Category C)
      b. Monistat (Category C)
      c. Mycostatin
      d. Topical Imidazole

I. GERD
   Antacids

J. Constipation/Hemorrhoids
   Dietary modifications including more bran and wheat

VI. Signs of Potential Problem
- A. Upper extremity and/or facial edema
- B. Unexplained Bleeding
- C. Unexplained elevated AFP levels
- D. Low maternal weight gain (in a non-obese patient) or excessive weight gain.
- E. Decrease or cessation of fetal movement
- F. No evidence of maternal blood pressure drop with increasing gestation
- G. Compounding maternal medical problems
- H. Substance use/abuse
- I. Nicotine dependence
- J. Preterm uterine cramping with severe pain
- K. Abnormal fetal growth
- L. Vaginal infection
- M. Exposure to fetotoxic agents
  1. Irradiation
  2. Viruses
  3. Gases
  4. Drugs

VII. Basic Principles of High Risk OB Management
- A. Frequency of visits
  Increase frequency as indicated throughout pregnancy to allow for close monitoring

- B. Additional Testing (as indicated)
  1. Ultrasound
  2. Amniocentesis
  3. Chorionic Villus sampling
  4. Fetal Blood Sampling
  5. Maternal Alfa-Fetoprotein testing
  6. Maternal and Paternal Karyotyping
  7. Pulmonary Maturity testing

- C. Biometric Evaluations of Fetal Well-being - done at appropriate intervals
  1. Fetal Movement Counting
  2. Doppler Ultrasound
  3. Nonstress Testing
  4. Contraction Stress Testing
  5. Biophysical Profile

- D. Management of specific concurrent maternal diseases according to recent research-based protocols

VIII. Postpartum Care
- A. In-hospital Care
  1. Rubella vaccine (if needed)
  2. Varicella vaccine (if needed)

3. Rh immune globulin (if needed)
4. TDaP vaccine (if not done during pregnancy)
5. Monitor bladder function, secondary to birth trauma
6. Monitory bowl function, secondary to birth trauma
7. Ensure general good hygiene, particularly of the perineal area
8. Monitor lochia drainage
9. Ambulate to prevent deep vein thrombosis
10. Ensure adequate nutrition
11. Discuss contraception
12. Discuss breastfeeding

B. At-home care
   1. First month
      a. Monitor for fever, pain, heavy bleeding, or excessive breast tenderness - call doctor immediately if experience these
      b. Rest
      c. Restrict activity level for first three weeks

   2. Consider contraceptive options

   3. Schedule postpartum exam appointment at four to six weeks (21-56 days after delivery to meet HEDIS guidelines), consider earlier visit if cesarean delivery, medical issues require follow-up, or at risk for post-partum depression.
      a. Maternal and newborn's weight
      b. Maternal blood pressure
      c. Maternal CBC with differentiation if indicated
      d. Breast exam
      e. Pelvic exam with rectal exam
      f. Episiotomy (and any other reparative sutures) examination
      g. Discuss contraception/family planning
      h. Ensure adequate newborn nutrition/breastfeeding issues
      i. Discuss any areas of concern to patient
      j. Assess maternal ability to return to work
      k. Discuss safe infant sleep patterns
      l. Screen for diabetes in individuals with previous gestational diabetes
      m. Screen for postpartum depression
      n. HEDIS requirements
         - Code V24.1, V24.2, or V25.1 as appropriate
         - Document at least one of the following:
            - A pelvic exam
            - Evaluation of weight, breasts, abdomen, and BP
            - A notation of postpartum care

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Sources:

1. *Guidelines: American College of Obstetrics and Gynecology*
2. *National Clearinghouse Guideline, http://www.guideline.gov/content.aspx?id=13174&search=post+partum+care*
3. *IOM (Institute of Medicine). Weight Gain During Pregnancy: Reexamining the Guidelines. Washington, DC: The National Academies Press. Posted online May 28, 2009.*

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10. Individuals who are Homeless

I. Principles & Goals
   A. Multi-disciplinary team approach to address the unique needs of the homeless patient, particularly:
      1. Physical illness
      2. Emotional illness
      3. Substance Abuse problems
      4. Nutritional problems
      5. Lack of:
         a. Stable housing arrangements
         b. Employment
         c. Income
         d. Health insurance
         e. Health care access
   B. Identify that they are four times more likely to die than age-matched controls

II. Complete Psychosocial Evaluation
   A. Psychosocial History Assessment
      1. Educational achievements
      2. Job/employment/armed forces history
      3. Housing history
      4. Substance abuse history & evaluation
      5. Family history
      6. Domestic violence
      7. History of survival sex
   B. Comprehensive Mental Health Assessment
      1. Mental status exam
      2. Previously diagnosed mental disorders
      3. Symptomatology
      4. Personality & Coping Assessment
      5. Medication history
   C. Lifestyle-related Disease Assessment
      1. Substance abuse
      2. Alcohol abuse
      3. Nicotine abuse
      4. Birth control evaluation
      5. Communicable diseases

III. Complete History & Physical Examination
   A. Comprehensive Medical History
   B. Hospitalizations
   C. Review of Current Symptoms

D. Comprehensive physical exam, with additional emphasis on:
    1. Skin integrity
    2. Oral mucosa integrity/teeth health
    3. Vision capabilities
    4. Hearing capabilities
    5. Foot examination

IV. Diagnostic Studies
A. Basic lab work
    1. Complete blood count
    2. Urinalysis & urine drug screen
    3. Automated chemistry panel
    4. Hepatitis Diagnostic Profile
    5. Prostate Specific Antigen (PSA), if indicated
B. Radiological studies
C. Tuberculosis screening
D. STD screening
E. HIV testing (with pre- & post-test counseling)
F. Immunization Assessment
    1. Influenza
    2. Tetanus
    3. Pneumococcal
    4. Hepatitis B, if indicated
G. Comprehensive GYN exam
H. Mammography, if indicated
I. Other tests, as needed & indicated

V. Treatment of Physical Problem
A. Medications appropriate to diagnoses established
B. Referral to specialty services
    1. Psychiatry
    2. Orthopedic
    3. Podiatry
    4. Dental
    5. Others

VI. Treatment of Emotional Problems
A. Medications appropriate to diagnoses established
B. Referral to In-house Mental Health Department
C. Referral to Adult Day Care
D. Referral to hospital, if indicated as necessary

VII. Treatment of Psychosocial Problems
A. Referral to appropriate social agencies
    1. Housing Authority
    2. Department of Social Services

3. Department of Education's Homeless Coordinator

B. Referral to Case-Management Social Work agencies

C. Referral to Substance Abuse Treatment programs
   1. Through primary care provider
   2. Through In-house Mental Health Department
   3. Through outside In-patient services

VIII. Treatment of Substance Abuse Problems - see extensive Substance Abuse Treatment Protocol and Substance Abuse Protocol Form including CAGE and MAST tool.

IX. Treatment of Housing Problems
   A. Identification of shelter for the night while in primary care providers's office
   B. Referral to City Housing Department for federally-subsidized housing, Section 8 housing, etc.
   C. Referral to Department of Social Service for assistance with household expenses, including utilities

X. Access appropriate Health Insurance
   A. Referral to Department of Social Services
   B. Maryland Primary Care
   C. Maryland Health Choice Program
   D. Maryland Children Health Program
   E. Others

Written by:
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Aye Lwin, M.D., Assistant Medical Director

Sources:

1. Developed protocol based on our own clinical experience obtained by working with the Homeless for 35 years.
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3. Homelessness in the United States: History, Epidemiology, Health Issues, Women, and Public Policy. Medscape Ob/Gyn and Women's Health 9 (2) 2004. Medscape 2004.
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11. Individuals with HIV/AIDS

I. Treatment guidelines for HIV/AIDS change frequently. Updates can be found at http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf.

II. HIV positive patients will be treated by the primary care providers with appropriate medication or referred to ID (e.g. Moore Clinic), depending on their comfort level.

III. Regular follow-ups will be made with the primary care provider. The CD4 counts and viral load should be checked every 3-6 months at a minimum. Patients diagnosed with HIV/AIDS are reported to the local health department.

IV. Indications for Antiretroviral Therapy

A. ART is now recommended for all HIV-infected patients.
   1. To reduce disease progression and virus transmission.
   2. Strength of recommendation varies by CD4 count: CD4 <350**(AI)**; CD4 350–500 **(AII)**; CD4 >500 **(BIII)**.
   3. The decision to initiate ART should be individualized for each patient and may incorporate assessment of the following factors:
      * Risk of progression to illness or death if untreated
      * Readiness and willingness to adhere to therapy; potential barriers to adherence, psychosocial issues
      * Co-morbidities and coexisting conditions
      * Risk of HIV transmission to others if untreated
      * Risk of toxicities and drug-drug interactions

B. Highest priority for ART treatment initiation:
   * Pregnant
   * AIDS-defining illness
   * HIV associated nephropathy
   * HIV associated dementia
   * Hepatitis B co-infection
   * Acute HIV-infection

V. Recommended Treatment

A. Genotype testing should be performed at the time of diagnosis if the viral load is >1,000 copies/ml. Consider repeat testing when treatment is initiated.
B. Three antiretroviral drugs are used. Treatment needs to be individualized depending on the CD4 count, viral load, and the compliance of the patient
C. Goal of Treatment: Reduction in viral load below detectable levels.
D. Continue treatment without interruption to reduce resistance mutations.
E. Pregnancy – preferred ART:
   1. NRTI's: Lamivudine, Zidovudine,
   2. NNRTI: Nevirapine,
   3. PI's: Atazanavir/Ritonavir, Lopinavir/Ritonavir

Table 5a. Preferred and Alternative Antiretroviral Regimens for Antiretroviral Therapy-Naive Patients (Last updated February 12, 2013; last reviewed February 12, 2013)

A combination antiretroviral therapy (ART) regimen generally consists of two NRTIs plus one active drug from one of the following classes: NNRTI, PI (generally boosted with RTV), INSTI, or a CCR5 antagonist. Selection of a regimen should be individualized on the basis of virologic efficacy, toxicity, pill burden, dosing frequency, drug-drug interaction potential, and the patient's resistance testing results and comorbid conditions. Refer to Table 6 for a list of advantages and disadvantages of the individual ARV agents listed below and to Appendix B, Tables 1–6 for dosing information. The regimens in each category are listed in alphabetical order. For more detailed recommendations on ARV use in HIV-infected pregnant women, refer to the latest perinatal guidelines available at http://aidsinfo.nih.gov/guidelines.

Preferred Regimens

Regimens with optimal and durable efficacy, favorable tolerability and toxicity profile, and ease of use.

The preferred regimens for non-pregnant patients are arranged by chronological order of FDA approval of components other than nucleosides and, thus, by duration of clinical experience.

NNRTI-Based Regimen	Comments
• EFV/TDF/FTC[a] **(AI)**	• **EFV** is teratogenic in non-human primates. A regimen that does not include EFV should be strongly considered in women who are planning to become pregnant or who are sexually active and not using effective contraception.
PI-Based Regimens *(in alphabetical order)*	
• ATV/r + TDF/FTC[a] **(AI)**	• **TDF** should be used with caution in patients with renal insufficiency.
• DRV/r (once daily) + TDF/FTC[a] **(AI)**	
INSTI-Based Regimen	• **ATV/r should not be used** in patients who require >20 mg omeprazole equivalent per day. Refer to Table 15a for dosing recommendations regarding interactions between ATV/r and acid-lowering agents.
• RAL + TDF/FTC[a] **(AI)**	

Alternative Regimens

Regimens that are effective and tolerable, but have potential disadvantages when compared with preferred regimens. An alternative regimen may be the preferred regimen for some patients.

NNRTI-Based Regimens *(in alphabetical order)*	Comments
• EFV + ABC/3TC[a] **(BI)**	• **RPV is not recommended** in patients with pretreatment HIV RNA >100,000 copies/mL.
• RPV/TDF/FTC[a] **(BI)**	• Higher rate of virologic failures reported in patients with pre-ART CD4 count <200 cells/mm^3 who are treated with RPV + 2NRTI
• RPV + ABC/3TC[a] **(BIII)**	• Use of PPIs with **RPV** is contraindicated.
PI-Based Regimens *(in alphabetical order)*	
• ATV/r + ABC/3TC[a] **(BI)**	• **ABC should not be used** in patients who test positive for HLA-B*5701.
• DRV/r + ABC/3TC[a] **(BII)**	• Use **ABC** with caution in patients with known high risk of CVD or with pretreatment HIV RNA >100,000 copies/mL (see text).
• FPV/r (once or twice daily) + ABC/3TC[a] or TDF/FTC[a] **(BI)**	
• LPV/r (once or twice daily) + ABC/3TC[a] or TDF/FTC[a] **(BI)**	• **Once-daily LPV/r is not recommended** for use in pregnant women.
INSTI-Based Regimen	
• EVG/COBI/TDF/FTC[a] **(BI)**	• **EVG/COBI/TDF/FTC** should not be started in patients with an estimated CrCl <70 mL/min, and should be changed to an alternative regimen if the patient's CrCl falls below 50 mL/min
• RAL + ABC/3TC[a] **(BIII)**	• **COBI** is a potent CYP 3A inhibitor. It can increase the concentration of other drugs metabolized by this pathway. Refer to Tables 15d and 16c for drug interaction information for concomitantly administered drugs.
	• **EVG/COBI/TDF/FTC** should not be used with other ARV drugs or with nephrotoxic drugs.

[a] 3TC may substitute for FTC or vice versa. The following combinations in the recommended list above are available as coformulated fixed-dose combinations: ABC/3TC, EFV/TDF/FTC, EVG/COBI/TDF/FTC, LPV/r, RPV/TDF/FTC, TDF/FTC, and ZDV/3TC.

Key to Abbreviations: 3TC = lamivudine, ABC = abacavir, ART = antiretroviral therapy, ARV = antiretroviral, ATV/r = atazanavir/ritonavir, COBI = cobicistat, CrCl = creatinine clearance, CVD = cardiovascular disease, DRV/r = darunavir/ritonavir, EFV = efavirenz, EVG = elvitegravir, FDA = Food and Drug Administration, FPV/r = fosamprenavir/ritonavir, FTC = emtricitabine, INSTI = integrase strand transfer inhibitor, LPV/r = lopinavir/ritonavir, NNRTI = non-nucleoside reverse transcriptase inhibitor, NRTI = nucleoside reverse transcriptase inhibitor, PI = protease inhibitor, PPI = proton pump inhibitor, RAL = raltegravir, RPV = rilpivirine, RTV = ritonavir, TDF = tenofovir disoproxil fumarate, ZDV = zidovudine

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Rating of Recommendations: *A = Strong; B = Moderate; C = Optional*

Rating of Evidence: *I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion*

VI. Monitoring ART (see table 3 below)

A. Obtain VL within 2-4 weeks after initiation of therapy (1 log drop or greater indicates adequate response)
B. Repeat VL q4-8 weeks until VL<200, then every 3-4 months if stable
C. Repeat CBC, LFT's, and creatinine every 3-6 months after initiating therapy
D. CD4 count can be checked every 6-12 months after virologic suppression met and above opportunistic threshold.

VII. Basic Prophylaxis Timetable

A. When diagnosed with HIV initially
   1. Administer necessary vaccines
   2. Get baseline lab work (CBC, CMP, VL, CD4, genotype, G6PD, toxoplasma IgG, RPR, gonorrhea, chlamydia, Hepatitis A,B,C, CMV IgG, VZV IgG (if no Hx of chickenpox), PPD or Quantiferon TB Gold
   3. Do baseline physical, pap smear if due
   4. Assess for other needs (e.g.: counseling, housing, health insurance)
   5. Assess allergies
   6. Discuss advanced directives

B. At CD4 of < 200, Prior AIDS-defining illness, or thrush
   1. Begin PCP prophylaxis
      - Most common prophylaxis is SMZ/TMP DS daily, every other day, or, 1 three times a week.
   2. If allergic to sulfa drugs, the patient should use Dapsone, Pyrimethamine, Leukovorin, Pentamidine, or Atovaquone.

C. At CD4 of < 100
   1. Continue above therapies
   2. Begin prophylaxis for Toxoplasma
      - Prophylaxis is the same as for PCP, if taking Bactrim DS
      - Alternatives are Bactrim SS, Dapsone + Pytimethamine + Leukovorin, and Atovaquone.
      - If using PCP prophylaxis that is not a preferred regimen for toxoplasma when CD4 drops <100, should change regimen if toxoplasma IgG antibodies are positive.

D. At CD4 of < 50
   1. Continue above therapies
   2. Begin MAC Prophylaxis
      - Most common prophylaxis is Azithromycin 1200 mg weekly or Clarithromycin 500 mg B.I.D.
      - Alternative is Rifabutin

VIII. Selected Commonly Seen Complications & Their Prophylaxis/Treatment

A. Tuberculosis - PPDs should be administered yearly.
   1. If the skin test is +, with ≥5mm induration, but a chest x-ray is negative, referral to the Local Health Department should take place immediately and the patient should begin a 9 month course of INH and B6 therapy. Liver enzymes should be done regularly to monitor for elevation.
   2. If the skin test is +, with a ≥5mm induration, and the chest x-ray is positive, the patient should be sent immediately to the hospital so that a rigorous and extensive medication regimen can begin. The patient will likely be hospitalized for at least a month to ensure that medication is being administered properly and in a timely manner.

B. Diarrhea
   1. Ensure hydration and appetite
   2. Assess for associated symptoms, such as pain with swallowing or defecation
   3. Obtain stool for cultures - look for parasites, WBCs, c.diff, etc.
   4. Treat as appropriate from the culture results
   5. Refer immediately to hospital if dehydrated, as evidenced by:
      a. Orthostatic hypotension
      b. Poor skin turgor
      c. Dry oral mucosa or sunken, glassy eyes

C. HIV Wasting Syndrome
   1. Ensure appetite and hydration
   2. Assess for presence or lack of other GI or endocrine disease
   3. Assess for malignancies
   4. Assess for febrile symptoms
   5. Megace, Marinol, and Nandrolone may be used as indicated.
   6. Prescribe nutritional supplement, if covered, (e.g.: Ensure) 1 can three times a day with regular meals

D. Mental Health Needs, Including Substance Abuse
   1. Identify and Diagnose the correct mental health problem
   2. Treat medically, as able, and
   3. Offer services of in-house counseling department
   4. If the patient suffers from chemical addiction:
      a. Manage detoxification and rehabilitation, if can meet patient's needs and patient is motivated.
      b. Refer to another program for detoxification and continue to manage the patient's rehabilitation needs through counseling and palliative medical care. ***(See extensive Substance Abuse Protocol)***

E. Sexual Dysfunction
   1. Identify cause: endocrine; substance abuse; cardiovascular
   2. Hypogonadism is more common than in general population.

3. Sildenafil (VIAGRA) may be used where indicated
    a. Concomitant use of the protease inhibitor RITONAVIR may substantially increase serum concentration of sildenafil (VIAGRA). Visual disturbances, decreased blood pressure, syncope, and prolonged erection were reported in volunteers exposed to high doses of sildenafil. <u>To decrease the chance of adverse events in patients on ritonavir, 25 mg dose of sildenafil is recommended.</u>
    b. Safe sex counseling must be discussed.

F. Cervical Cancer
    1. Consider initial screening within 1 yr of onset of sexual activity.
    2. Pap Q6mon x2, then annual if normal.
    3. HPV testing **alone** is not recommended for follow-up of abnormals

IX. Selected Situations for Referrals - See Referral Protocol
A. Karposi's sarcoma – ID, oncology
B. CMV retinitis - hospital
C. PCP, active - hospital or outpatient
D. TB, active - hospital or outpatient
E. MAC, active - hospital or outpatient
F. Change in mental status or new seizures - hospital
G. Severe Oral Candidiasis with Dysphagia - hospital or outpatient
H. Positive RPR - Local Health Department
I. Positive PPD & Positive chest x-ray - Local Health Dept and hospital
J. Pneumonia - hospital

X. Recommended Immunizations
A. Flu Vaccine - annual, inactivated only
B. Pneumonia Vaccine
    1. If no prior PPV23->Give PCV13->after 8wk or more give PPV23 (option to wait for CD4 ≥ 200 on ART before giving PPV23 dose).
    2. If PPV23 has been given->Give PCV13 after 1yr or more.
    3. Give 2nd PPV23 after 5 or more yr
C. Hepatitis A vaccine if chronic liver disease, IVDA, and MSM populations
D. Hepatitis B vaccine – preferably before CD4 falls to < 350
E. The following live vaccines may be used if otherwise indicated, only if CD4 > 200:
    1. MMR
    2. Varicella
    3. Zoster
    4. Yellow Fever

Table 3. Laboratory Monitoring Schedule for Patients Before and After Initiation of Antiretroviral Therapya (page 1 of 2) (Last updated February 12, 2013; last reviewed February 12, 2013)

	Entry into care	Follow-up before ART	ART initiation or modification[b]	Follow-up 2–8 weeks post-ART initiation or modification	Every 3–6 months	Every 6 months	Every 12 months	Treatment failure	Clinically indicated
HIV serology	√ If diagnosis has not been confirmed								
CD4 count	√	√ Every 3–6 months	√		√	In clinically stable patients with suppressed viral load, CD4 count can be monitored every 6–12 months (see text).		√	√
HIV viral load	√	√ Every 3–6 months	√	√[c]	√[d]			√	√
Resistance testing	√		√[e]					√	√
HLA-B*5701 testing			√ If considering ABC						
Tropism testing			√ If considering a CCR5 antagonist					√ If considering a CCR5 antagonist, or for failure of CCR5 antagonist-based regimen	√
Hepatitis B serology[f]	√		√ May repeat if HBsAg (-) and HBsAb (-) at baseline						√
Hepatitis C serology, with confirmation of positive results	√								√
Basic chemistry[g,h]	√	√ Every 6–12 months	√	√	√				√

Table 3. Laboratory Monitoring Schedule for Patients Before and After Initiation of Antiretroviral Therapya (page 2 of 2) (Last updated February 12, 2013; last reviewed February 12, 2013)

	Entry into care	Follow-up before ART	ART initiation or modification[b]	Follow-up 2–8 weeks post-ART initiation or modification	Every 3–6 months	Every 6 months	Every 12 months	Treatment failure	Clinically indicated
ALT, AST, T. bilirubin	√	√ Every 6–12 months	√	√	√				√
CBC with differential	√	√ Every 3–6 months	√	√ If on ZDV	√				√
Fasting lipid profile	√	√ If normal, annually	√	√ Consider 4–8 weeks after starting new ART regimen that affects lipids		√ If abnormal at last measurement	√ If normal at last measurement		√
Fasting glucose or hemoglobin A1C	√	√ If normal, annually	√		√ If abnormal at last measurement	√ If normal at last measurement			√
Urinalysis[g]	√		√			√ If on TDF[i]	√		√
Pregnancy test			√ If starting EFV						√

[a] This table pertains to laboratory tests done to select an ARV regimen and monitor for treatment responses or ART toxicities. Please refer to the HIV Primary Care guidelines for guidance on other laboratory tests generally recommended for primary health care maintenance of HIV patients.[1]

[b] ART may be modified for treatment failure, adverse effects, or regimen simplification.

[c] If HIV RNA is detectable at 2 to 8 weeks, repeat every 4 to 8 weeks until suppression to <200 copies/mL, then every 3 to 6 months.

[d] Viral load typically is measured every 3 to 4 months in patients on ART. However, for adherent patients with suppressed viral load and stable immunologic status for more than 2 to 3 years, monitoring at 6 month intervals may be considered.

[e] In ART-naive patients, if resistance testing was performed at entry into care, repeat testing before initiation of ART is optional. The exception is pregnant women; repeat testing is recommended in this case. For virologically suppressed patients who are switching therapy for toxicity or convenience, viral amplification will not be possible and therefore resistance testing should not be performed. Results from prior resistance testing can be used to help in the construction of a new regimen.

[f] If HBsAg is positive at baseline or before initiation of ART, TDF plus either FTC or 3TC should be used as part of the ARV regimen to treat both HBV and HIV infections. If HBsAg, and HBsAb, and anti-HBc are negative at baseline, hepatitis B vaccine series should be administered.

[g] Serum Na, K, HCO_3, Cl, BUN, creatinine, glucose (preferably fasting). Some experts suggest monitoring the phosphorus levels of patients on TDF. Determination of renal function should include estimation of CrCl using Cockcroft-Gault equation or estimation of glomerular filtration rate based on MDRD equation.

[h] For patients with renal disease, consult the Guidelines for the Management of Chronic Kidney Disease in HIV-Infected Patients: Recommendations of the HIV Medicine Association of the Infectious Diseases Society of America.[2]

[i] More frequent monitoring may be indicated for patients with evidence of kidney disease (e.g. proteinuria, decreased glomerular dysfunction) or increased risk of renal insufficiency (e.g., patients with diabetes, hypertension).

Acronyms: 3TC = lamivudine, ABC = abacavir, ALT = alanine aminotransferase, ART = antiretroviral therapy, AST = aspartate aminotransferase, CBC = complete blood count, CrCl = creatinine clearance, EFV = efavirenz, FTC = emtricitabine, HBsAb = hepatitis B surface antibody, HBsAg = hepatitis B surface antigen, HBV = hepatitis B virus, MDRD = modification of diet in renal disease (equation), TDF = tenofovir, ZDV = zidovudine

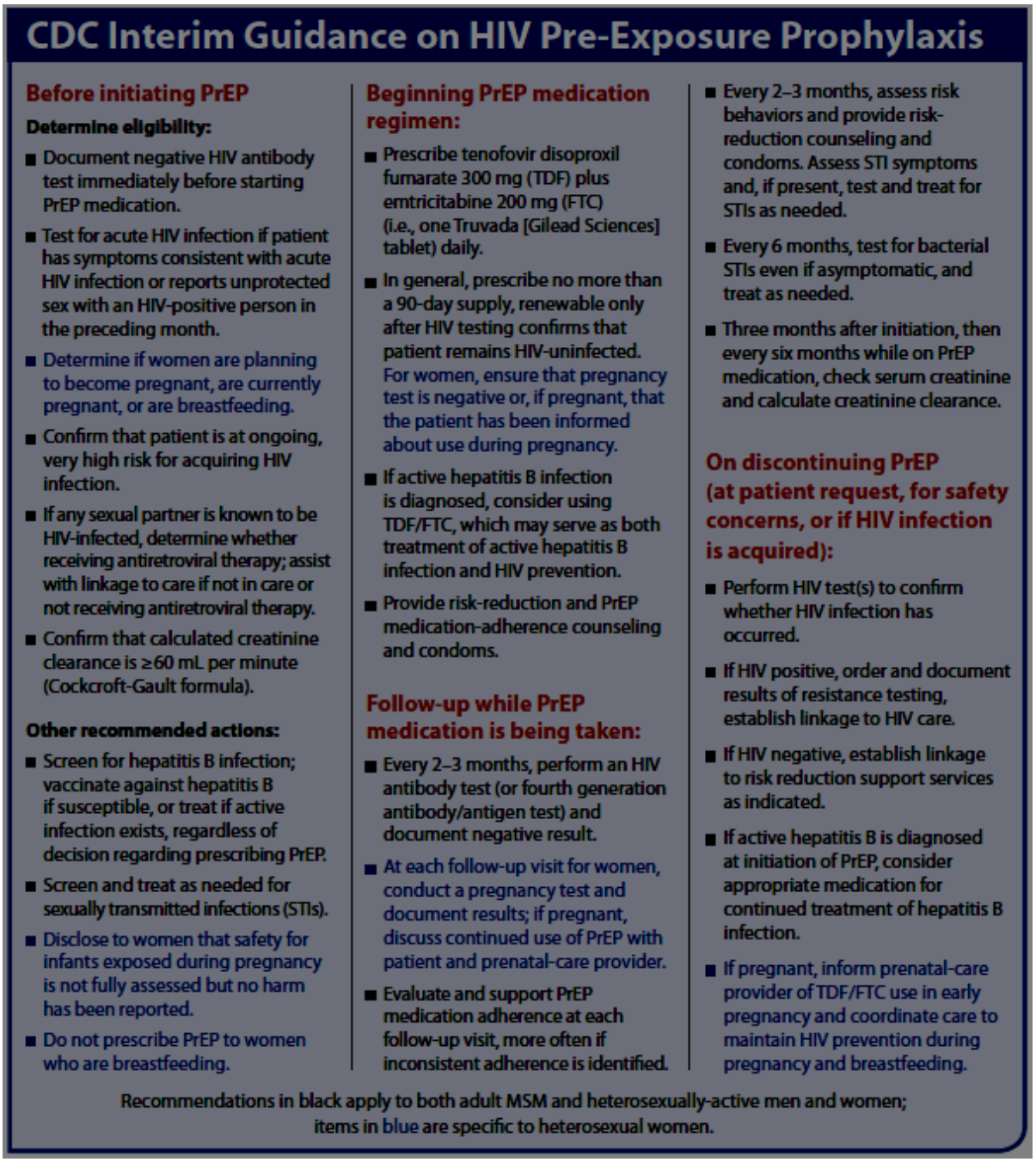
XI. Strategies to Improve Adherence to Antiretroviral Therapy

Table 12. Strategies to Improve Adherence to Antiretroviral Therapy

Strategies	Examples
Use a multidisciplinary team approach Provide an accessible, trusting health care team	• Nurses, social workers, pharmacists, and medications managers
Establish a trusting relationship with the patient	
Establish patient readiness to start ART	
Assess and simplify the regimen, if possible	
Identify potential barriers to adherence before starting ART	• Psychosocial issues • Active substance abuse or at high risk of relapse • Low literacy • Low numeracy • Busy daily schedule and/or travel away from home • Nondisclosure of HIV diagnosis • Skepticism about ART • Lack of prescription drug coverage • Lack of continuous access to medications
Provide resources for the patient	• Referrals for mental health and/or substance abuse treatment • Resources to obtain prescription drug coverage • Pillboxes
Involve the patient in ARV regimen selection	• For each option, review regimen potency, potential side effects, dosing frequency, pill burden, storage requirements, food requirements, and consequences of nonadherence
Assess adherence at every clinic visit	• Use a simple checklist that the patient can complete in the waiting room • Ensure that other members of the health care team also assess adherence • Ask the patient open-ended questions (e.g., *In the last 3 days, please tell me how you took your medicines.*)
Identify the type of nonadherence	• Failure to fill the prescription(s) • Failure to take the right dose(s) at the right time(s) • Nonadherence to food requirements
Identify reasons for nonadherence	• Adverse effects from medications • Complexity of regimen (pill burden, dosing frequency, etc.) • Difficulty swallowing large pills • Forgetfulness • Failure to understand dosing instructions • Inadequate understanding of drug resistance and its relationship to adherence • Pill fatigue • Other potential barriers
If resources allow, select from among available effective interventions	• See http://www.cdc.gov/hiv/topics/research/prs/ma-good-evidence-interventions.htm

Key to Abbreviations: ART – antiretroviral therapy; ARV – antiretroviral

XII. Pre-Exposure Prophylaxis



CDC Interim Guidance on HIV Pre-Exposure Prophylaxis

Before initiating PrEP

Determine eligibility:

- Document negative HIV antibody test immediately before starting PrEP medication.
- Test for acute HIV infection if patient has symptoms consistent with acute HIV infection or reports unprotected sex with an HIV-positive person in the preceding month.
- Determine if women are planning to become pregnant, are currently pregnant, or are breastfeeding.
- Confirm that patient is at ongoing, very high risk for acquiring HIV infection.
- If any sexual partner is known to be HIV-infected, determine whether receiving antiretroviral therapy; assist with linkage to care if not in care or not receiving antiretroviral therapy.
- Confirm that calculated creatinine clearance is ≥60 mL per minute (Cockcroft-Gault formula).

Other recommended actions:

- Screen for hepatitis B infection; vaccinate against hepatitis B if susceptible, or treat if active infection exists, regardless of decision regarding prescribing PrEP.
- Screen and treat as needed for sexually transmitted infections (STIs).
- Disclose to women that safety for infants exposed during pregnancy is not fully assessed but no harm has been reported.
- Do not prescribe PrEP to women who are breastfeeding.

Beginning PrEP medication regimen:

- Prescribe tenofovir disoproxil fumarate 300 mg (TDF) plus emtricitabine 200 mg (FTC) (i.e., one Truvada [Gilead Sciences] tablet) daily.
- In general, prescribe no more than a 90-day supply, renewable only after HIV testing confirms that patient remains HIV-uninfected. For women, ensure that pregnancy test is negative or, if pregnant, that the patient has been informed about use during pregnancy.
- If active hepatitis B infection is diagnosed, consider using TDF/FTC, which may serve as both treatment of active hepatitis B infection and HIV prevention.
- Provide risk-reduction and PrEP medication-adherence counseling and condoms.

Follow-up while PrEP medication is being taken:

- Every 2–3 months, perform an HIV antibody test (or fourth generation antibody/antigen test) and document negative result.
- At each follow-up visit for women, conduct a pregnancy test and document results; if pregnant, discuss continued use of PrEP with patient and prenatal-care provider.
- Evaluate and support PrEP medication adherence at each follow-up visit, more often if inconsistent adherence is identified.
- Every 2–3 months, assess risk behaviors and provide risk-reduction counseling and condoms. Assess STI symptoms and, if present, test and treat for STIs as needed.
- Every 6 months, test for bacterial STIs even if asymptomatic, and treat as needed.
- Three months after initiation, then every six months while on PrEP medication, check serum creatinine and calculate creatinine clearance.

On discontinuing PrEP (at patient request, for safety concerns, or if HIV infection is acquired):

- Perform HIV test(s) to confirm whether HIV infection has occurred.
- If HIV positive, order and document results of resistance testing, establish linkage to HIV care.
- If HIV negative, establish linkage to risk reduction support services as indicated.
- If active hepatitis B is diagnosed at initiation of PrEP, consider appropriate medication for continued treatment of hepatitis B infection.
- If pregnant, inform prenatal-care provider of TDF/FTC use in early pregnancy and coordinate care to maintain HIV prevention during pregnancy and breastfeeding.

Recommendations in black apply to both adult MSM and heterosexually-active men and women; items in blue are specific to heterosexual women.

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12. Individuals in Need of Substance Abuse Treatment

I. Identification & Definition of Substance Abuse Problem

A. Entrance into Program
1. According to DSM-IV criteria
2. Patient self-referral

B. Comprehensive History & Physical, focusing on:
1. Duration of substance abuse
2. General mental health
3. Presence of or Risk Factors for sexually transmitted &/or blood-born diseases
4. Identify "self-treatment" for underlying issues, e.g. depression, schizophrenia

C. Use of the Substance Abuse Protocol form including CAGE & MAST Tool.
1. Define duration of abuse
2. Drug(s) of abuse
3. Route of administration
4. Desire for treatment and rehabilitation
5. General tract for treatment method

D. Comprehensive Lab work & Other Diagnostic Work
1. Automated chemistry panel
2. Hepatitis diagnostic profile
3. Urine drug screens
4. HIV testing (with pre- and post-test counseling)
5. PPD skin test for TB (annually)
6. Chest x-ray if anergic (no reaction to controls)
7. STD screening, including syphilis serology

II. Detoxification Resources

A. In-house Resources
1. Primary care providers
2. Mental Health Department

B. Outside Out-patient Resources
1. Baltimore Recovery Center
2. Baltimore Addiction Services
3. Glenwood Life Counseling Center
4. Jones Falls Counseling Center
5. Outpatient Addiction Services at GBMC

C. Outside In-patient Resources
1. Baltimore Addiction Services
2. Mercy Hospital
3. Other local hospitals (for alcohol withdrawal)

III. Detoxification Plan for In-house Treatment

A. Tapering off abused substance - only possible with benzodiazepines (e.g.: Xanax, Ativan or Valium)
Gradual decrease of abused substance done by in-house primary care providers

B. Substitution for abused substance
1. Opiates (e.g.: heroin, morphine, demerol, percocet, etc.)
   a. Drug of choice for detoxification is clonidine
   b. Other drugs used for symptomatic relief
      i. Motrin for aches and pains
      ii. Doxepin for insomnia
      iii. Imodium for diarrhea
      iv. Bentyl for lower bowel cramps
      v. Zantac for stomach aches
2. Benzodiazepines (e.g.: Xanax, Valium)
   a. Drug of choice is Phenobarbital
   b. Primary care providers use an established conversion formula to establish dose
3. Stimulants (e.g.: cocaine)
   Drug of choice is a Tricyclic anti-depressant
4. Depressants (e.g.: alcohol)
   a. Drug of choice is Librium
   b. Consider tegretol taper (it is non-sedating)
   c. 5 days thiamine 100 mg PO QD and consider folic acid 1mg PO QD

IV. In-house Rehabilitation Services

A. Regular medical follow-up
1. Health maintenance
2. Periodic drug screening
3. Medications
   a. To aid sleep.
   b. To cope with pain
   c. To supplement diet

B. Mental Health follow-up
1. Individual therapy
2. Group therapy
3. Support groups

V. Outside Rehabilitation Services

A. Glenwood Life Counseling Center
B. Baltimore Addiction Services
C. Jones Falls Counseling Center
D Baltimore Recovery Center

E. Outpatient Addiction Services at GBMC

VI. Other Support Services

A Alcoholics Anonymous
B. Narcotics Anonymous

VII. Tracking & Aftercare

A. Primary care providers record all aspects of patient care in patient's chart
B. Evaluate and Assess patient progress at each visit
C. Review of client records weekly to:
   1. Ensure continuity of care
   2. Adherence to program protocols
   3. Assess and remind them that detox is not simply replacement (e.g. Suboxone or methadone)

D. Long-term follow-up
   1. Physical health by primary care providers
   2. Mental health by in-house department

Sample Screening Tool:

THE RAPID ALCOHOL PROBLEMS SCREEN (RAPS)

- Do you sometimes take a drink in the morning when you first get up?
- During the past year, has a friend or family member ever told you about things you said or did while you were drinking that you could not remember?
- During the past year, have you had a feeling of guilt or remorse after drinking?
- During the past year, have you failed to do what was normally expected of you because of drinking?
- During the past year, have you lost friends or girlfriends or boyfriends because of drinking?

NOTE: A positive answer to one of the questions is considered a positive test.
SOURCE: Adapted from Cherpitel 1995d.

The Rapid Alcohol Problems Screen (RAPS) asks questions similar as the CAGE test, but from a different perspective. One "yes" answer on the RAPS4 test indicates a possible alcohol abuse problem and the results have shown to be very accurate across gender and ethnic groups. (1997)

The RAPS4 Questions (2007)

The RAPS4 test has been found to be highly effective in detecting alcohol dependence in the past year across gender and ethnic groups-- white, black and Hispanic.

Research has also shown that the RAPS4 is more effective than the CAGE test, which has traditionally been the most widely used test in clinical settings.

The RAPS4 gets its name from the questions it poses to the patient which pertain to remorse (R), amnesia (A), performance (P), and starter drinking behavior (S). Each question pertains to the patient's behaviors in the past year.

1. Have you had a feeling of guilt or remorse after drinking?
2. Has a friend or a family member ever told you about things you said or did while you were drinking that you could not remember?
3. Have you failed to do what was normally expected of you because of drinking?
4. Do you sometimes take a drink when you first get up in the morning?

A "yes" answer to at least one of the four questions suggests that your drinking is harmful to your health and well-being and may adversely affect your work and those around you.
If you answered "no" to all four questions, your drinking pattern is considered safe for most people and your results do not suggest that alcohol is harming your health.

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13. Immunizations

The immediate goal of administering immunizations is the prevention of disease; the ultimate goal is eradication of disease. To accomplish these goals, physicians must maintain timely immunizations as a high priority in the care of children, adolescents, and adults. This is even more important in children in whom immunizations provide the best available defense against many dangerous childhood diseases. Physicians should ensure that the primary series of vaccinations are given before children are 2 years old in order for them to be protected during their most vulnerable period.

This protocol represents the current recommended Childhood Immunization Schedule from the American Academy of Pediatrics, the Center for Disease Control and the Maryland Department of Health and Mental Hygiene.

Primary Immunizations for Children Beginning Immunization Under 4 Months of Age

At Birth	Hep B[(1)]
2 Months	Hep B, DTaP[(2)], Hib[(4)], IPV[(5)], PCV [(8)], RV[(11)]
4 Months	DTaP, Hib, IPV, PCV, RV
6 Months	Hep B, DTaP, Hib, IPV, PCV, RV
12-15 Months	MMR[(6)], Var[(7)], DTaP, Hib, PCV, HepA[(10)]
18 Months	Hep A
4-6 Years	DTaP, IPV, MMR, Var
11-12 Years	TdaP[(3)], MCV4[(9)], HPV[(12)]
16 Years	MCV4

Primary Immunizations for Children Beginning Immunizations Between 4 Months and 6 Years of Age

First Visit (>/ 4 months of age)	DTaP, IPV, Hib, Hep B, PCV, RV Var, MMR and HepA should be given as soon as child is 12 months
Second Visit (1month after 1st visit)	DTaP, IPV, Hib[(4)], Hep B, RV
Third Visit (1 month after 2nd visit)	DTaP, IPV, Hib, PCV, RV

Fourth Visit (6 months after 3rd visit) DTaP, Hib, Hep B, PCV

Additional Visits (Age 4-6 years) DTaP[(2)], IPV[(5)], MMR, Var

Age 11-16 Years Tdap, MCV4, HPV

Immunization Schedule for Persons 7 Years of Age and Older Who Were Not Vaccinated at the Recommended Time in Early Infancy

First Visit Tdap, IPV, MMR, Hep B, Hep A Var[(7)]

Second Visit (6-8 weeks after 1st visit) Td[(3)], IPV, MMR, Hep B, Var

Third Visit (6 months after 2nd visit) Td, IPV, Hep B, Hep A

Additional Visits Tdap, MCV4, HPV (given once child is 11 years of age and older)

Notes

1) Hep B - All newborns should receive the first dose of Hep B vaccine at birth, before hospital discharge. Four doses of vaccine may be administered if combination vaccines are used. Children who have not previously received 3 doses of Hep B vaccines should initiate or complete the series. The second dose should be administrated at least 1 month after the first; the third dose should be at least 4 months after the first dose and at least 2 months after the second.

2) DTaP - DTaP should be used in children less than 7 years of age. Use DT pediatric vaccine when Pertussis vaccine is contraindicated. The fourth dose of DTaP can be given as early as 12 months of age if administered at least 6 months after the third dose of DTaP. If the fourth dose of DTaP is given after the fourth birthday, a fifth DTaP is not necessary.

3) Tdap (Td) - Td should be used for children 7 years of age and older. Tdap should be substituted for a single dose of Td in the primary catch up series. Give a Tdap dose to adolescents 11-18 years who have not previously received a dose. Boost every 10 years with Td. Administer one dose of Tdap to pregnant adolescents during each pregnancy(preferred during 27 through 36 weeks gestation) regardless of years from prior Td or Tdap vaccination.

4) Hib - Four doses may not be needed if the Hib series is begun late in infancy; one dose at ≥15 months of age precludes the need for more doses. If child is 5 years of age or older, Hib is not indicated.

5) IPV - If the third IPV is administered after the fourth birthday, a fourth dose is not necessary.

6) MMR - MMR should be administered on or after the first birthday. The second dose of MMR is routinely recommended at 4-6 years of age. It may be administered at any visit >/12 months of age, provided at least 1 month has elapsed since receipt of first dose.

7) Var - Varicella may be administered to susceptible children, i.e. those who lack a reliable history of chicken pox disease, at any time at or after the first birthday. A second dose of varicella is recommended routinely at 4-6 years. Give a routine second dose to all older children and adolescents with history of only one dose.

8) PCV - PCV13 has replaced PCV7. PCV13 is recommended as a series of 4 doses at 2, 4, 6 and 12-15 months of age. If the first dose is administered at 2-6 months of age, 4 doses should be given. All additional doses can be given at least 6 weeks apart. If the first dose is given at 7-11 months of age, 3 doses are recommended. For immunization beginning at 12-23 months, 2 doses are required. If the vaccine is given after 24 months, only one dose is necessary. Children who have begun the series with PCV7 should complete it with PCV 13. Children< 5 years of age who have completed the series with PCV7 should get one additional dose of PCV13. Pneumococcal vaccine is recommended for children at moderate to high risk of invasive pneumococcal disease up to 59 months of age. This vaccine is not required for children > 5 years of age.

9) MCV4 - MCV4 is recommended for 11-12 years with a booster dose at 16 years. MCV4 may be given to younger children at high risk for invasive disease.

10) Hepatitis A - Hepatitis A vaccine is recommended for all children 12-23 months of age. Two doses should be administered, given at least 6 months apart. Older unvaccinated children should be vaccinated.

11) RV - The Rotavirus (Rotateq) vaccine is recommended for all children between 6 and 12 weeks of age. Do not start the series later than 14 weeks, 6 days. All three doses should be received by 32 weeks of age. Do not administer after 32 weeks. The doses should be administered at 4 to 10 week intervals. The two dose vaccine (Rotarix) should be administered at 2 and 4 months.

12) HPV- Two HPV vaccines are available: a quadrivalent vaccine (Gardasil) for cervical, oral, and anal cancer and genital warts and a bivalent vaccine (Cervarix) for prevention of cervical cancer. Administer the Human Papilloma Vaccine to adolescent females and males 11 years of age and older. Three doses should be administered with the second dose given at least 2 months after the first and the third dose at least 6 months after the first. Gardasil should be administered to males.

13) The seasonal influenza vaccine is recommended for all children 6 months of age and older. Children under 9 years who are receiving that vaccine for the first time should receive 2 doses, 4 weeks apart. Healthy children 2 years and older may receive the live attenuated influenza vaccine (Flumist).

Recommended Adult Immunizations

Adults 19 years and older should receive the following vaccines if age appropriate or because of medical conditions or risk factors:

Influenza vaccine
Tdap/Td vaccine
Varicella vaccine
HPV vaccine
Herpes Zoster vaccine
MMR vaccine
Pneumococcal vaccine (PPSV23 and PCV13)
Meningococcal vaccine
Hep A vaccine
Hep B vaccine

Notes

1) The influenza vaccine is recommended for all adults. Adults younger than 50 years without high risk medical conditions may receive the intranasal live attenuated influenza vaccine.

2) Administer a 1-time dose of Tdap to all adults who have not received Tdap previously. Administer one dose of Tdap to pregnant women during each pregnancy(preferred during 27-36 weeks gestation), regardless of number of years since prior Td or Tdap vaccination. Boost with Td every 10 years.

3) All adults without evidence of immunity to varicella should receive 2 doses of the varicella vaccine unless medically contraindicated.

4) HPV vaccination with either quadrivalent (HPV4) or bivalent(HPV2) is recommended for females and males up to 26 years.

5) A single dose of zoster vaccine is recommended for adults 60 years or older.

6) Adults born before 1957 generally are considered immune to measles and mumps. All adults born in 1957 or later who lack documentation of measles, mumps or rubella immunity should receive 2 doses of MMR vaccine unless contraindicated.

7) Vaccinate all persons with PPSV23 with the following indications: Chronic lung disease, chronic cardiovascular disease, diabetes mellitus, chronic alcoholism, chronic liver disease, chronic renal failure, functional or anatomic asplenia and immunocompromising conditions. Vaccinate all adults aged 65 and older.

8) Adults aged 19 years or older with immunocompromising conditions including chronic renal failure, functional or anatomic asplenia, and who have not previously received PCV13 or PPSV23 should receive a single dose of PCV13 followed by a dose of PPSV23 at least 8 weeks later. Adults aged 19 or older with the aforementioned conditions who have previously

received one dose of PPSV23 should receive a dose of PCV13 one or more years after the last PPSV23 dose was received.

9) Meningococcal vaccine should be administered to adults with anatomic or functional asplenia, complement deficiencies or HIV infection.

10) Vaccinate any person seeking protection from hepatitis A and those with the following indications: men who have sex with men, intravenous drug users or persons with chronic liver disease.

11) Vaccinate any person seeking protection from hepatitis B or any person with the following indications: health care personnel, diabetics, persons with HIV, end-stage renal disease or chronic liver disease, sexually active persons not in long term monogamous relationships, men who have sex with men and intravenous drug users.

Vaccine abbreviations:
Hep B - hepatitis B
Hep A - hepatitis A
DTaP - diphtheria and tetanus toxoids and acellular pertussis
Td - tetanus toxoid (full dose) and diphtheria toxoid (reduced dose)
Tdap - tetanus and diptheria toxoids and acellular pertussis
Hib - haemophilus influenza type B conjugate
IPV - inactivated poliovirus
MMR - measles, mumps, rubella
Var - varicella
PCV - pneumococcal conjugate vaccine
MCV4 - meningococcal conjugate vaccine
HPV - human papilloma vaccine
PPSV- pneumococcal polysaccharide vaccine

Written By:
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Sources:

1. *Advisory Committee on Immunization Practices(ACIP) Recommended Immunization Schedule for Persons Aged 0 through 18 Years- Unites States, 2013, Morbidity and Mortality Weekly Report MMWR February 1,,2013/62(01);2-8*
2. *Advisory Committee on Immunization Practices(ACIP) Recommended Immunization Schedule for Adults Aged 19 Years and Older _ United States, 2013, Morbidity and Mortality Weekly Report MMWR February 1,2013/62(01); 9-19*

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14. Pediatric and Adult Asthma

Asthma is a chronic disease whose prevalence, morbidity, and mortality have continued to increase despite our understanding of its pathophysiology and the development of new pharmacologic agents. The highest incidence is in the pediatric population, where it affects approximately 7% of children, yet a large population of adults also struggles with asthma. Additionally, asthma is a leading cause of pediatric emergency room visits and hospitalizations.

This protocol represents updated guidelines on the diagnosis and management of asthma. It also revises the asthma severity classification and recommendation therapy.

I. At the initial visit, a comprehensive history and physical examination should be performed. Essential elements of the history that should be documented include:
1. Symptom frequency during both the day and the night
2. Precipitating triggers of symptoms
3. Pattern and frequency of medication used to control symptoms
4. Age of onset of wheezing
5. # of E.R. visits and hospitalizations for asthma exacerbations
6. # of days absent from school/work
7. Family history of asthma
8. Interference with normal activity
9. Exacerbations requiring oral systemic corticosteroids
10. Screen for GERD
11. Smoking history/environmental tobacco smoke exposure

II Diagnosis of asthma:
1. Presence of recurrent symptoms of airway obstruction by history/exam.
   a. Recurrent cough, wheezing, chest tightness, difficulty breathing.
   b. Symptoms occur/worsen at night, with exercise/URI/allergen exposure/stress
2. In all patients ≥ 5, use spirometry to document at least partial reversibility of airway obstruction
3. Consider other causes of obstruction

III. Pulmonary function testing should be done in any child able to perform reliable (usually 5 years and older):
1. Peak flow measurement
   OR
2. Spirometry

IV. The severity of asthma should be classified:
1. Intermittent -Daytime symptoms ≤ 2 times per week
   -Nighttime symptoms ≤ 2 times per month
   -FEV1 or PEF ≥ 80% predicted

2. Mild Persistent -Daytime symptoms > 2 times per week

-Nighttime symptoms - 3-4 times per month
-FEV1 or PEF ≥ 80% predicted

3. Moderate Persistent -Daily symptoms
-Nighttime symptoms > 1 time per week, but not nightly
-FEV1 or PEF > 60% but < 80% predicted

4. Severe Persistent -Continuous symptoms
-Often or nightly nighttime symptoms
-FEV1 or PEF ≤ 60% predicted

V. Step-wise approach to pharmacologic management **(First check adherence to medications, appropriate inhaler technique, environmental triggers, and comorbidities)**:

1. Intermittent -Short acting Beta 2 Agonists

2. Mild Persistent -Short acting Beta 2 Agonists
-Low doses of Inhaled Corticosteroids (preferred)
-Leukotriene Modifiers (alternative)

3. Moderate Persistent -Short acting Beta 2 Agonists
-Inhaled Corticosteroids (medium dose)
-± long acting Beta 2 Agonists (preferred)
-± Leukotriene Modifiers (alternative)

4. Severe Persistent -Short acting Beta 2 Agonists
-Inhaled Corticosteroids (high doses)
-+ long acting Beta 2 Agonists
-Consider Oral Corticosteroids
-Consult asthma specialist

5. Step down if possible - if asthma has been well controlled for at least three months.

VI. Care Management:

< Educate on disease process, medication use, inhaler/spacer technique, and peak flow monitoring; offer educational handouts on asthma, available in each physician office.
< Develop an individualized Asthma Care Plan with the patient, reviewing treatment goals, self-monitoring results, medication lists, and barriers to meeting goals at each visit. One copy of the Asthma Care Plan should go home with the patient and one copy should be retained in the chart behind the Wellness Plan. The patient should be instructed to bring the Asthma Care Plan back with them to subsequent office visits with self-monitoring results recorded in the appropriate section and progress towards goals should be assessed. Asthma Care Plans should be reviewed at each appropriate visit and up-dated as necessary to improve asthma control and patient adherence.
< Discuss avoidance of environmental triggers, including tobacco smoke

- < Stress importance of follow-up visits
- < Need for compliance to minimize exacerbations and improve quality of life
- < Document patient's/family's understanding of disease process and management.

VII. Follow Up:

- < Visit PCP at least every 3 months
- < Complete history and physical annually
- < Complete Asthma Flowsheet at least once annually, more frequently if asthma status is changing
- < Review the Asthma Care Plan at least annually after it is initially completed with the patient. Updates to the Asthma Care Plan can be made more frequently if asthma status is changing
- < Review control of symptoms; modify medications if necessary; re-discuss asthma action plan; monitor growth and quality of life
- < If the patient is achieving good outcomes, document this in continuation notes
- < Track # of acute asthma episodes: office and ER visits and hospitalizations
- < Annual influenza vaccine recommended, and for adults19-64 years of age, a single pneumococcal polysaccharide vaccination is recommended.

VIII. Please note: HEDIS quality assurance guidelines require Rx of a controller medication for persistent asthma if:

1. Prescribing asthma medication on four occasions

OR

2. Two outstanding asthma visits and two asthma medications prescribed

OR

3. One emergency room visit for asthma

OR

4. One hospitalization for asthma

Written by:
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Sources:

1. Kwong, K. and Jones, C. 1999. Chronic asthma therapy. Pediatrics in Review, 20: 327-333.
2. Demper, K. 1997. A practical approach to chronic asthma management. Contemporary Pediatrics. 14: 86-111.
3. US Department of Health and Human Services. 1997. National Asthma Education and Prevention Program: Expert Panel Report II: Guidelines for the Diagnosis and Management of Asthma, 97:4051.
4. NIH Asthma Guidelines obtained from www.nhlbi.nih.gov/guidelines/asthma/index.com, 3/8/11, Revised Sept, 2012

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15. LYME DISEASE

Lyme Disease

Lyme disease was first recognized in the United States in 1975, after a **mysterious outbreak of arthritis near Lyme, Connecticut.** Since then, reports of Lyme disease have increased dramatically, and the disease has become an important public health problem in some areas of the United States.

Lyme disease is an infection caused by the corkscrew-shaped bacterium *Borrelia burgdorferi,* a member of the family of spirochetes.

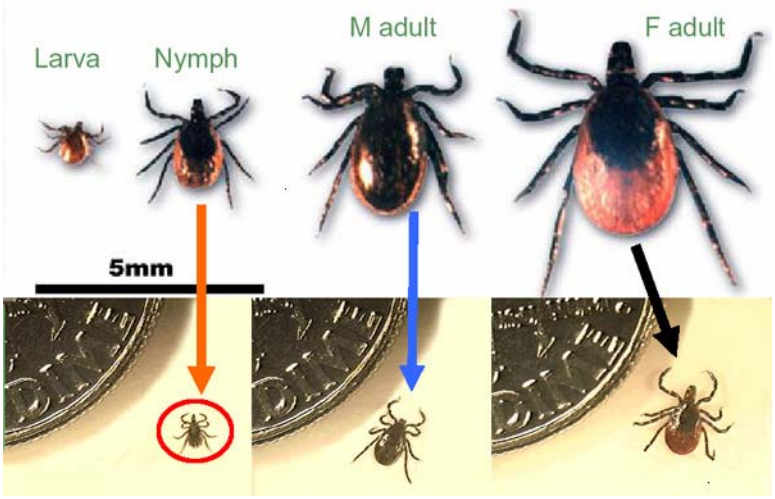
How Ticks Spread the Disease

The bite of ticks spreads the bacterium that causes Lyme disease. The black-legged deer tick, *Ixodes scapularis,* which normally feeds on the white-footed mouse, the white-tailed deer, other mammals, and birds, is responsible for transmitting Lyme disease bacteria to humans in the northeastern and north-central United States.

Nymphal ticks are the primary source for transmitting Lyme disease bacteria to humans, probably because nymphs are more likely to feed on people and are rarely noticed because they are tiny, less than 2mm. Thus, nymphs have the necessary time to feed and transmit the bacteria, typically after feeding for 2 or more days, but it can happen more quickly. Also, nymphal ticks feed during the spring and summer months when people spend the most time outdoors.

Ticks can attach to any part of the human body but are often found in hard places to see and hairy areas such as the groin, armpits, and scalp. In many cases, the tick must be attached for 48 hours or more before the bacteria can be transmitted. Not all deer ticks are infected with the bacteria that cause Lyme disease, and only a small percentage of people bitten by deer ticks actually become sick.

Ixodes ticks are much smaller than the common dog or cattle ticks. In their larval and nymphal stages, they are no bigger than the eye of a common sewing needle. Adult ticks are larger, about the size of a small apple seed.



Adult ticks can also transmit the bacteria, but because adult ticks are larger and more noticeable, they are more likely to be removed from a person's body within a few hours, and therefore are less likely to have sufficient time to transmit the bacteria. Moreover, adult *Ixodes* ticks are most active during the cooler months of the year, when people spend less time outdoors and additional clothing may provide added protection.

Ticks search for host animals from the leaf litter of the forest floor, especially during the nymph stage, or from the tips of grasses and shrubs, during the adult stage, and crawl onto animals or persons they contact. Ticks found on the scalp usually have crawled there from the lower parts of the body. Ticks can feed on blood by inserting their mouthparts into the skin of a person or animal. They are slow feeders: a complete blood meal can take several days. As they feed, their bodies slowly enlarge.

Campers, hikers, outdoor workers, and others are commonly exposed to ticks when frequenting wooded, brushy, and grassy places. People living in houses built in wooded areas where infected ticks are common may also have increased exposure to the Lyme disease bacteria. The risk of exposure to ticks is greatest in the woods and in the edge area between lawns and woods of properties, but ticks can also be carried by animals into lawns and gardens.

Geographic Distribution

Lyme disease has a wide distribution in northern temperate regions of the world. In the United States, the highest incidence occurs in the following regions:

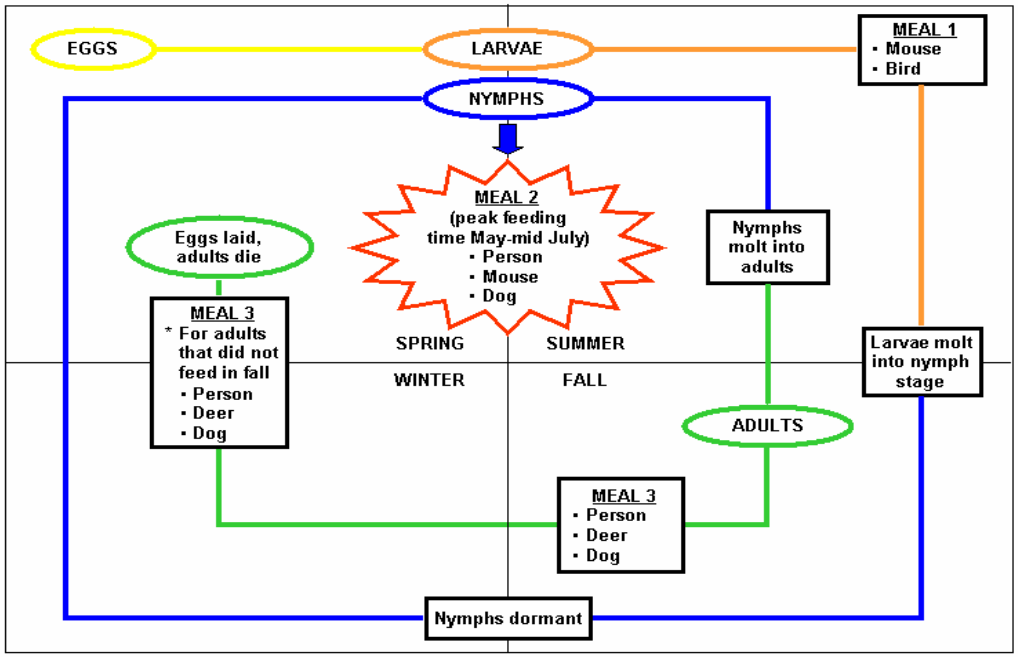
- Northeast, from Massachusetts to Maryland
- North-central states, mostly limited to Wisconsin and Minnesota
- West coast, particularly northern California

For Lyme disease to exist in an area, three closely interrelated elements must be present in the natural environment: (1) animals that carry Lyme disease bacteria, (2) ticks that can transmit the bacteria, and (3) mammals, such as mice and deer, that provide food for

the ticks in their various life stages. In highly endemic areas, as many as 50 percent of deer ticks may carry Lyme disease bacteria (Borrelia burdorferi).

Life Cycle of Ticks That Cause Lyme Disease

Knowing the complex life cycle of the ticks that transmit Lyme disease bacteria is important in understanding the risk of getting Lyme disease and in preventing it.



The life cycle of the deer tick requires 2 years to complete. Adult ticks feed and mate on large animals, especially deer, in the fall and early spring. Female ticks then drop off of these animals to lay eggs on the ground. By summer, eggs hatch into larvae.

Larvae feed on mice and other small mammals and birds in the summer and early fall. The larvae are inactive until the next spring when they change into nymphs.

Nymphs feed on small rodents and other small mammals and birds in the late spring and summer and molt into adults in the fall, completing the 2-year life cycle.

Larvae and nymphs typically become infected with Lyme disease bacteria when they feed on small animals infected with Lyme bacteria, particularly the white-footed mouse. The bacteria remain in the tick as it changes from larva to nymph to adult. Infected nymphs and adult ticks then bite and transmit Lyme disease bacteria to other small rodents, other animals, and humans.

Lyme Disease in Domestic Animals

Domestic animals may become infected with Lyme disease bacteria and some of these animals; dogs for instance, may develop arthritis. Domestic animals can carry infected ticks into areas where humans live. Studies of a possible increased risk of Lyme disease among pet owners is inconclusive.

Symptoms and Signs of Lyme Disease

Early Lyme Disease: The early stages of Lyme disease is usually marked by one or more of the following symptoms and signs:

- Fatigue
- Chills and fever
- Headache
- Muscle and joint pain
- Swollen lymph nodes
- A characteristic skin rash shaped like a bull's eye, called erythema migrans

Erythema migrans rash is a red circular patch that appears at the site of the tick bite usually within 3 days to 1 month after the bite of an infected tick. The patch then grows larger. Sometimes many patches appear, in varying shapes and sizes, depending on their location. Common sites are the thighs, groin, trunk, and armpits. The center of the rash may clear as it enlarges, resulting in a "bull's-eye" appearance. The rash may be warm, but it usually is not painful. However, not all rashes that occur at the site of a tick bite are due to Lyme disease. An allergic reaction to tick saliva often occurs at the site of a tick bite. The resulting allergic reaction rash can be confused with the rash of Lyme disease. Allergic reactions to tick saliva occur within hours after the tick bite, usually do not expand, and disappear within a few days.

Late Lyme Disease: Some symptoms and signs of Lyme disease may not appear until weeks, months, or years after a tick bite:

- Arthritis is most likely to appear as brief bouts of pain and swelling, usually in one or more large joints, especially the knees.
- Nervous system abnormalities can include numbness, pain, nerve paralysis (often of the facial muscles), and meningitis (fever, stiff neck, and severe headache).
- Pericarditis.
- In some persons the rash never appears; in some, the first and only sign of Lyme disease is arthritis, and in others, nervous system problems are the only evidence of Lyme disease.

Lyme Disease and Pregnancy

Rarely, Lyme disease acquired during pregnancy may lead to infection of the placenta and possibly to stillbirth, but studies of women infected during pregnancy have found no

adverse effect to the fetus when the mother received appropriate treatment for her Lyme disease. Please see the Antibiotic Section for the appropriate treatment of pregnant women.

Diagnosis

Many of the symptoms of Lyme disease are similar to those of other diseases. The fever, muscle aches, and fatigue of Lyme disease can be mistaken for viral infections, such as influenza or infectious mononucleosis. Joint pain can be mistaken for other types of arthritis, such as rheumatoid arthritis, and neurologic signs can mimic those caused by other conditions, such as multiple sclerosis. On the other hand, other types of infections, arthritis, or neurologic disease can be misdiagnosed as Lyme disease.

Diagnosis of Lyme disease should take into account the following:

- History of possible exposure to ticks in areas where Lyme disease is known to occur,
- Symptoms and signs of the illness, and
- The results of blood tests used to detect whether the patient has antibodies to the Lyme disease bacterium.

Laboratory tests for Lyme disease must be interpreted in relation to the patient's clinical presentation. Both false-positive and false-negative test results may occur. Two tests that measure the body's production of antibodies to the Lyme disease bacterium are recommended: (1) an enzyme-linked immunosorbent assay, ELISA, or indirect immunofluorescence assay, IFA, followed by (2) a Western immunoblot of positive or equivocal samples. These tests do not detect infection until the body begins to produce detectable levels of antibodies to Lyme disease bacteria, usually 2-4 weeks after an infected tick bite. Even then, however, the tests aren't entirely foolproof. History and physical findings become ever so important.

Treatment and Prognosis

Lyme disease is treated with antibiotics. Several antibiotics are effective and are usually given by mouth but may be given intravenously in more severe cases. Patients treated in the early stages with antibiotics usually recover rapidly and completely. Most patients who are treated in later stages of the disease also respond well to antibiotics. A few patients who are treated for Lyme disease may have persistent or recurrent symptoms, and may require additional antibiotic treatment. Varying degrees of permanent damage to joints or the nervous system can develop in patients with late chronic Lyme disease. Typically these are patients in whom Lyme disease was unrecognized in the early stages or for whom the initial treatment was unsuccessful.

Antibiotics

Antibiotic	Adults	Children	Duration
Early Infection Lyme Disease (Local and Disseminated)			
Doxycycline (Vibramycin)	PO: 100 mg bid	2-4 mg/kg/d in two divided doses	14 to 21 days
Amoxicillin	PO: 500 mg tid	40-50 mg/kg/d in three divided doses	14 to 21 days
Cefuroxime axetil (Ceftin)	PO: 500 mg bid	30 mg/kg/d in two divided doses	14 to 21 days
Arthritis			
Doxycycline	PO: 100 mg bid	2-4 mg/kg/d in two divided doses	28 days
Amoxicillin	PO: 500 mg tid	40-50 mg/kg/d in three divided doses	28 days
Pregnant Women and Nursing Mothers			
Amoxicillin*	PO: 500 mg tid	40-50 mg/kg/d in three divided doses	14 to 21 days

*No medication is absolutely safe during pregnancy, therefore the physician should consult with the obstetrician before beginning any treatment. Doxycyline has toxic effects on the development of bone in the fetus. Doxycycline is not recommended for pregnant women and nursing mothers unless there is no other appropriate antibiotic available.

Other Forms of Lyme Disease Such as Late Arthritis, Pericarditis, and Meningitis

Please refer to Conn's Current Therapy 2009 or other up-to-date reliable source.

Prevention

Tick Control: Removing leaves, leaf litter, and clearing brush around houses and at the edges of lawns may reduce the numbers of ticks that transmit Lyme disease. This is particularly important in the eastern United States, where most transmissions of Lyme disease are thought to occur near the home.

A relationship exists between the abundance of deer and the abundance of *Ixodes* ticks in the eastern United States.

Reducing and managing deer populations in geographic areas where Lyme disease occurs can reduce tick abundance. Removing plants that attract deer and constructing physical barriers may help discourage deer from coming near homes.

Personal Protection From Tick Bites

You can decrease the chance of being bitten by a tick by following a few precautions.

- Avoid tick-infested areas, especially in May, June, and July. Many local health departments and park or extension services have information on the local distribution of ticks.

- Wear light-colored clothing so that you can spot ticks more easily.
- Tuck pant legs into socks or boots and shirt into pants.
- Tape the area where pants and socks meet so that ticks cannot crawl under clothing.
- Wear a long-sleeved shirt for added protection.
- Spray insect repellent containing a 20-30% concentration of DEET on clothes and on exposed skin other than the face, or treat clothes, especially pants, socks, and shoes, with permethrin, which kills ticks on contact.
- Walk in the center of trails to avoid contact with over-grown grass and brush at trail edges.

Removal of Ticks

After being outdoors, remove your clothing and wash and dry it at a high temperature: inspect your body carefully and remove attached ticks with tweezers, grasping the tick as close to the skin surface as possible and pulling straight back with a slow steady force: avoid crushing the tick's body.

Preventive Antibiotic Treatment

A controlled study has demonstrated that a single dose of 200 mg of Doxycycline effectively prevents Lyme disease if given within 72 hours of a tick bite. Physicians must determine whether the benefits of using antibiotics outweigh the risks in any particular instance.

Lyme Disease Vaccine

The LYMErix vaccine has been withdrawn, after studies showed it to be ineffective in some cases and to occasionally cause Lyme disease and/or potentially harmful side effects. There are no other vaccines available for Lyme disease at this time. However, research on new vaccines against Lyme disease continues.

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Updated by:
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Sources:
1. Centers for Disease Control and Prevention
2. National Center for Infectious Diseases
3. Division of Vector-Bourne Infectious Diseases
4. Mayo Clinic
5. Conn's Current Therapy 2009

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16. INDIVIDUALS WITH DIABETES MELLITUS

Diabetes is a chronic illness that requires continuing medical care and patient self-management education to prevent acute complications and to reduce the risk of long-term complications.

Classification

In 1997, the ADA issued new diagnostic and classification criteria; in 2003, modifications were made regarding the diagnosis of impaired fasting glucose (IFG). The classification of diabetes includes four clinical classes:

- **Type 1 diabetes** (results from ß-cell destruction, usually leading to absolute insulin deficiency).
- **Type 2 diabetes** (results from a progressive insulin secretory defect on the background of insulin resistance).
- Other specific types of diabetes (secondary to other causes, e.g., genetic defects in ß-cell function, genetic defects in insulin action, diseases of the exocrine pancreas, drug or chemical induced).
- Gestational diabetes mellitus (GDM) (diagnosed during pregnancy).

Diagnosis

Criteria for Diagnosis

i. Type 1 typically present with acute symptoms of diabetes and markedly elevated blood glucose levels
ii. Type 2

A1C $\geq$6.5%	The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.*
OR	
FPG $\geq$126mg/dl (7.0mmol/l)	Fasting is defined as no caloric intake for at least 8 hours.*
OR	
2-h plasma glucose $\geq$200mg/dl (11.1mmol/l) during an OGTT.	The test should be performed as described by the WHO, using a glucose load containing the equivalent of 75g anhydrous glucose dissolved in water.*
OR	
Random plasma glucose $\geq$200mg/dl (11.1mmol/l)	In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis

*In the absence of unequivocal hyperglycemia, criteria 1-3 should be confirmed by repeat testing

iii. Pre-diabetes includes impaired fasting glucose (IFG) and impaired glucose tolerance (IGT). Both categories are risk factors for future diabetes and cardiovascular disease (CVD). Modest weight loss and regular physical activity can reduce the rate of progression to Type 2 diabetes:
   - IFG = FPG 100 – 125 mg/dl
   - IGT = 2-h plasma glucose 140 0 199 mg/dl
   - Hga1c 5.7 –6.4%

iv. Gestational diabetes

Detection and diagnosis of Gestational Diabetes Mellitus

Risk assessment for GDM should be undertaken at the first prenatal visit. Women with clinical characteristics consistent with a high risk for GDM (those with marked obesity, personal history of GDM, glycosuria, or a strong family history of diabetes) should undergo glucose testing as soon as possible. An FPG ≥126 mg/dl or a casual plasma glucose ≥200 mg/dl meets the threshold for the diagnosis of diabetes and needs to be confirmed on a subsequent day unless unequivocal symptoms of hyperglycemia are present. High-risk women not found to have GDM at the initial screening and average-risk women should be tested between 24 and 28 weeks of gestation. Testing should follow one of two approaches:

Screening for and diagnosis of GDM

Perform a 75-g OGTT ,with plasma glucose measurement fasting and at 1 and 2h, at 24-48 weeks of gestation in women not previously diagnosed with overt diabetes	
The OGTT should be performed in the morning after an overnight fast of at least 8h	
The diagnosis of GDM is made when any of the following plasma glucose values are exceeded	
	Fasting: ≥92 mg/dl (5.1 mmol/l)
	1h: ≥180 mg/dl (10.0 mmol/l)
	2h: ≥153 mg/dl (8.5 mmol/l)

- One-step approach: perform a diagnostic 100-g OGTT
- Two-step approach: perform an initial screening by measuring the plasma or serum glucose concentration 1 h after a 50-g oral glucose load (glucose challenge test [GCT]) and perform a diagnostic 100-g OGTT on that subset of women exceeding the glucose threshold value on the GCT.
- Diagnostic criteria for the 100-g OGTT are as follows: ≥95 mg/dl fasting, ≥180 mg/dl at 1 h, ≥155 mg/dl at 2 h, and ≥140 mg/dl at 3 h. Two or more of the plasma glucose values must be met or exceeded for a positive diagnosis. The test should be done in the morning after an overnight fast of 8–14 h.
- Low-risk status requires no glucose testing, but this category is limited to those women meeting all of the following characteristics:

- Age <25 years.
- Weight normal before pregnancy.
- Member of an ethnic group with a low prevalence of GDM.
- No known diabetes in first-degree relatives.
- No history of abnormal glucose tolerance.
- No history of poor obstetric outcome.

Screening

Generally, people with type 1 diabetes present with acute symptoms of diabetes and markedly elevated blood glucose levels. Type 2 diabetes is frequently not diagnosed until complications appear, and approximately one-third of all people with diabetes may be undiagnosed. Criteria for testing for diabetes in asymptomatic, undiagnosed adults are listed in below. The recommended screening test for non-pregnant adults is the FPG. The OGTT is more sensitive for the diagnosis of diabetes and pre-diabetes, but is impractical and expensive as a screening procedure.

Criteria for testing for diabetes in asymptomatic adult individuals

1. Testing for diabetes should be considered in all individuals at age 45 years and above, particularly in those with a BMI > 25 kg/m^2, and, if normal, should be repeated at 3-year intervals.
2. Testing should be considered at a younger age or be carried out more frequently in individuals who are overweight (BMI > 25 kg/m^2) and have additional risk factors:
    - are habitually physically inactive
    - have a first-degree relative with diabetes
    - are members of a high-risk ethnic population (e.g., African American, Latino, Native American, Asian American, Pacific Islander)
    - have delivered a baby weighing >9 lb or have been diagnosed with GDM
    - are hypertensive (>140/90 mmHg)
    - have an HDL cholesterol level < 35 mg/dl and/or a triglyceride level > 250 mg/dl
    - have PCOS
    - on previous testing, had IGT or IFG
    - have other clinical conditions associated with insulin resistance (e.g. PCOS or acanthosis nigricans)
    - have a history of vascular disease

Evaluation

Complete medical evaluation should be performed to classify the patient, detect the presence or absence of diabetes complications, assist in formulating a management plan, and provide a basis for continuing care. If the diagnosis of diabetes has already been made, the evaluation should review the previous treatment and the past and present degrees of glycemic control. Laboratory tests appropriate to the evaluation of each patient's general medical condition should be performed.

Components of the comprehensive diabetes evaluation

Medical history

- Symptoms, results of laboratory tests, and special examination results related to the diagnosis of diabetes
- Prior A1C records
- Eating patterns, nutritional status, and weight history; growth and development in children and adolescents
- Details of previous treatment programs, including nutrition and diabetes self-management education, attitudes, and health beliefs
- Current treatment of diabetes, including medications, meal plan, and results of glucose monitoring and patients' use of data
- Exercise history
- Frequency, severity, and cause of acute complications such as ketoacidosis and hypoglycemia
- Prior or current infections, particularly skin, foot, dental, and genitourinary infections
- Symptoms and treatment of chronic eye, kidney, nerve, genitourinary (including sexual), bladder, and gastrointestinal function (including symptoms of celiac disease in type 1 diabetic patients), heart, peripheral vascular, foot, and cerebrovascular complications associated with diabetes
- Other medications that may affect blood glucose levels
- Risk factors for atherosclerosis: smoking, hypertension, obesity, dyslipidemia, and family history
- History and treatment of other conditions, including endocrine and eating disorders
- Assessment for mood disorder
- Family history of diabetes and other endocrine disorders
- Lifestyle, cultural, psychosocial, educational, and economic factors that might influence the management of diabetes
- Tobacco, alcohol, and/or controlled substance use
- Contraception and reproductive and sexual history

Physical examination

- Height and weight measurement (and comparison to norms in children and adolescents)
- Sexual maturation staging (during pubertal period)
- Blood pressure, including orthostatic measurements when indicated, and comparison to age-related norms
- Fundoscopic examination
- Oral examination
- Thyroid palpation
- Cardiac examination
- Abdominal examination (e.g., for hepatomegaly)
- Evaluation of pulses by palpation and with auscultation
- Hand/finger examination
- Foot examination, including evaluation of dorsalis pedis pulses, monofilament sensation, and reflexes)
- Skin examination (for acanthosis nigricans and insulin-injection sites)
- Neurological examination
- Signs of diseases that can cause secondary diabetes (e.g., hemochromatosis, pancreatic disease)

Laboratory evaluation

- A1C
- Fasting lipid profile, including total cholesterol, HDL cholesterol, triglycerides, and LDL cholesterol
- Test for microalbuminuria in type 1 diabetic patients who have had diabetes for at least 5 years and in all patients with type 2 diabetes; some advocate beginning screening of pubertal children before 5 years of diabetes
- Serum creatinine in adults (in children if proteinuria is present)
- Thyroid-stimulating hormone (TSH) in all type 1 diabetic patients; in type 2 if clinically indicated
- Electrocardiogram in adults, if clinically indicated
- Urinalysis for ketones, protein, sediment

Referrals

- Eye exam, to an optometrist or ophthalmologist (at least once yearly)
- Family planning for women of reproductive age
- MNT, as indicated
- Diabetes educator, if not provided by physician or practice staff
- Behavioral specialist, as indicated
- Foot specialist, as indicated
- Other specialties and services as appropriate

Management

Develop an individualized Diabetes Care Plan with the patient, reviewing treatment goals, self-monitoring results, medication lists, and barriers to not meeting goals. One copy of the Diabetes Care Plan should go home with the patient and one copy should be retained in the chart behind the Wellness Plan. The patient should be instructed to bring the Diabetes Care Plan back with

them to subsequent office visits with self-monitoring results (including blood sugars) recorded in the appropriate sections. Diabetes Care Plans should be reviewed at each appropriate visit, progress towards goals should be assessed, and the plan should be up-dated at least annually, or more frequently as necessary to improve diabetes control and patient adherence. The care plan should be formulated as an individualized therapeutic alliance among the patient and family and the physician. Any plan should recognize diabetes self-management education as an integral component of care. In developing the plan, consideration should be given to the patient's age, school or work schedule and conditions, physical activity, eating patterns, social situation and personality, cultural factors, and presence of complications of diabetes or other medical conditions.

Offer educational handouts on diabetes, available in each physician office, at each visit.

Refer all patients who are not meeting diabetes goals or who would benefit from further diabetes education to the Diabetes Education Classes.

Complete the Diabetes Flow Sheet at each visit where diabetes is discussed to gather longitudinal data on diabetes control

If the patient is achieving good outcomes, document this in continuation notes.

Glycemic control

Glycemic control is fundamental to the management of diabetes. Prospective randomized clinical trials such as the Diabetes Control and Complications Trial (DCCT) and the U.K. Prospective Diabetes Study (UKPDS), which targeted fasting blood glucose, have shown that improved glycemic control is associated with sustained decreased rates of retinopathy, nephropathy, and neuropathy. In these trials, treatment regimens that reduced average A1C to ~7% (~1% above the upper limits of normal) were associated with fewer long-term microvascular complications; however, intensive control was found to increase the risk of severe hypoglycemia and weight gain.

An A1C test should be performed quarterly in patients whose therapy has changed or who are not meeting treatment goals. It should be checked at least twice a year in those with stable glycemic control.

Recommended glycemic goals for non-pregnant individuals are shown below.

Summary of recommendations for adults with diabetes

Glycemic control	
AIC	<6.5%
Pre-prandial plasma glucose	90–130 mg/dl
Postprandial plasma glucose	<140 mg/dl
Blood pressure	<130/80 mmHg
Lipids	
LDL	<100 mg/dl (<70 if CAD)
Triglycerides	<150 mg/dl
HDL	>40 mg/dl

Monitoring

- Self Monitoring Self Monitoring
  - Three times daily for Type 1 diabetics and pregnant women and those on insulin therapy
  - Unclear frequency for Type 2 diabetes on non-insulin therapy
- Hba1c
  - Twice annually if treatment goals are met
  - Quarterly for individuals with unmet treatment goals or changes in therapy
  - Point of care testing as needed to guide therapy

CVD: Management of Risk Factors and Screening for Coronary Artery Disease
CVD is the major cause of mortality for persons with diabetes. Type 2 diabetes is an independent risk factor for macrovascular disease, and its common coexisting conditions (e.g., hypertension and dyslipidemia) are also risk factors. Studies have shown the efficacy of reducing cardiovascular risk factors in preventing or slowing CVD.

A. Blood Pressure Control

Recommendations

Screening and Diagnosis

- Blood pressure should be measured at every routine diabetes visit. Patients found to have systolic blood pressure ≥130 or diastolic blood pressure ≥80 mmHg should have blood pressure confirmed on a separate day.

Goals

- Patients with diabetes should be treated to a systolic blood pressure <130 mmHg.
- Patients with diabetes should be treated to a diastolic blood pressure <80 mmHg.

Treatment

- Patients with hypertension (systolic blood pressure ≥140 or diastolic blood pressure ≥90 mmHg) should receive drug therapy in addition to lifestyle and behavioral therapy.
- Multiple drug therapy (two or more agents at proper doses) is generally required to achieve blood pressure targets.
- Patients with a systolic blood pressure of 130–139 mmHg or a diastolic blood pressure of 80–89 mmHg should be given lifestyle and behavioral therapy alone for a maximum of 3 months and then, if targets are not achieved, in addition, be treated with pharmacological agents that block the renin-angiotensin system.
- Initial drug therapy for those with a blood pressure >140/90 mmHg should be with a drug class demonstrated to reduce CVD events in patients with diabetes (ACE inhibitors, ARBs, ß-blockers, diuretics, and calcium channel blockers).
- All patients with diabetes and hypertension should be treated with a regimen that includes either an ACE inhibitor or ARB. If one class is not tolerated, the other should be substituted. If needed to achieve blood pressure targets, a thiazide diuretic should be added.
- If ACE inhibitors, ARBs, or diuretics are used, monitor renal function and serum potassium levels.
- In elderly hypertensive patients, blood pressure should be lowered gradually to avoid complications.
- Patients not achieving target blood pressure despite multiple drug therapy should be referred to a physician experienced in the care of patients with hypertension.

B. Lipid Management - Dyslipidemia

Patients with type 2 diabetes have an increased prevalence of lipid abnormalities that contributes to higher rates of CVD. Lipid management aimed at lowering LDL cholesterol, raising HDL cholesterol, and lowering triglycerides has been shown to reduce macrovascular disease and mortality in patients with type 2 diabetes, particularly those who have had prior cardiovascular events.

Recommendations

Screening

- In adult patients, test for lipid disorders at least annually and more often if needed to achieve goals. In adults with low-risk lipid values (LDL <100 mg/dl, HDL >50 mg/dl, and triglycerides <150 mg/dl), repeat lipid assessments every 2 years.

Treatment Recommendations and Goals

- Lifestyle modification focusing on the reduction of saturated fat and cholesterol intake, weight loss, increased physical activity, and smoking cessation has been shown to improve the lipid profile in patients with diabetes.
- Patients who do not achieve lipid goals with lifestyle modifications require pharmacological therapy.
- Lower LDL cholesterol to <70 mg/dl as the primary goal of therapy for adults.
- Lowering LDL cholesterol with a statin is associated with a reduction in cardiovascular events.
- In people with diabetes over the age of 40 with a total cholesterol ≥135 mg/dl, statin therapy to achieve an LDL reduction of ~30% regardless of baseline LDL levels may be appropriate.
- Lower triglycerides to <150 mg/dl and raise HDL cholesterol to >40 mg/dl. In women, an HDL goal 10 mg/dl higher may be appropriate.

C. Anti-platelet Agents in Diabetes

Aspirin has been recommended as a primary and secondary prevention therapy to prevent cardiovascular events, including stroke and myocardial infarctions, in diabetic and non-diabetic individuals.

Recommendations

- Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of myocardial infarction, vascular bypass procedure, stroke or transient ischemic attack, peripheral vascular disease, claudication, and/or angina.
- Use aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 2 diabetes at increased cardiovascular risk, including men over 50 and women over 60 years of age with one additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, albuminuria) or individuals who have a 10 year risk of CVD of >10%.
- Use aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 diabetes at increased cardiovascular risk, including those who are over 40 years of age or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, albuminuria).
- Daily aspirin is not recommended for low risk patients including women < 60 yrs, men < 50 yrs without any cardiac risk factors, or those whose 10 yr risk is < 5%.
- Daily aspirin not recommended for individuals < 21 yrs because of increased risk of Reye's Syndrome.
- In patients with aspirin allergies, history of bleeding or can not tolerate aspirin, clopidigrel may be used.

D. Smoking Cessation

The routine and thorough assessment of tobacco use is important as a means of preventing smoking or encouraging cessation. Special considerations should include assessment of level of nicotine dependence, which is associated with difficulty in quitting and relapse.

Recommendations

- Advise all patients not to smoke.
- Include smoking cessation counseling and other forms of treatment as a routine component of diabetes care.

E. CHD Screening and Treatment

Recommendations

- Known CHD should be treated with an ace inhibitor, aspirin and a statin
- Refer patients with signs and symptoms of CVD or with positive noninvasive test for CAD to a cardiologist for further evaluation.
- Metformin may be used in stable CHF with normal renal function abut should be avoided in unstable or hospitalized individuals.
- Caution in prescribing thiazolidinediones in the setting of known congestive heart failure or other heart disease as well as in patients with pre-existing edema or concurrent insulin therapy. Avoid this medication in symptomatic CHF
- In patients >55 years of age, with or without hypertension but with another cardiovascular risk factor (history of CVD, dyslipidemia, microalbuminuria, smoking), an ACE inhibitor (if not contraindicated) should be considered to reduce the risk of cardiovascular events.
- In patients with a prior myocardial infarction or in patients undergoing major surgery, ß-blockers, in addition, should be considered to reduce mortality.

G. Nephropathy Screening and Treatment

Diabetic nephropathy occurs in 20–40% of patients with diabetes and is the single leading cause of end-stage renal disease (ESRD). Intensive diabetes management with the goal of achieving near normoglycemia has been shown to delay the onset of microalbuminuria and the progression of micro- to macroalbuminuria in patients with type 1 and type 2 diabetes.

Recommendations

<u>General Recommendations</u>

- To reduce the risk and/or slow the progression of nephropathy, optimize glucose control.
- To reduce the risk and/or slow the progression of nephropathy, optimize blood pressure control.

Screening

- Perform an annual test for the presence of microalbuminuria in type 1 diabetic patients with diabetes duration of ≥5 years and in all type 2 diabetic patients, starting at diagnosis.
- Monitor creatinine annually and eGFR to stage CKD

Treatment

- In the treatment of both micro- and macroalbuminuria, either ACE inhibitors (for Type 1 diabetic patients) or ARBs (for Type 2 diabetic patients) should be used.
- Decrease protein intake to 0.8 – 1 g/kg body weight

H. Diabetic Retinopathy Screening and Treatment

Diabetic retinopathy is a highly specific vascular complication of both type 1 and type 2 diabetes. The prevalence of retinopathy is strongly related to the duration of diabetes. Diabetic retinopathy is estimated to be the most frequent cause of new cases of blindness among adults aged 20–74 years. Intensive diabetes management with the goal of achieving near normoglycemia has been shown in large prospective randomized studies to prevent and/or delay the onset of diabetic retinopathy.

Recommendations

General Recommendations

- Optimal glycemic control can substantially reduce the risk and progression of diabetic retinopathy.
- Optimal blood pressure control can reduce the risk and progression of diabetic retinopathy.
- Aspirin therapy does not prevent retinopathy or increase the risks of hemorrhage.

Screening

- Adults and adolescents with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 3–5 years after the onset of diabetes.
- Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist shortly after the diagnosis of diabetes.
- Subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management. Less frequent exams (every 2 years) may be considered with the advice of an eye care professional in the setting of a normal eye exam. Examinations will be required more frequently if retinopathy is progressing.
- When planning pregnancy, women with preexisting diabetes should have a comprehensive eye examination and should be counseled on the risk of development

and/or progression of diabetic retinopathy. Women with diabetes who become pregnant should have a comprehensive eye examination in the first trimester and close follow-up throughout pregnancy and for 1 year postpartum. This guideline does not apply to women who develop GDM because such individuals are not at increased risk for diabetic retinopathy.

Treatment

- Promptly refer patients with any level of macular edema, severe NPDR, or any PDR to an ophthalmologist who is knowledgeable and experienced in the management and treatment of diabetic retinopathy.

I. Neuropathy

The diabetic neuropathies are heterogeneous with diverse clinical manifestations. They may be focal or diffuse. Most common among the neuropathies are chronic sensorimotor, DPN, and autonomic neuropathy. Although DPN is a diagnosis of exclusion, complex investigations to exclude other conditions are rarely needed. The early recognition and appropriate management of neuropathy in the patient with diabetes is important for a number of reasons: *1*) nondiabetic neuropathies may be present in patients with diabetes and may be treatable; *2*) a number of treatment options exist for symptomatic diabetic neuropathy; *3*) up to 50% of DPN may be asymptomatic, and patients are at risk of insensate injury to their feet; *4*) autonomic neuropathy may involve every system in the body; and *5*) cardiovascular autonomic neuropathy causes substantial morbidity and mortality.

J. Foot Care

Amputation and foot ulceration are the most common consequences of diabetic neuropathy and major causes of morbidity and disability in people with diabetes. Early recognition and management of independent risk factors can prevent or delay adverse outcomes. The risk of ulcers or amputations is increased in people who have had diabetes >10 years, are male, have poor glucose control, or have cardiovascular, retinal, or renal complications.

Recommendations

- The foot examination can be accomplished in a primary care setting and should include the use of a Semmes-Weinstein monofilament, tuning fork, palpation, and a visual examination.
- Educate all patients, especially those with risk factors, including smoking, or prior lower-extremity complications, about the risk and prevention of foot problems and reinforce self-care behavior.
- Refer high-risk patients to foot care specialists for ongoing preventive care and life-long surveillance.
- Initial screening for PAD should include a history for claudication and an assessment of the pedal pulses. Consider obtaining an ABI, as many patients with PAD are asymptomatic.

- Refer patients with significant claudication or a positive ABI for further vascular assessment and consider exercise, medications, and surgical options.

Perform a comprehensive foot examination annually on patients with diabetes to identify risk factors predictive of ulcers and amputations. Perform a visual inspection of patients' feet at each routine visit.

K. Preventive Care

Immunization

Influenza and pneumonia are common, preventable infectious diseases associated with high mortality and morbidity in the elderly and in people with chronic diseases.

Recommendations

- Annually provide an influenza vaccine to all diabetic patients 6 months of age or older.
- Provide at least one lifetime pneumococcal vaccine for adults with diabetes. A one-time revaccination is recommended for individuals >64 years of age previously immunized when they were <65 years of age if the vaccine was administered >5 years ago. Other indications for repeat vaccination include nephrotic syndrome, chronic renal disease, and other immuno-compromised states, such as after transplantation.

Written by:
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Adrienne Flowers, M.D., Internal Medicine
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17. Lead Screening

Significant exposure to lead is a preventable environmental threat to optimal health and developmental outcomes for young children. An estimated half a million children aged 1 - 5 years have elevated blood lead levels (BLL). In 2012, the CDC revised the guidelines for childhood lead poisoning and reduced the acceptable blood lead level to less than 5 micrograms per deciliter (mcg/dl). This was based on evidence from studies that showed that the effects of lead are irreversible and can occur at levels < 10 mcg/dl. The major source of lead exposure is lead-based paint and lead contaminated dust found in deteriorating buildings. Lead based paints were banned for use in housing in 1978. However, approximately 24 million housing units have deteriorated lead paint and elevated level of lead contaminated dust. Children of all socioeconomic levels can be affected, although children in low-income households who live in older homes are at greatest risk. The highest rates are among African-American and urban children. Other sources of lead include costume jewelry and toys.

The detrimental effect of lead on cognitive functions has been well documented. In general, approximately a half "IQ" point is lost, possibly permanently, for each 1 mcg/dl increase in BLL. Research has also shown an association with lead exposures and problems with attention, aggression, and antisocial and delinquent behaviors.
Fewer than 5% of children are diagnosed as having lead poisoning based on clinical presentation. Gastrointestinal related symptoms include anorexia, nausea, vomiting, abdominal pain and constipation. At very high levels, some children may develop encephalopathy with changes in mental status, ataxia, seizures or coma.

The diagnosis can be suspected if responses to routine questions are affirmative for sources of exposure such as peeling paint in old housing and behaviors such as pica and placing non-food items in the mouth. Ultimately, the diagnosis depends on the results of blood testing.

The goal of screening is to ensure that children at risk of exposure to lead are tested.
A brief community-specific risk assessment questionnaire should be administered during well childcare visits continuing until 6 years of age. If answers indicate risk, BLLs should be measured. All questionnaires should include the following 3 risk assessment questions:

1) Does your child live in or regularly visit a house built before 1950?
2) Does your child live in or regularly visit a house built before 1978 that is being renovated or remodeled?
3) Does your child have a sibling or playmate who has lead poisoning?

It is recommended that a blood lead test be administered to all children at risk at ages 12 & 24 months; children who have not previously been screened should be tested at ages 36-72 months. If children are exposed to lead, BLLs tend to increase during 0 to 2 years and peak at 18-24 months as the toddler gains mobility and practices hand to mouth behavior.

Screening is thus recommended at both ages 1 and 2 years to identify children who need medical and environmental management. Identifying a child with an elevated BLL at age 1 year might prevent additional increases during ages 1-2 years. In addition, a child with a normal BLL at 1 year might have an elevated level by age 2, underscoring the importance of rescreening at age 2

years. Screening is recommended for previously untested children < 6 years to rule out subclinically elevated BLLs during critical stages of development.

The standard to determine BLLs requires a properly collected venous sample. A capillary blood sample may be a practical screening alternative.

Children identified with elevated BLLs should be evaluated and treated in accordance with approved guidelines from the CDC, AAP and DHMH.

Few children will have levels high enough to warrant intensive medical treatment (e.g. chelation therapy). However, many children with elevated BLLs will need follow up services, including more frequent blood lead testing, environmental investigation and case management.

Recommended Follow Up Services According to BLLs

BLL	**/ Action**
<5	Continue to assess for lead exposure every well child visit.
5-14	Obtain a confirmatory venous lead level within **three months**; if still in this range, provide education to decrease lead exposure. Repeat BLL within **three months** until < 5 for 6 months.
15-29	Obtain a confirmatory venous lead level within **one week;** if still in this range, conduct a complete medical history including environmental and nutritional assessment, and physical exam. Provide education to decrease lead exposure. Refer the patient to local health department or provide case management that should include a detailed environmental investigation with lead hazard reduction and appropriate referrals for support services. Repeat BLL at 1-2 month intervals until <5 for 6 months.
30-44	**As above**
45 –69	Obtain a confirmatory venous lead level within **48 hours**; if still in this range, perform a complete medical history and physical exam. Provide educational services. Refer Patient to local health department and case management. Begin chelation therapy in consultation with clinician experienced with lead toxicity therapy. Retest monthly until BLL is<5 for 6 months.
>70	Hospitalize the patient and begin medical treatment immediately in consultation with a clinician experienced with lead toxicity therapy. Obtain a confirmatory BLL **within 24 hours.** Consult with special care center for follow up.

Environmental health specialists from the health department are essential in providing environmental assessment, lead abatement or alternative housing. Retest monthly until BLL is < 5 for 6 months.

Lead poisoning and its sequelae can be prevented by blood lead screening followed, when appropriate, by education, case management, environmental abatement and referrals for social services and medical management as needed.

Written By:
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18. Obesity Guidelines

Obesity is an epidemic in the United States:

- Two-thirds of the population is classified as overweight or obese
- Poor diet and physical inactivity are the two greatest risk factors
- Rates of obesity are highest among African Americans and less economically affluent, less educated populations
- Health consequences of obesity are myriad, including but not limited to:
  - Diabetes mellitus
  - Hypertension
  - Dyslipidemia
  - Myocardial infarction
  - Cerebrovascular accidents
  - Fertility problems
  - Liver disease
  - Pulmonary disease
- Mortality increases significantly in overweight and obese populations and directly correlates with the degree of obesity

Classification:

Adults: Obesity is classified according to body mass index (BMI), which is calculated by taking a person's weight in kilograms and dividing it by the square of the person's height in meters (kg/m^2). BMI can also be measured by taking the person's height in inches squared divided into the person's weight in pounds multiplied by 703. Obesity is categorized as follows:

Classification	BMI	Disease Risk*
Normal	18.5 – 24.9	Normal
Overweight	25 – 29.9	Increased
Obesity		
• Class I	30 – 34.9	High
• Class II	35 – 39.9	Very High
• Class III (morbid obesity)	40+	Extremely High

* for type 2 diabetes, high blood pressure, and coronary vascular disease

Children: Obesity is classified slightly differently for children two years of age and older. BMI is first calculated and then plotted on sex-specific BMI-for-age growth charts to give a BMI percentile. BMI percentiles take into account the fact that percentage of body fat changes with age and the fact that body fat content differs between boys and girls. Obesity is then classified according to BMI percentile, as below:

Classification	BMI Percentile Range
Normal	5^{th} to 85^{th} percentile
Overweight	85^{th} to just under 95^{th} percentile
Obese	95^{th} percentile and above

Screening:
Both the National Institutes of Health and the U.S. Preventive Services Task Force (USPSTF) recommend screening for obesity at regular intervals.

Diagnosis:
At the initial clinical visit, weight and height should be measured and BMI calculated (online free BMI calculator available at http://www.nhlbisupport.com/bmi/). At each subsequent office visit, weight should be taken and BMI re-calculated and tracked on the appropriate form. Though a patient may not appear to be overweight or obese, BMI should be calculated for every patient at each visit.

A full history and physical examination should be undertaken and the patient should be asked questions regarding:

- Diet (types of foods, frequency of meals, snacking, eating out, access to healthy foods, portion sizes, cultural traditions, etc.)
- Exercise
- Complications noted from obesity
- Family history of obesity, diabetes, and cardiovascular disease
- Previous weight loss efforts
- Presence of eating disorder symptoms (such as binging, purging, etc.)
- Symptoms of possible secondary causes of obesity (such as oral contraceptive use, pregnancy, smoking cessation, medications, and symptoms consistent with endocrinopathies)

Diagnostic Evaluation:

I. Screening for:
   - Diabetes
   - Dyslipidemia
   - Liver dysfunction

II. Further diagnostic work up should be patient-specific, based on history and physical examinations:
   - Signs/symptoms of hypothyroidism: check TSH and free T4
   - Signs/symptoms of Cushing syndrome: check 24-hour urinary free cortisol level

Physical examination:

- Full vitals
- Waist circumference (optional)
- Full examination
- Subsequent office visits: full set of vitals and focused exam based on co-morbidities

Management:
Many patients do not know or understand that they are considered overweight or obese, but increased awareness has been shown to lead to more attempts at weight loss and the USPSTF recommends offering intensive counseling and behavioral interventions to obese patients. Physicians should:

- Alert patients to their overweight or obese status
- Counsel regarding food choices:
  - Eliminate non-nutritive calories like fried foods, fast foods, added sugars, sodium, and refined grains
  - Emphasize eating nutrient-dense foods such as fruits, vegetables, whole grains, legumes (beans, peas, nuts), low-fat milk products, and lean meats
- Discussions on healthy eating should include any additional family members when possible, as meal preparation may not be solely in the hands of the patient
- Advise patients to start an exercise regimen that they find sustainable (and that requires little to no equipment) and that incorporates both aerobic and anaerobic exercise; goal: 30-60 minutes of exercise approximately five times per week
- Offer educational handouts at each visit: brochures on exercise, healthy eating, and weight control are available in each physician office
- Refer all obese or overweight patients to Jai Medical Center's Obesity/Weight Loss class and document this in the chart. In the Obesity/Weight Loss Class, patients write individualized diet, exercise, and/or weight loss goals with plans for attaining these goals and they are given tools to assess their progress and better understand the barriers they face if treatment goals are not attained
- Develop an individualized Weight Management Care Plan with the patient annually, reviewing treatment goals, self-monitoring results, medication lists, and barriers to not meeting goals at each visit; one copy of the Weight Management Care Plan should go home with the patient and one copy should be retained in the chart behind the Wellness Plan
- Instruct the patient to bring the Weight Management Care Plan back with them to subsequent office visits with self-monitoring results recorded in the appropriate section
- Start a Weight Management Flow Sheet to record in a longitudinal fashion the patient's height, weight, and weight loss goals; track weight management information during each visit where the physician and patient discuss weight management issues and goals

Other Treatments

- Several commercial weight loss programs are available; however, if a patient chooses to participate in one, encourage them to choose one with a maintenance phase of at least two years after the end of the program to be successful
- Many weight loss programs and fad diets undertake weight loss in a manner that is neither healthy nor lasting
- Weight loss goals should be reasonable and sustainable and should focus on enduring lifestyle changes, not on quick fixes; a maximum of 0.9 – 1.5 kg/week (or 2-3 pounds/week) of weight loss is usually medically safe; however, weight loss goals should be individualized, taking into consideration the patient's co-morbidities, family life, and cultural background
- Weight loss should be closely monitored by a physician, as sudden loss of large amounts of weight can lead to complications including cardiac arrhythmias, electrolyte derangements, hyperuricemia, and possibly even the development of eating disorders
- Few medications for weight loss are approved by the FDA: none of the medications available have proven long-term effectiveness; several weight loss medications have been

pulled off of the market; physicians should use caution if considering prescribing weight loss medications
- Bariatric surgery is the only therapeutic modality which has been associated with sustained weight loss in morbidly obese patients; consider referring patients with-a BMI of >40 or a BMI 35- 40 with significant co-morbidities to a bariatric surgeon for further consideration

Follow Up

- Assess progress towards goals at each appropriate follow-up visit and review and update the Weight Management Care Plan as needed
- Complete the Weight Management Flow Sheet during each visit where the physician and patient discuss weight management issues and goals
- If the patient is achieving good outcomes, document this in the continuation notes
- Encourage patients to visit their PCP at least every 3 months and to complete an annual history and physical

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Biological Agents:

ANTHRAX

Fact Sheet

Description of Agent: Inhalation anthrax is a highly lethal infection caused by inhalation of aerosols of the spore form of the bacteria *Bacillus anthracis*. In naturally occurring cases, spread may be by entry through skin wounds, causing a localized infection.

Signs and Symptoms: Incubation period of inhalation anthrax is 1 to 6 days. Fever, malaise, fatigue, cough, and mild chest discomfort are followed by severe respiratory distress with dyspnea, diaphoresis, stridor, and cyanosis. Shock and death occur within 24 to 36 hours of severe symptoms.

In cutaneous anthrax, a papule develops, then vesicles, followed by a black eschar surrounded by moderate to severe edema. The lesions are usually not painful. Without treatment, the disease may progress to septicemia and death, with a case-fatality rate of 20%. With treatment, fatalities are rare.

Diagnosis: Physical findings are nonspecific in inhalation cases with initial complaints of malaise, fever, headache, and possibly some substernal chest pain. A widened mediastinum is often seen on x-ray. Detectable by Gram stain of the blood and by blood culture late in the course of illness.

Treatment: Although usually not effective for inhalation cases after symptoms are present, high-dose antibiotic treatment with penicillin, ciprofloxacin, or doxycycline should be undertaken. Without antibiotic sensitivities, treatment should be started with IV ciprofloxacin (400 mg q 8 to 12 h) or IV doxycycline (200 mg initially, followed by 100 mg q 12 h). Supportive therapy may be necessary.

Prophylaxis: A licensed vaccine for use in those considered at risk of exposure. Vaccine schedule is 0, 2, and 4 weeks for the initial series, followed by boosters at 6, 12, and 18 months and then a yearly booster. Oral ciprofloxacin (500 mg PO b.i.d.) or doxycycline (100 mg PO b.i.d.) for known or imminent exposure. After confirmed exposure, all unimmunized individuals should have two 0.5-mil doses of the vaccine 2 weeks apart, and those vaccinated with less than 3 doses prior to exposure should have a single 0.5-mil booster. Anyone vaccinated with the initial 3-dose series in the previous 6 months does not need any boosters. Everyone exposed should continue antibiotics for 4 weeks. If no vaccine is available, antibiotics should be used beyond 4 weeks and withdrawn under medical supervision.

Decontamination: Secretion and lesion precautions should be practiced. Anthrax has not been transmitted by the aerosol route person to person. After an invasive procedure or autopsy is performed, the instruments and area used should be thoroughly disinfected with a sporicidal agent (iodine or 0.5% sodium hypochlorite).

ANTHRAX

Treatment Protocol

1. General

Anthrax is a highly lethal infection spread by inhalation or entry through skin wounds. The inhalation form progresses rapidly and is more dangerous than the skin form. Incubation period is 1 to 6 days. Fever, malaise, fatigue, cough, and mild chest discomfort are followed by severe respiratory distress with dyspnea, diaphoresis, stridor, and cyanosis. Shock and death occur within 24 to 36 hours of severe symptoms.

2. Treatment

a. Evaluate patient for fever, cyanosis, and respiratory distress.

b. Administer oxygen during transport, as needed.

c. All patients should receive cardiac monitoring and evaluation of oxygenation saturation via pulse oximeter.

d. Obtain IV access with lactated Ringers at a rate to KVO.

e. Although usually not effective after symptoms are present, high-dose antibiotic treatment with penicillin, ciprofloxacin, or doxycycline should be undertaken. Without antibiotic sensitivities, treatment should be started with IV ciprofloxacin (400 mg q 8 to 12 h) or IV doxycycline (200 mg initially, followed by 100 mg q 12 h). Supportive therapy may be necessary.

f. Before transporting, check for additional victims.

g. Transport patient to medical facility as directed by dispatcher.

h. Secretion and lesion precautions should be practiced. Anthrax has not been transmitted by the aerosol route person to person. After an invasive procedure or autopsy is performed, the instruments and area used should be thoroughly disinfected with a sporicidal agent (iodine or 0.5% sodium hypochlorite). Wiping the ambulance interior with a 70% alcohol or other disinfectant is probably unnecessary, but would not be unreasonable; that need not be completed before the next run.

i. Public health officials may recommend that others who may have been initially exposed take prophylactic antibiotics and immunizations before they show signs of illness. If a registry is established, all emergency personnel should identify themselves and indicate when, where, and to what extent they might have been exposed.

BOTULINUM TOXINS

Fact Sheet

Description of Agent: Botulinum toxins are poisonous substances produced by a bacterium, *Clostridium botulinum*. They are usually formed in canned foods and eaten but can be spread by aerosol and inhalation. The toxin blocks acetylcholine release at the neuromuscular junction and in the central and peripheral nervous systems.

Signs and Symptoms: Ptosis, generalized weakness, dizziness, dry mouth and throat, blurred vision and diplopia, dysarthria, dysphonia, and dysphagia followed by symmetrical descending flaccid paralysis and development of respiratory failure. Symptoms begin as early as 24 to 36 hours but may take several days after inhalation of toxin.

Diagnosis: Clinical diagnosis. No routine laboratory findings. Bio-warfare or terrorist attack should be suspected if numerous co-located casualties have progressive descending bulbar, muscular, and respiratory weakness.

Treatment: Intubation and ventilatory assistance for respiratory failure. Tracheostomy may be required. Administration of botulinum antitoxin as soon as possible – trivalent licensed product made by the Centers for Disease Control and Prevention (CDC) or heptavalent investigational new drug (IND) product – may prevent or decrease progression to respiratory failure and hasten recovery. Skin testing must be performed before administration of the antitoxin.

Prophylaxis: Pentavalent toxoid (types A, B, C, D, and E) is available as an IND product for those at high risk of exposure. The dosage schedule is 0, 2, and 12 weeks, with yearly boosters.

Decontamination: Hypochlorite and/or soap and water. Toxin is not dermally active and secondary aerosols are not a hazard from patients.

BOTULINUM TOXIN

Treatment Protocol

1. General

Botulinum toxin is a poisonous substance produced by a bacterium, *Clostridium botulinum*. It is usually formed in canned foods and eaten but can be spread by aerosol and inhalation. Onset of symptoms is hours to days after taking the poison into the body, so there is virtually no chance that the poison carried by a victim would endanger emergency responders. Symptoms typically include drooping eyelids, blurred or double vision, trouble swallowing, dry mouth, and sore throat followed by a flaccid limp paralysis that beings near the head and moves downward. Death most often results from respiratory failure, so respiratory support is the most important aspect of pre-hospital care. Symptoms begin as early as 24 to 36 hours, but may take several days after inhalation of toxin.

2. Treatment

a. Evaluate patient for paralysis, cyanosis, respiratory distress, and signs of pneumonia superimposed on paralysis.

b. Patient may require artificial respiration during transport.

c. All patients should receive cardiac monitoring and evaluation of oxygenation saturation via pulse oximeter.

d. Patient should be given oxygen during transport, as needed, but mechanical ventilation may be more important than oxygen.

e. IV access is not critical, but will be helpful in the hospital setting where a specific antitoxin will be administered and where the patient will probably remain for a few days to several weeks. If desired, obtain IV access with lactated Ringers at a rate to KVO.

f. Intubation and ventilatory assistance may be necessary for respiratory failure. Tracheostomy may be required. Administration of botulinum antitoxin – trivalent licensed product made by CDC or heptavalent IND product– may prevent or decrease progression to respiratory failure and hasten recovery. Skin testing must be performed before administration of the antitoxin.

g. Before transporting, check for additional victims.

h. Transport patient to medical facility as directed by dispatcher.

i. Decontaminate with hypochlorite and/or soap and water. Toxin is not dermally active and secondary aerosols are not a hazard from patients.

CHOLERA

Fact Sheet

Description of Agent: Cholera is a bacterial infection causing severe diarrhea and fluid loss. The causal organism, *Vibrio cholerae*, is spread through water or food. IV fluids may be exhausted in a hospital or an isolated community during an epidemic.

Signs and Symptoms: Incubation period is 1 to 5 days. Asymptomatic to severe with sudden onset. Vomiting, abdominal distention, and pain with little or no fever followed rapidly by a profuse watery diarrhea with a "rice water" appearance. Fluid losses may exceed 5 to 10 liters per day. Without treatment, death may result from severe dehydration, hypovolemia, and shock.

Diagnosis: Clinical diagnosis. Watery diarrhea and dehydration. Microscopic exam of stool samples reveals few or no red or white cells. Can be identified in stool by darkfield or phase contrast microscopy, and can be grown on a variety of culture media.

Treatment: Fluid and electrolyte replacement. Often can be accomplished by the use of oral rehydration salts or dilute Gatorade™, with the need for IV fluids for severe dehydration. Antibiotics will shorten the duration of diarrhea and thereby decrease fluid loss – tetracycline (50 mg q 6 h x 3 days) or doxycycline (30 mg once or 100 mg q 12 h x 3 days). There is widespread tetracycline resistance and ciprofloxacin (500 mg q 12 h x 3 days), or erythromycin (500 mg q 6 h x 3 days) should also be considered.

Prophylaxis: A licensed, killed vaccine is available, but provides only about 50% protection. Vaccine schedule is 0 and 4 weeks, with booster doses every 6 months.

Decontamination: Personal contact rarely causes infection; however, enteric precautions and careful handwashing should be employed. Gloves should be used for patient contact and specimen handling. Bacterial solutions (hypochlorite) would provide adequate decontamination.

CHOLERA

Treatment Protocol

1. General

Cholera is a bacterial infection causing severe diarrhea and fluid loss. The causal organism, *Vibrio cholerae*, is spread through water or food. When growing in the intestines, the organism releases a toxin. The toxin, bot the infection itself, is the cause of diarrhea. Fluid loss through watery diarrhea is profound and may exceed 5 to 10 liters per day. IV fluids may be exhausted in a hospital or an isolated community during an epidemic. Without treatment, death may result from severe dehydration, hypovolemia, and shock.

2. Treatment

a. Evaluate patient for rehydration and shock.

b. Obtain IV access with a large-bore needle and run lactated Ringers at a rate sufficient to correct volume loss and replace fluids.

c. Telemetered electrocardiogram (ECG)may provide information on electrolyte balance.

d. Protect yourself and others from contact with diarrheal fluids; they are highly infectious.

(1) Don gloves and aprons or other protective garments.

(2) Try to contain stools, to minimize contamination of the ambulance. Blanket rolls may be used to create a dike, and plastic or other sheeting may be used to contain fluid within the dike.

(3) Change contaminated clothing and wash hands thoroughly.

e. Before transporting, check for additional victims.

f. Transport patient to medical facility as directed by dispatcher.

g. Fluid and electrolyte replacement should be undertaken and often can be accomplished by the use of oral rehydration salts or dilute Gatorade™. IV fluids are needed with severe dehydration. Antibiotics will shorten the duration of diarrhea and thereby decrease fluid loss – tetracycline (50 mg q 6 h x 3 days) or doxycycline (30 mg once or 100 mg q 12 h x 3 days). There is widespread tetracycline resistance and ciprofloxacin (500 mg q 12 h x 3 days), or erythromycin (500 mg q 6 h x 3 days) should also be considered.

h. Personal contact rarely causes infection; however, enteric precautions and careful handwashing should be employed. Bactericial solutions (hypochlorite) would provide adequate decontamination. Wash the ambulance interior, if necessary, and wipe with a 70% alcohol, dilute chlorine bleach, or other disinfectant. If practical, complete the decontamination before the next run.

PLAGUE

Fact Sheet

Description of Agent: Plague is an infectious disease caused by the bacteria *Yersina pestis*. In nature, fleas that feed on infected rodents, then incidentally bite humans most often spread plague. When spread by that route, it classically causes a local abscess with formation of very large, abscessed, regional lymph nodes called buboes. Plague can also spread by aerosol and inhalation of sputum droplets from a coughing patient. In that manner, a primary pneumonic form develops and progresses rapidly to death without treatment. Person-to-person spread from a pneumonic plague patient can occur.

Signs and Symptoms: Pneumonic plague incubation period is 2 to 3 days. High fever, chills, headache, hemoptysis, and toxemia progress rapidly to dyspnea, stridor, and cyanosis. Death results from respiratory failure, circulatory collapse, and a bleeding diathesis. Bubonic plague incubation period is 2 to 10 days. Malaise, high fever, and tender lymph nodes (buboes); may progress spontaneously to the septicemic form, with spread to the CNS, lungs, and elsewhere.

Diagnosis: Clinical diagnosis. Gram or Wayson strain of lymph node aspirates, sputum, or CSF can make a presumptive diagnosis. Plague can also be cultured.

Treatment: Early administration of antibiotics is very effective, but must be started within 24 hours of onset of symptoms in pneumonic plague. Treatment of choice is streptomycin, 30 mg/kg/day IM in two divided doses x 10 days. Intravenous doxycycline, (200 mg, then 100 mg q 12 h x 10 to 14 days) is also effective. Chloramphenicol is necessary for plague meningitis. Supportive therapy for pneumonic and septicemic forms is required.

Prophylaxis: A licensed, killed vaccine is available. Initial dose followed by a second smaller dose 1 to 3 months later, and a third 3 to 6 months later. A booster dose is given at 6, 12, and 18 months, and then every 1 to 2 years. This vaccine does not protect against aerosol exposure. After face-to-face contact with a pneumonic plague patient or after a confirmed or suspected attack with aerosolized plague, doxycycline (100 mg PO b.i.d. x 7 days or for the duration of exposure, whichever is longer) should be used.

Decontamination and Isolation: Secretion and lesion precautions with bubonic plague. Strict isolation of patients with pneumonic plague. Respiratory isolation with the use of a filtered respirator for those with direct contact with patients, and secretion precautions are necessary until the patient has been on antibiotics for at least 48 hours and there has been a favorable response to treatment. Heat, disinfectants, and exposure to sunlight render the bacteria harmless.

PLAGUE

Treatment Protocol

1. General

Plague is an infectious disease caused by the bacteria *Yersina pestis*, (formerly *Pasteurella pestis*). In nature, fleas that feed on infected rodents, then incidentally bite humans most often spread plague. When spread by that route, it classically causes a local abscess with formation of very large, abscessed, regional lymph nodes called buboes (hence the term "bubonic plague"). Incubation period is 2 to 10 days. Symptoms of malaise, high fever, and tender lymph nodes may progress spontaneously to the septicemic form, with spread to the CNS, lungs, and elsewhere. Plague can also spread by aerosol and inhalation of sputum droplets from a coughing patient. In that manner, a primary pneumonic form develops and progresses rapidly to death without treatment. Person-to-person spread from a pneumonic plague victim can occur; protective measures are needed to protect against plague as well as other, more common, disease.

Pneumonic plague incubation period is 2 to 3 days. High fever, chills, headache, hemoptysis, and toxemia progress rapidly to dyspnea, stridor, and cyanosis. Death results from respiratory failure, circulatory collapse, and a bleeding diathesis.

2. Treatment

a. Wear a well-fitting mask with a high-efficiency particulate (HEPA) filter, following the guidelines for control of tuberculosis.

b. If breathing allows, the patient should be masked to stop as many of the cough droplets as possible before they evaporate to form small-diameter droplet nuclei, which are harder to filter out.

c. Evaluate patient for fever, cyanosis, and respiratory distress.

d. Administer oxygen during transport, as needed.

e. All patients should receive cardiac monitoring and evaluation of oxygenation saturation via pulse oximeter.

f. Obtain IV access with lactated Ringers at a rate to KVO.

g. Early administration of antibiotics is very effective, but must be started within 24 hours of onset of symptoms in pneumonic plague. Treatment of choice is streptomycin, 30 mg/kg/day IM in two divided doses x 10 days. Intravenous doxycycline, (200 mg, then 100 mg q 12 h x 10 to 14 days) is also effective. Chloramphenicol is necessary for plague meningitis. Supportive therapy for pneumonic and septicemic forms is required.

PLAGUE

Treatment Protocol

h. Before transporting, check for additional victims.

i. Transport patient to medical facility as directed by dispatcher.

j. Secretion and lesion precautions should be observed with bubonic plague. Strict isolation of patients with pneumonic plague is needed. Respiratory isolation and secretion precautions are necessary until the patient has been on antibiotics for at least 48 hours and there has been a favorable response to treatment. Heat, disinfectants, and exposure to sunlight render the bacteria harmless.

k. Wiping the ambulance interior with a 70% alcohol or other disinfectant must be done if there is gross contamination with secretions or pus; this is a reasonable precaution in all cases. The organisms do not survive well outside a host; therefore, in an emergency with heavy demand on transport resources, decontamination need not be done before the next run unless there is gross contamination.

Q FEVER

Fact Sheet

Description of Agent: Q fever is an infectious disease caused by a rickettsial organism, *Coxiella burnetti*. It is usually spread by aerosolized organisms from infected animal products, such as the placenta, but could be made into an aerosol and disseminated as a terrorist weapon. Person-to-person transmission rarely, if ever, occurs. Case fatality rates are usually below 1%.

Signs and Symptoms: Fever, chills, sweats, cough, headache, weakness, and pleuritic chest pain may occur as early as 10 days after exposure. Onset may be sudden or insidious and present as a "fever of unknown origin". Pneumonia is present in some cases, but pulmonary syndromes are usually not prominent. Patients are not generally critically ill, and the illness lasts from 2 days to 2 weeks.

Diagnosis: Q fever is not a clinically distinct illness and may resemble a viral illness or other types of atypical pneumonia. The diagnosis is confirmed serologically.

Treatment: Q fever is generally a self-limited illness even without treatment. Tetracycline (500 mg/kg q 6 h) or doxycycline, (100 mg q 12 h) are the treatments of choice and are given orally for 5 to 7 days. Q fever endocarditis (rare) is much more difficult to treat.

Prophylaxis: Treatment with tetracycline or doxycycline, starting between the 8th to 12th day post-exposure and continued for 5 days, should prevent the onset of symptoms. An inactivated whole cell vaccine (investigational) is effective in eliciting protection against exposure, but severe local reactions to this vaccine may be seen in those who already possess immunity.

Decontamination: Patients who are exposed to Q fever by aerosol do not present a risk for secondary contamination or reaerosolization of the organism. Decontamination is accomplished with soap and water or by the use of weak (0.5%) hypochlorite solutions.

Q FEVER

Treatment Protocol

1. General

Q fever is an infectious disease caused by a rickettsial organism. Rickettsias are smaller than bacteria but larger than viruses. They usually live within cells, but have more complete metabolic systems than viruses. The organism that causes Q fever is called, *Coxiella burnetti*. The organism is robust, and infection occurs via inhalation of organisms. After an incubation period, which may require from 10 days to 3 weeks, onset may be sudden with chills, a headache behind the eyes, weakness, malaise, and severe sweats, or onset may be insidious and present as a "fever of unknown origin". Pneumonia is present in some cases, but pulmonary symptoms are usually not prominent. Person-to-person transmission rarely, if ever, occurs. Case fatality rates are usually below 1%.

2. Treatment

a. Evaluate patient for dehydration and shock (which would suggest an alternate diagnosis). If effects are mild, it might be practical to send the patient for medical care via private conveyance; hospitalization may not be necessary.

b. IV fluids are not usually necessary, but if the patient's condition suggests dehydration or the possibility of some other diagnosis, obtain IV access and run lactated Ringers as a rate sufficient to correct volume loss and replace fluids.

c. Universal precautions should be practices with respect to body fluids.

d. Q fever is generally a self-limited illness even without treatment. Tetracycline (500 mg/kg q 6 h) or doxycycline, (100 mg q 12 h) are the treatments of choice and are given orally for 5 to 7 days starting between the 8th to 12th day postexposure. Q fever endocarditis (rare) is much more difficult to treat.

e. Before transporting, check for additional victims.

f. Transport patient to medical facility as directed by dispatcher.

g. Patients who are exposed to Q fever by aerosol do not present a risk for secondary contamination or reaerosolization of the organism. Decontamination is accomplished with soap and water or by the use of weak (0.5%) hypochlorite solutions. Wash the ambulance interior if necessary and wipe with dilute (0.5%) chlorine bleach or other appropriate disinfectant. Decontamination is not absolutely necessary before the next run unless there has been unusually heavy contamination.

SALMONELLA

Fact Sheet

Description of Agent: Several distinct bacteria within the group *Salmonella* cause diarrheal illnesses, sometimes with a septicemia. *Salmonella typhimurium*, which causes a typhoid fever-like illness in mice and rats but usually only a diarrheal illness in humans, in 1984 was used by terrorists in Oregon to contaminate foods in restaurants (720 people became ill as a result). *Salmonella* illnesses are not rare and cannot be distinguished on the basis of clinical signs from other causes of diarrhea. The illness would typically be less profound than with cholera. Infants are at greatest risk of severe illness and death.

Signs and Symptoms: Acute onset of headache, abdominal pain, bloody diarrhea, nausea, and sometimes vomiting 6 to 72 hours after exposure to contaminated food; incubation is usually 12 to 36 hours. Fever is usually present. Diarrhea and anorexia often last several days. Dehydration may be severe, especially in infants.

Diagnosis: Fecal Gram stain and culture; serologic tests are not useful. Salmonella is a commonly occurring disease in the United States with an estimated 5 million annual cases.

Treatment: For uncomplicated cases, oral rehydration therapy alone is indicated. IV fluids may be needed with severe dehydration. Antibiotics may prolong the carrier state, but should be considered with infants, the elderly, or those with underlying illnesses. Ciprofloxacin (500 mg q 12 h x 3 days) is effective.

Prophylaxis: No immunization available.

Decontamination: Enteric precautions should be practiced. Hypochlorite and/or soap and water are effective. Destroy any remaining contaminated food. Wear gloves for patient contact and specimen handling.

SALMONELLA

Treatment Protocol

1. General

Several distinct bacteria within the group *Salmonella* cause diarrheal illnesses, sometimes with a septicemia (where organisms are also multiplying in the blood and other tissue). *Salmonella typhimurium*, which causes a typhoid fever-like illness in mice and rats but usually only a diarrheal illness in humans, in 1984 was used by terrorists in Oregon to contaminate foods in restaurants (720 people became ill as a result). *Salmonella* illnesses are not rare and cannot be distinguished on the basis of clinical signs from other causes of diarrhea. The illness would typically be less profound than with cholera. Infants are at greatest risk of severe illness and death. Signs and symptoms include acute onset of headache, abdominal pain, bloody diarrhea, nausea, and sometimes vomiting 6 to 72 hours after exposure to contaminated food; incubation is usually 12 to 36 hours. Fever is usually present. Diarrhea and anorexia often last several days. Dehydration may be severe, especially in infants.

2. Treatment

a. Evaluate patient for dehydration and shock. If the patient has only mild effects, it might be practical to send them for medical care via private conveyance; hospitalization may not be necessary.

b. Obtain IV access with a large-bore needle and run lactated Ringers at a rate sufficient to correct volume loss and replace fluids.

c. Telemetered ECG may provide information on electrolyte balance.

d. Protect yourself and others from contact with diarrheal fluids; they are highly infectious.

(1) Don gloves and aprons or other protective garments.

(2) Try to contain stools, to minimize contamination of the ambulance. Blanket rolls may be used to create a dike, and plastic or other sheeting may be used to contain fluid within the dike.

(3) Change contaminated clothing and wash hands thoroughly.

e. For uncomplicated cases, oral rehydration therapy alone is indicated. IV fluids may be needed with severe dehydration. Antibiotics may prolong the carrier state, but should be considered with infants, the elderly, or those with underlying illnesses. Ciprofloxacin (500 mg q 12 h x 3 days) is effective.

SALMONELLA

Treatment Protocol

f. Before transporting, check for additional victims.

g. Transport patient to medical facility as directed by dispatcher.

h. Enteric precautions should be practiced. Hypochlorite and/or soap and water are effective. Destroy any remaining contaminated food. Wear gloves for patient contact and specimen handling. Wash the ambulance interior, if necessary, and wipe with a 70% alcohol, dilute chlorine bleach, or other disinfectant. If practical, complete the decontamination before the next run.

STAPHYLOCOCCAL ENTEROTOXIN B

Fact Sheet

Description of Agent: Staphylococcus enterotoxin B (SEB) is one of several toxins produced by the bacteria *Staphylococcus aureus*. SEB is a common contributor to staphylococcal food poisoning but can also be disseminated as an aerosol and inhaled.

Signs and Symptoms: From 3 to 12 hours after aerosol exposure, sudden onset of fever, chills, headache, myalgia, and nonproductive cough. Some patients may develop shortness of breath and retrosternal chest pain. Fever may last 2 to 5 days, and cough may persist for up to 4 weeks. Patients may also present with nausea, vomiting, and diarrhea if they swallow toxin. Higher exposure levels can lead to pulmonary edema and, rarely, death.

Diagnosis: Diagnosis is clinical. Patients present themselves with a febrile respiratory syndrome without CRX abnormalities. Large numbers of people presenting themselves with typical symptoms and signs of SEB pulmonary exposure would suggest an intentional attack with this toxin.

Treatment: Treatment is limited to supportive care. Artificial ventilation might be needed for very severe cases, and attention to fluid management is important.

Prophylaxis: Use of protective mask. There is currently no human vaccine n available to prevent SEB intoxication.

Decontamination: Hypochlorite (bleach) and/or soap and water are effective. Destroy any that may have been contaminated.

STAPHYLOCOCCAL ENTEROTOXIN B

Treatment Protocol

1. General

Staphylococcus enterotoxin B (SEB) is one of several toxins produced by *Staphylococcus aureus*. SEB is a common contributor to food borne enteritis outbreaks but can also be disseminated as an aerosol and inhaled. Symptoms usually follow inhalation by 3 to 12 hours and include sudden onset of fever, chills, headache, pain in the muscles, and a nonproductive cough. Nausea, vomiting, and watery diarrhea may be accompanied by heavy fluid losses and a feeling of profound malaise leading to incapacitation; higher doses can lead to toxic shock syndrome and death. Reddening of the eyes is common. Overall, the mortality rate from an attack would be lower than that from many other biological agents.

2. Treatment

a. Evaluate patient for dehydration and shock.

b. Obtain IV access with a large-bore needle and run lactated Ringers at a rate sufficient to correct volume loss and replace fluids.

c. Telemetered ECG may provide information on electrolyte balance.

d. Diarrheal fluids are not dangerous, but you may not know whether you are dealing with SEB, cholera, or Salmonellosis. Therefore, treat diarrheal fluid as highly infectious.

(1) Don gloves and aprons or other protective garments.

(2) Try to contain stools, to minimize contamination of the ambulance. Blanket rolls may be used to create a dike, and plastic or other sheeting may be used to contain fluid within the dike.

(3) Change contaminated clothing and wash hands thoroughly.

e. Treatment is limited to supportive care. Artificial ventilation might be needed for very severe cases, and attention to fluid management is important.

f. Before transporting, check for additional victims.

g. Transport patient to medical facility as directed by dispatcher.

h. Decontaminate with hypochlorite (bleach) and/or soap and water. Destroy any food that may have been contaminated. Wash the ambulance interior, if necessary, and wipe with a 70% alcohol, dilute chlorine bleach, or other disinfectant. If practical, complete the decontamination before the next run.