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. 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

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. Cushing's 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. 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:

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

III. JNC 8 Recommendations:

A. Who Should be Treated
- Patients <60 years of age: start pharmacotherapy at 140/90 mmHg.
- Patients with diabetes: start pharmacotherapy at 140/90 mmHg.
- Patients with CKD: start pharmacotherapy at 140/90 mmHg.
- Patients 60 years of age and older: start pharmacotherapy at 150/90 mmHg.

B. What is Goal Blood Pressure?
- Patients <60 years of age: <140/90 mmHg
- Patients with diabetes: <140/90 mmHg [Evidence level A]
- Patients with CKD: <140/90 mmHg
- Patients 60 years of age and older: <150/90 mmHg [Evidence level B]

C. What pharmacotherapy is recommended?
- Thiazides no longer given preference as initial therapy
- JNC 8 options for DM same as for the general population; no evidence they benefit differently from general hypertensive population
- Nonblack, including those with diabetes: thiazide, CCB, ACEI, or ARB

- African American, including those with diabetes: thiazide or CCB
- CKD: regimen should include an ACEI or ARB (including African Americans)
- Can initiate with two agents, especially if systolic >20 mmHg above goal or diastolic >10 mmHg above goal.
- If goal not reached: stress adherence to medication and lifestyle; increase dose or add a second or third agent from one of the recommended classes; choose a drug outside of the classes recommended above only if these options have been exhausted. Consider specialist referral.

D. Comorbidities (American Society of Hypertension)
   1. Diabetes:
      a. First-line: ACEI or ARB [Evidence level C; consensus] (can start with CCB or thiazide in African Americans)
      b. Second-line: add CCB or thiazide (can add ACEI or ARB in African Americans)
      c. Third-line: CCB plus ACEI or ARB plus thiazide
   2. CKD
      a. First-line: ARB or ACEI (ACEI for African Americans)
      b. Second-line (add-on): CCB or thiazide
      c. Third-line: CCB plus ACEI or ARB plus thiazide
   3. CAD:
      a. First-line: BB plus ARB or ACEI
      b. Second-line (add-on): CCB or thiazide
      c. Third-line: BB plus ARB or ACEI plus CCB plus thiazide
   4. Stroke history:
      a. First-line: ACEI or ARB
      b. Second-line: add CCB or thiazide
      c. Third-line: CCB plus ACEI or ARB plus thiazide
   5. Heart failure: ACEI or ARB plus BB plus diuretic plus aldosterone antagonist. Amlodipine can be added for additional BP control. (Start with ACEI, BB, diuretic. Can add BB even before ACEI optimized. Use diuretic to manage fluid.)

IV. 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 infarction	Beta blocker + ace inhibitor

V. 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

VI. 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

VII. 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)

VIII. 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.

IX. Screening for Primary Hypertension in Children and Adolescents: Clinical Summary of the USPSTF Recommendation

A. Primary hypertension in children and adolescents is associated with several risk factors, the strongest of which is elevated body mass index. The prevalence of hypertension in children and adolescents has increased over the past several decades, which is probably attributable to the increase in the prevalence of childhood overweight and obesity. The prevalence of hypertension in children and adolescents in the US has been reported at 1% - 5% and among obese children in the United States, is estimated at 11%.

Population	Children and adolescents without symptoms of hypertension
Recommendation	No recommendation Grade: I statement
Risk assessment	The strongest risk factor for primary hypertension in children is elevated body mass index. Other risk factors include low birth weight, male sex, ethnicity, and a family history of hypertension.
Screening tests	Blood pressure screening with sphygmomanometry in the clinical setting may identify children and adolescents with hypertension with reasonable sensitivity; however, false-positive results may occur with normalization of subsequent blood pressure measurements.
Treatment	Stage 1 hypertension in children is treated with lifestyle and pharmacologic interventions; medications are not recommended as first-line therapy.
Balance of benefits and harms	The USPSTF found inadequate evidence on the diagnostic accuracy of screening for primary hypertension. The USPSTF also found inadequate evidence on the effectiveness of treatment and the harms of screening or treatment. Therefore, the USPSTF cannot determine the balance of benefits and harms of screening for hypertension in children and adolescents.
Other relevant USPSTF recommendations	The USPSTF has made recommendations on screening for lipid disorders in children and adolescents. These recommendations are available at http://www.uspreventiveservicestaskforce.org/.

NOTE: *For a summary of the evidence systematically reviewed in making this recommendation, the full recommendation statement, and supporting documents, go to http://www.uspreventiveservicestaskforce.org/.*

USPSTF = U.S. Preventive Services Task Force.

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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:

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

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

C. Specific diagnosis is established.

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

   1. Medications
      a. NSAIDS, like Ibuprofen, Naproxen
      b. Muscle relaxants like Flexeril
      c. Narcotic analgesic like codeine derivations (Percocet, Dylox, etc.) for short term use only

   2. Physical Therapy
      a. Hydroculator packs
      b. Ultrasound

c. Electrical stimulation (TENS)
d. Massage
e. Therapeutic exercise
f. Yoga
g. Spinal manipulation – chiropractic care

3. 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) recommends HIV screening for ages 13-64. USPSTF recommends HIV screening for ages 15-65, younger/older if high risk, and all pregnant women (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, perform complete history and physical examination.

A. Medication review

B. History or evidence of opportunistic infections, malignancy, STIs

III. Patient education is focused on safer sex practices, proper condom use, proper needle handling and disposal, regional needle exchange programs, and substance abuse treatment, as needed.

IV. PEP (Post-Exposure Prophylaxis)

A. If significant exposure, initiate ≥3 drug regimen ASAP (within 72 hours to be effective), for 4 weeks.

B. Preferred regimen: Truvada (tenofovir/emtricitabine) QD + raltegravir 400mg BID (reference #7 for alternative regimens)

C. Can use same treatment for occupational and nonoccupational exposures.

D. Consider expert consultation, but do not delay treatment

E. 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 concluded at 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).

F. 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)

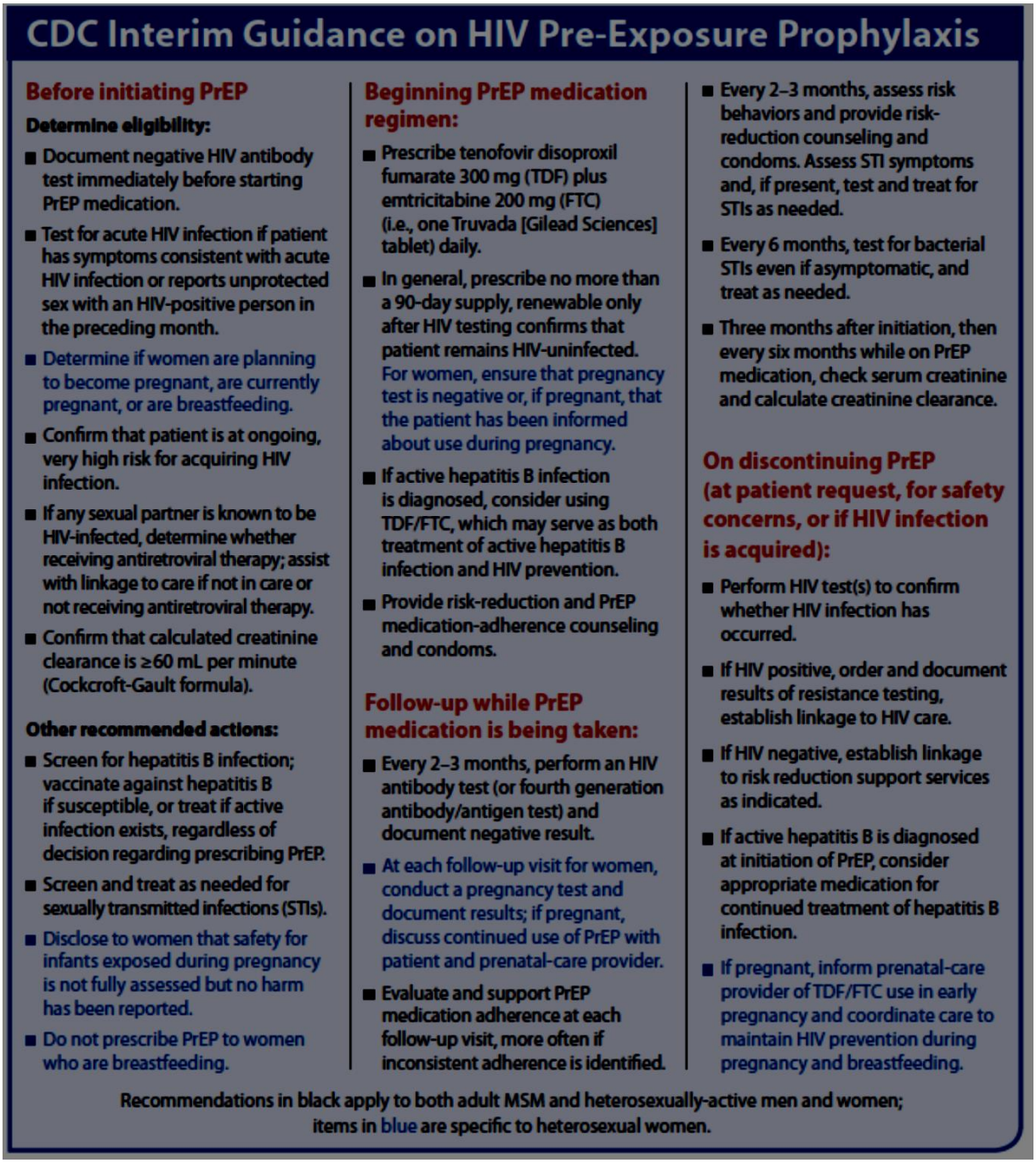
A. Only in those with very high risk of contracting HIV through sex or injection drug use.

B. Truvada (tenofovir/emtricitabine) is FDA approved for PrEP among 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 on risk reduction.
   2. Screen for other STI's Q6 months
   3. Monitor BUN/Cr Q3months for first year, annually thereafter
   4. Check b-HCG in women of reproductive age before and periodically during tx.

E. PrEP Hotline: PrEPline, 1-855-448-7737 (1-855 HIV-PREP)



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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Sources:

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5. Women's Health Protocol

I. At the initial visit, a complete history including menstrual and reproductive health and physical exam are performed.

II. The components of the annual women's health preventative services:
- A. Blood pressure, weight check 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, alcohol, and drug use screening and counseling
- G. Dietary/ nutrition, and physical activity assessment
- H. Sexual practices

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. IUD
- E. Implantable contraception
- F. Tubal Ligation

IV. If the patient desires to become pregnant, preconception 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 and their options for symptom management. Treatment should be based on the delicate balance between benefit versus risk.

VIII. The patient should be counseled regarding diet and nutrition and incorporating regular physical activity into daily routines. 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. High risk reduction education and STD including 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; Tdap is recommended with each pregnancy
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 and Diagnostic studies as indicated:

A. Blood and/or urine tests

1. Chromosome microarray
2. Fluorescent in situ hybridization
3. Screening for inborn errors of metabolism e.g., urine for amino and organic acids, plasma for amino acids and acylcarnitines

B. MRI
C. X-rays, EKG, EEG

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

IV. Develop a chronic condition management plan. Administer medical treatment in accordance to the plan. Refine the treatment plan regarding symptom management and surveillance for known complications. 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 the child. Ensure the best health and social services for the child and family.

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. Coordinate care

with mental health and behavioral health professionals, and the educational system. Provide condition-specific family support.

VIII. Review care plan at least annually.

IX. Assure accessibility to necessary durable medical equipment.

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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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8. Individuals with a Developmental Disability

I. Definition of Developmental Disability:

Group of chronic, non-progressive 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 psycho-educational testing. Prior assessment results should be reviewed and additional testing requested when indicated.

V. Establish a diagnosis based on the above information:

A. Intellectual Disability
B. Motor skills disorders
C. Speech disorders
D. Learning disorders
E. Mood disorders
F. Autism spectrum disorders
G. ADHD and disruptive behavior disorders
H. Medical/neurological primary diagnoses, e.g., fetal alcohol syndrome, 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.

IX. The patient should have access to medically necessary equipment

X. 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.

XI. 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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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 PCPs 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.

Note II: Given that nearly half of pregnancies are unintended, preconception counseling/care should be considered an integral part of primary care for women of reproductive age. It is important to assess for:

A. Environmental exposures (toxicants at work and in the home)
B. Family genetic history
C. Substance Use
D. Medications
E. Nutritional considerations
F. Psychiatric Illness
G. Infectious Diseases
H. Overweight / Underweight / history of Bariatric surgery

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
    c. Sickle Cell Trait/Anemia
    d. Hepatitis (all types)
    e. HIV
    f. Thyroid Dysfunction
    g. 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 36th 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. Amniocentesis (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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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 provider'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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Sources:
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5. The Homeless in America: Adaping your practice: http://www.aafp.org/afp/2006/1001/p1132.html
6. Care of the Homeless: An overview: www.aafp.org

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11. Individuals with HIV/AIDS

I. Treatment guidelines for HIV/AIDS change frequently. Updates can be found at https://aidsinfo.nih.gov/guidelines.

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 to reduce disease progression and virus transmission.
   1. Strength of recommendation varies by pre-treatment CD4 count: CD4 <350**(AI)**; CD4 350–500 **(AII)**; CD4 >500 **(BIII)**.
   2. 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

VI. Monitoring ART

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 $\geq$ 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

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Sources:

1. Human Immunodeficiency Virus Infection and its Complications: Marshall K. Kubota, M.D., University of California, San Francisco CA 1999.
2. John G. Bartlett, M.D.: Johns Hopkins School of Medicine, 2004 Medical Management of HIV Infection, Johns Hopkins School of Medicine Baltimore, MD 2004.
3. Department of Health and Mental Hygiene, parameters, 1999.
4. DHHS Guidelines, Accessed September 2013 (http://www.aidsinfo.nih.gov).
5. CDC Guidelines - http://www.cdc.gov/hiv/prep/
6. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf, accessed September 15, 2015.

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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—To be initiated immediately after Detox (if necessary) but within 14 days of initial diagnosis

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

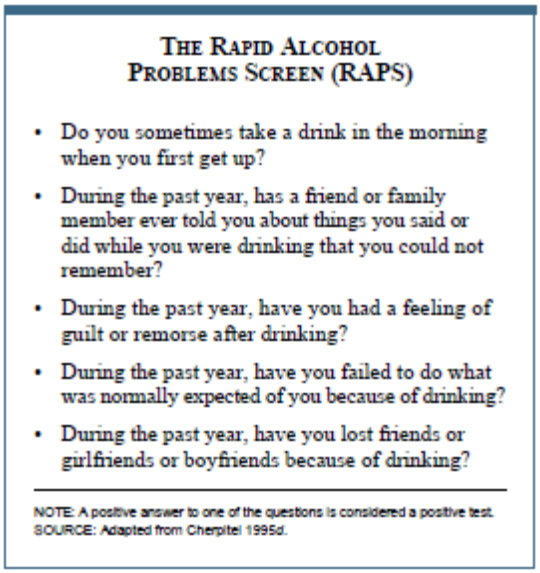
A Alcoholics Anonymous
B. Narcotics Anonymous

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, including at least two follow-up visits within 30 days of initiation of treatment
   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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Sources:
1. *Michael Hays, M.D., Addiction Medicine Specialist, Maryland General Hospital*
2. *Alcoholism: Stephen M. Jurd MB, BS, University of Sydney: Syndney, Australia, 1999.*
3. *Drug Abuse: Cocain, Opioids, Benzodiazepines, Leslie K. Jacobsen, MD & Thomas R. Kosten, MD. Yale University School of Medicine, New Haven CT.*
4. *Michigan Alcohol Screening Test*
5. *Alcohol Concern. "Primary Care Alcohol Information Service - Screening tools for healthcare settings". Retrieved 2007.*
6. *RAPS 4, http://alcoholism.about.com/od/tests/a/raps.htm (accessed 3/14)*

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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 Hep A 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. Hib is not routinely recommended for patients 5 years or older. However, 1 dose of Hib vaccine should be administered to unimmunized persons aged 5 years or older who have asplenia or HIV infection.
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 2 doses of varicella vaccine to all older children and adolescents without evidence of immunity.
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 healthy children > 5 years of age.
   For children aged 6- 18 years with immunodeficiencies, hemoglobinopathies, renal disease, asplenia, chronic heart disease or chronic liver disease, a dose of PCV13 should be administered followed by a dose of PPSV23 at least 8 weeks later.
9) MCV4 - MCV4 is recommended for 11-12 years with a booster dose at 16 years. Administer at age 13-18 years if not previously vaccinated. MCV4 may be given to younger children with asplenia or complement deficiency 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 new vaccine (Gardasil) with 9 serotypes 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 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, persons with chronic liver disease or those traveling to or working in countries where hepatitis A is endemic.
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.
12) One dose of Hib vaccine should be administered to persons who have asplenia or are

undergoing splenectomy if not previously vaccinated.

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

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Sources:
Advisory Committee on Immunization Practices(ACIP) Recommended Immunization Schedule for Persons Aged 0 through 18 Years- Unites States, 2015, Morbidity and Mortality Weekly Report MMWR February 6,2015/64(04);93-94.

Advisory Committee on Immunization Practices(ACIP) Recommended Immunization Schedule for Adults Aged 19 Years and Older _ United States, 2015, Morbidity and Mortality Weekly Report MMWR February 6,2015/64(04);91-92.

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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 8% 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.

I. At the initial visit, a comprehensive history and physical examination should be performed. Essential elements of the history that should be documented include:
- A. Symptom frequency during both the day and the night
- B. Precipitating triggers of symptoms
- C. Pattern and frequency of medication used to control symptoms
- D. Age of onset of wheezing
- E. # of E.R. visits and hospitalizations for asthma exacerbations
- F. # of days absent from school/work due to symptoms
- G. Family history of asthma
- H. Interference with normal activity
- I. Exacerbations requiring oral systemic corticosteroids
- J. Screen for GERD
- K. Smoking history/environmental tobacco smoke exposure

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

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

IV. The severity of asthma should be classified:

A. Intermittent	-Daytime symptoms ≤ 2 times per week -Nighttime symptoms ≤ 2 times per month -FEV1 or PEF ≥ 80% predicted
B. Mild Persistent	-Daytime symptoms > 2 times per week

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

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

D. 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)**:

A. Intermittent
-Short acting Beta 2 Agonists

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

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

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

D. 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:

A. Prescribing asthma medication on four occasions

OR

B. Two outstanding asthma visits and two asthma medications prescribed

OR

C. One emergency room visit for asthma

OR

D. One hospitalization for asthma

Written by:
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Sources:

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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, accessed 9/2015.

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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.

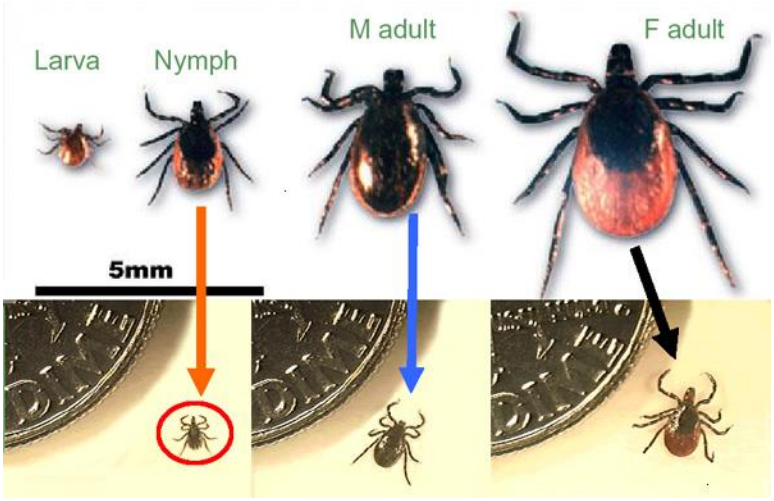
How Ticks Spread the Disease

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:

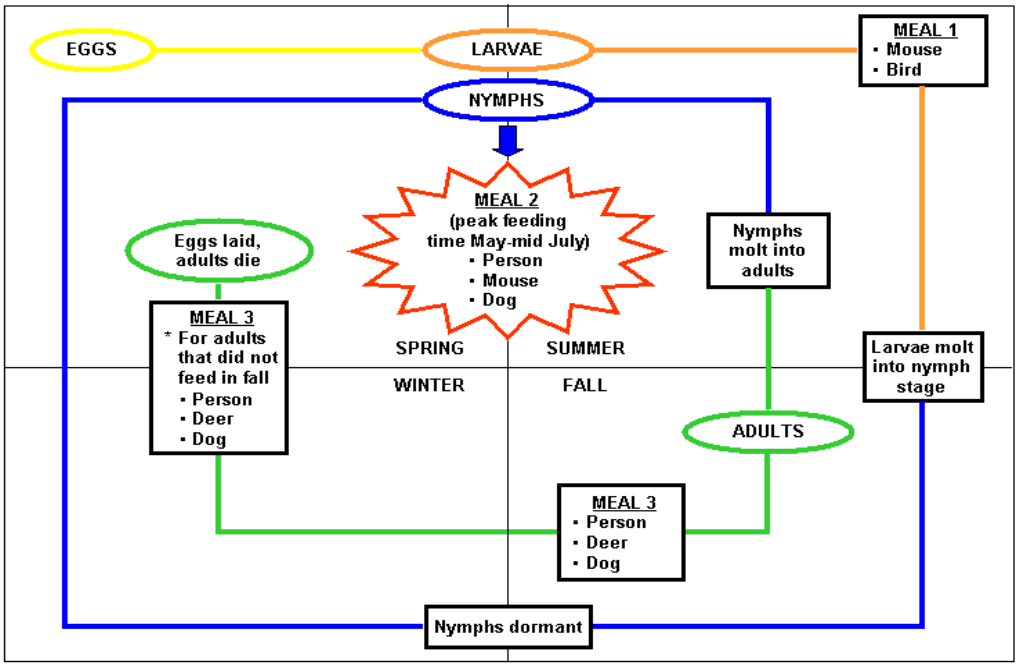
- Northeast, from Massachusetts to Maryland
- North-central states, mostly limited to Wisconsin and Minnesota
- West coast, particularly northern California

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. Doxycycline 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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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 ≥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 ≥126mg/dl (7.0mmol/l)	Fasting is defined as no caloric intake for at least 8 hours.*
OR	
2-h plasma glucose ≥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 ≥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 to 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 2 hour 75-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	<7.0%
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
  - 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, clopidogrel 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.

F. 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

General Recommendations

- 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

G. 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.

H. 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.

I. 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.

J. 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.

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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.

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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 • Class II • Class III (morbid obesity)	 30 – 34.9 35 – 39.9 40+	 High Very High 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's 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

Resources

- Rethink Your Drink Brochure: http://www.cdc.gov/nccdphp/dnpa/nutrition/pdf/rethink_your_drink.pdf
- Food Diary: http://www.cdc.gov/healthyweight/pdf/food_diary_cdc.pdf
- Physical Activity Diary: http://www.cdc.gov/healthyweight/pdf/physical_activity_diary_cdc.pdf
- Healthy Choices in the Workplace: http://www.cdc.gov/obesity/downloads/tips-for-offering-healthier-options-and-pa-at-workplace.pdf

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NEWS & TERRORISM
COMMUNICATING IN A CRISIS

A fact sheet from the National Academies and the U.S. Department of Homeland Security

"Communication before, during and after a biological attack will be a critical element in effectively responding to the crisis and helping people to protect themselves and recover."

A Journalist's Guide to Covering Bioterrorism *(Radio and Television News Director's Foundation, 2004)*

BIOLOGICAL ATTACK
HUMAN PATHOGENS, BIOTOXINS, AND AGRICULTURAL THREATS

WHAT IS IT?

A **biological attack** is the intentional release of a pathogen (disease-causing agent) or biotoxin (poisonous substance produced by a living organism) against humans, plants, or animals. An attack against people could be used to cause illness, death, fear, societal disruption, and economic damage. An attack on agricultural plants and animals would primarily cause economic damage, loss of confidence in the food supply, and possible loss of life. It is useful to distinguish between two kinds of biological agents:

- Transmissible agents that spread from person to person (e.g., smallpox, Ebola) or animal to animal (e.g., foot and mouth disease).
- Agents that may cause adverse effects in exposed individuals but that do not make those individuals contagious to others (e.g., anthrax, botulinum toxin).

Availability of Agents

The Centers for Disease Control and Prevention (CDC) lists the biothreat agents considered to pose the highest threat (see Table 1). Once obtained, agents must be cultured or grown in quantity and then processed for use in an attack ("weaponized"). Agents can be:

- **Isolated from sources in nature.** The threat agents in Table 1 are either biotoxins or agents that cause zoonotic diseases (that occur in wildlife and are transmissible to humans)—except for smallpox, which is solely a human disease and has been eradicated from nature.
- **Acquired from laboratories or bioweapons stockpile.** Smallpox virus is officially studied in only two laboratories in the world. Anthrax is widely studied in labs. Hemorrhagic fever viruses are studied only in limited high-security locations. Most high threat agents had been studied and stockpiled in bioweapons programs outside the United States until as recently as the 1990s.
- **Synthesized or genetically manipulated in a laboratory.** This would require expertise and access to advanced technology.

How Biological Agents Could Be Disseminated

For an attack on people, biological agents could be disseminated in one or more of the following ways:

- **Aerosol dissemination** is the dispersal of an agent in air from sprayers or other devices. The agent must be cultured and processed to the proper size to maximize human infections, while maintaining the agent's stability and pathogenicity (ability to produce illness). An aerosol attack might take place outdoors in a populated area or

Table 1. Diseases/Agents Listed by the CDC as Potential Bioterror Threats (as of March 2005). The U.S. Department of Agriculture maintains lists of animal and plant agents of concern.

CATEGORY A: Easily disseminated and/or contagious; high mortality rates; might disrupt society; requires special action for public health preparedness.

Bacteria (single-celled organisms):
- Anthrax *(Bacillus anthracis)*
- Plague *(Yersinia pestis)*
- Tularemia *(Francisella tularensis)*

Viruses (DNA or RNA requiring other host cells to replicate):
- Smallpox (Variola major virus)
- Viral Hemorrhagic Fevers: Ebola, Marburg, Lassa, Machupo *(various families of viruses)*

Biotoxins (poisonous substances produced by living organisms):
- Botulism *(Clostridium botulinum toxin)*

CATEGORY B: Moderately easy to disseminate; moderate illness rates, low mortality; requires enhanced diagnostic capacity, surveillance.

Bacteria:
- Brucellosis *(Brucella species)*
- Glanders *(Burkholderia mallei)*
- Melioidosis *(Burkholderia pseudomallei)*
- Psittacosis *(Chlamydia psittaci)*
- Food safety threats *(e.g., Salmonella species, Escherichia coli O157:H7, Shigella)*
- Water safety threats *(e.g., Vibrio cholerae, Cryptosporidium parvum)*

Viruses:
- Viral encephalitis (Alphaviruses)

Rickettsia (micro-organisms that live in cells):
- Q fever *(Coxiella burnetii)*
- Typhus fever *(Rickettsia prowazekii)*

Biotoxins:
- Epsilon toxin of Clostridium perfringens
- Ricin toxin from castor beans
- Staphylococcal enterotoxin B

CATEGORY C: Emerging infectious diseases that could be a future threat. (not all-inclusive)

Viruses:
- Examples are Nipah virus and Hantavirus

indoors, e.g., in the ventilation system of a building, in the subway, on planes. It takes expertise to process biological agents to *maximize* the effect of aerosol dissemination, but even relatively crude devices could have an impact.

- **Food or water,** especially ready-to-eat food (vegetables, salad bars) could be intentionally contaminated with pathogens or toxins. The water supply is less vulnerable because dilution, filtration, and the addition of chlorine can kill most disease-causing organisms.
- **Human carriers** could spread transmissible agents by coughing, through body fluids, or by contaminating surfaces. Most agents would make people ill or incapacitated before they become highly contagious, thereby reducing transmission of the disease.
- **Infected animals** can cause people to become ill through contact with the animals or contaminated animal products.
- **Insects** naturally spread some agents such as plague bacteria (vector borne illnesses) and potentially could be used in an attack.
- **Physically distributed** through the U.S. mail or other means.

For an agricultural attack:

- **A point introduction** of an infected plant or animal or its fluids could spread disease through the rest of the crop or livestock. Agricultural biothreat agents (e.g., foot and mouth disease, avian influenza, soy bean rust, and karnal bunt of wheat) do not have to be aerosolized to be effectively disseminated.

Historical Perspective on Biological Attack

- In 2001, the anthrax attacks through the U.S. mail infected 11 people with inhalational anthrax, of which five died. An additional 11 people were infected with cutaneous (skin) anthrax, of which there were no fatalities.
- In the 1990s, the cult Aum Shinrikyo failed in attempts to release anthrax and botulinum toxin in Tokyo but did succeed in a chemical attack with Sarin nerve agent.
- In 1984, the cult followers of Baghwan Shree Rajneesh sickened 751 people in Oregon by placing salmonella bacteria in salad bars in 10 restaurants to keep people from voting in an election.
- In World War II, Unit 731 in Japanese-occupied Manchuria dropped plague-infected fleas in China, allegedly resulting in more than 50,000 deaths.
- In World War I, German agents successfully infected Allied livestock with anthrax and glanders.
- In the 1340s, Europeans threw plague-infected cadavers over city walls to infect those within.

Laws and Treaties Governing Biological Weapons

- The Geneva Convention of 1925 was the first international agreement to address chemical and biological weapons. It prohibits "bacteriological methods of warfare," but did not outlaw the development of such weapons.
- The Biological and Toxins Weapons Convention (BWC) of 1972 is the first arms control treaty to outlaw an entire class of weapons and forbids States from developing, producing, stockpiling, or retaining biological weapons or assisting other States in developing these weapons systems.
- The Australia Group is a loose association of nations that agrees not to export tools and technologies, including pathogens, that have "dual uses"—that is, they can be used for both legitimate and nefarious purposes.

Table 2. Onset, Health Impacts, and Treatments for Some Agents of Concern

Disease (agent)	**Incubation period***	**Symptoms**
HIGH THREAT AGENTS (CATEGORY A)		
Anthrax *(Bacillus anthracis)* (inhalational)	typically 1–6 days, but up to 42	Fever, cough, profound sweats malaise, fatigue, myalgiaus
Plague *(Yersinia pestis)*	1–7 days (usually 2–3 days)	Fever, cough, shortness of breath, sore lymph nodes
Tularemia *(Francisella tularensis)*	1–21 days (avg 3–6)	Fever, cough, pneumonia, headache
Marburg (Viral hemorrhagic fever)	4–21 days	Sudden onset, fever, headache, followed by vomiting and diarrhea, rash, generalized bleeding in severe cases
Ebola (Viral hemorrhagic fever)	4–21 days	Sudden onset, fever, headache, followed by vomiting and diarrhea, rash, generalized bleeding in severe cases
Smallpox (Variola major virus)	7–17 days (avg 12)	Fever, aches, after 2–4 days rash appears
Botulism *(Clostridium botulinum* toxin)	12 hours–5 days	Muscle paralyzing illness
LOWER THREAT AGENTS (SELECTED CATEGORY B AGENTS)		
Cholera (*Vibrio cholerae*)	4 hours–5 days (usually 2–3 days)	Sudden onset of voluminous watery diarrhea, vomiting, cramps, dehydration
Glanders *(Burkholderia mallei)*	1–14 days via aerosol	Pneumonia with or without blood poisoning, ulcers in nose, mouth, throat and lungs
Q fever *(Coxiella burnetii)*	7–41 days	Flu-like illness that can lead to pneumonia and hepatitis
Encephalitis (Alphaviruses)	2–6 days	Fever, aches, pain behind the eye, nausea, vomiting
Ricin *(Ricinus communis)*	18–24 hours	Can shut down organ function

** Incubation periods listed are for naturally occurring outbreaks, which could differ for agents used as weapons. Data for incubation p*

IMPACT FOLLOWING THE RELEASE OF A PATHOGEN

Detection of a Biological Attack

Unlike a chemical or nuclear attack, a biological attack may go undetected for hours, days, or potentially weeks (depending on the agent) until people, animals, or plants show symptoms of disease. If there are no immediate signs of the attack as with the anthrax letters, a biological attack will probably first be detected by local health care workers observing a pattern of unusual illness or by early warning monitoring systems that detect airborne pathogens. Evidence of an attack may appear in animals before humans.

The Area Affected

For an aerosol release, the area affected would depend on the quantity of agent released, whether the release is indoors or outdoors, and weather conditions. Agents released outdoors would disperse roughly in the direction of the prevailing wind and could degrade with sunlight and by drying out from environmental exposure. Agents released indoors could initially have a higher concentration. Sometimes agents can be re-aerosolized by machinery, foot traffic, or other means.

Finding the Cause and Source of Illness

There may be uncertainties about crucial facts such as the exact location or extent of the initial release, the type of biological agent used, and likelihood of additional releases. Laboratory scientists will work quickly to identify the specific agent. Epidemiologists will attempt to trace the path of infections back toward a single person, vector (insect or animal), vehicle (food or water), or other point of origin. Attribution of a biological attack is typically much more difficult than attribution of a conventional terrorist attack.

Spread (person to person)	**Lethality if untreated**	**Persistence of Organism**	**Vaccine Status** (as of March 2005)	**Medical Treatment**
No (only skin form spreads)	High (if inhaled) viable in soil > 40 yrs	Very stable spores	Licensed	Antibiotics
Moderate	High unless treated within 12–24 hours (pneumonic)	For up to 1 year in soil; 270 days in live tissue	Not current	Antibiotics
No	Moderate	For months in moist soil or other media	Not current	Antibiotics
Via fluids	>25% lethal	Relatively unstable	None	Supportive treatment only
Via fluids	50–80% lethal	Relatively unstable	Investigational	Supportive treatment only
Moderate	High to moderate ≥30% lethal	Very stable	Licensed	Supportive
No	High without respiratory support	Stable for weeks in nonmoving food/water	Licensed (availability uncertain)	Antitoxin if administered quickly
Rare, although spreads rapidly via untreated water	Low with treatment, high without	Unstable in aerosols & fresh water, stable in salt water	Investigational	Antibiotics
No	Death in 7–10 days in blood poisoning form	Very stable	None	Antibiotics
No	Very low	For months on wood and sand	Not licensed in U.S.	Antibiotics
Low	Low	Relatively unstable	None	Supportive treatment
No	High (injected)	Stable supportive treatment	Investigational	No antidote;

period, lethality, and persistency from U.S. Army Medical Research Institute of Infectious Diseases Blue Book, August 2004.

WHAT IS THE DANGER?

Impact on Human Health

Biothreat agents have the potiential to produce a life-threatening illness. Biotoxins are essentially poisons that can be fatal at high enough doses. Table 2 lists health impacts and medical treatments for the Category A and some Category B agents. Even a small amount of some biothreat agents released in air could result in significant loss of life, depending on a number of factors that include the:

- Infectivity of the agent (how many particles are needed to cause illness).
- Lethality of the agent.
- Length of time it takes to detect and treat those who are exposed or have become ill.

Dose Response in Humans

The exact infectious dose (the number or organisms needed to make one sick) of most biological agents is unknown; approximate doses are extrapolated from animal studies. Whether a person becomes ill after exposure to a biological agent depends on a number of factors including:

- Type and amount of agent taken into the body.
- Duration of exposure.
- Route of exposure (inhalation, ingestion, insect bite).
- "Host" factors (e.g., age, immune status, other illnesses of the person exposed).

Differences in Intentional vs. Natural Outbreaks of Disease

Naturally occurring outbreaks of category A agents have become rare because of improved living standards, hygiene, and health services in developed nations. For example, human bubonic plague,which was transmitted by rats and fleas to humans in past centuries resulting in large losses of life, has virtually been wiped out. However, agents used in an aerosol attack may act differently than naturally occurring outbreaks and could produce a form of the disease with a shorter time of onset of illness, making timely diagnosis, treatment, and containment more difficult.

Spread of Diseases

Some transmissible (contagious) diseases can spread through respiratory droplets from coughing and sneezing or when a person comes in contact with a surface harboring a virus or bacteria and then touches their mouth or nose. The viral hemorrhagic fevers and cholera are spread by direct contact with body fluids or feces. People infected with contagious diseases may widely disseminate the disease by travel.

Psychological Impact

Psychological responses following a bioterrorism event may include anger, fear, and social isolation. Following the 2001 anthrax attacks, thousands of people who thought they were infected sought treatment. Trying to distinguish those who haven't been infected could complicate medical centers' ability to treat those who have been exposed and infected, especially when diagnoses are unclear.

WHAT SHOULD PEOPLE DO TO PROTECT THEMSELVES?

Practical Steps

During a declared biological emergency:

1. People in the group or area that authorities have linked to exposure who have symptoms that match those described should seek emergency medical attention.

Infectious Is Different From Contagious

The terms "infectious" and "contagious" are often confused. Infectious refers to the number of particles (spores or organisms) needed to infect an individual. The fewer number of particles needed, the more in-fectious the agent. Agents are contagious if they spread from person to person. Some agents that are highly infectious, such as Tularemia and Q fever, are not contagious.

2. Use common sense, practice good hygiene and cleanliness to avoid spreading germs.

People who are potentially exposed should:

1. Follow instructions of health care providers and other public health officials.
2. Expect to receive medical evaluation and treatment. Be prepared for long lines. If the disease is contagious, persons exposed may be quarantined.

If people become aware of a suspicious substance nearby, they should:

1. Quickly get away.
2. Cover their mouths and noses with layers of fabric that can filter the air but still allow breathing.
3. Wash with soap and water.
4. Contact authorities.
5. Watch TV, listen to the radio, or check the Internet for official news and information including the signs and symptoms of the disease, if medications or vaccinations are being distributed, and where to seek medical attention if they become sick.
6. Seek emergency medical attention if they become sick.

Medical Treatment

Table 2 lists general medical treatments for several biothreat agents. In general, bacterial illnesses are treated with antibiotics, and viral illnesses are treated with supportive care, although there are a few specific medications to treat viral infections. Biotoxins are treated with antidotes or antitoxins, if available. Vaccines can prevent or mitigate the effects of a disease. The smallpox vaccine may provide protection even if given 1–4 days after exposure, and the anthrax vaccine can be given after inhalation exposure if accompanied by treatment with antibiotics for a number of weeks.

Controlling the Spread of Contagious Diseases

Methods to control contagious disease include isolation, quarantine, barrier methods (gloves, filter masks, eye protection), and hand washing. Rapid identification of potentially infected persons increases the effectiveness of these methods.

WHAT ARE THE LONG-TERM CONSEQUENCES?

Monitoring and Clean-up

After a biological agent has been identified, officials will take steps to characterize how long the agent will persist. Clean-up within buildings may entail the use of gas or liquid decontaminants to kill the agent. For example, chlorine dioxide gas was released through ventilation systems of buildings contaminated with anthrax. In some cases, multiple rounds of decontamination may be necessary. Decisions regarding how much clean-up is necessary will depend on:

- The amount of agent released.
- How far the agent has spread.
- How the space will be used following clean-up.

Long-term Health Consequences Following Exposure

The long-term health consequences for those who survive exposure to biological attack agents are unknown. A long-term medical surveillance program would likely be established to monitor potential health effects of those exposed.

Economic Impact of an Agricultural Attack

Once detected, an act of agricultural bioterrorism may quickly halt the movement and export of livestock or the affected crop, resulting in potentially severe economic consequences for producers, shippers, and consumers. It may also disrupt normal travel and commerce.

ADDITIONAL INFORMATION

Centers for Disease Control and Prevention—**http://www.bt.cdc.gov**

Infectious Disease Society of America—**http://www.idsociety.org**

National Institute of Allergy and Infectious Disease—**http://www.niaid.nih.gov/biodefense/**

U.S. Army Medical Research Institute of Infectious Diseases—**http://www.usamriid.army.mil**

U.S. Department of Health and Human Services —**http://www.hhs.gov/emergency**

U.S. Department of Homeland Security—**http://dhs.gov/dhspublic** • **http://www.ready.gov**

This report brief was prepared by the National Academy of Engineering and National Research Council of the National Academies in cooperation with the Department of Homeland Security. For more information or referrals to subject-matter experts, contact Randy Atkins at 202-334 1508, atkins@nae.edu, or visit www.nae.edu/factsheets. *Making the Nation Safer, Tracking the Atmospheric Dispersion of Hazardous Materials Releases* and other National Research Council reports related to this topic are available from the National Academies Press, 500 Fifth Street, NW, Washington, DC 20001; 800-624-6242; www.nap.edu.

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