COMPREHENSIVE Hemôphilia Management:

Leveraging Collaborative Care Strategies and Resources

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This activity is supported by educational grants from Baxter BioScience, Bayer HealthCare Pharmaceuticals Inc., Biogen Idec, and Novo Nordisk, Inc.

Educational Objectives

After completing this activity, the participant should be better able to:

- Discuss the impact of hemophilia with and without inhibitors on clinical, economic, and humanistic outcomes
- Assess current and emerging hemophilia therapies for children and adults, with and without inhibitors
- Implement the Medical and Scientific Advisory Council (MASAC) Quality of Care Guidelines for the treatment of hemophilia
- Employ collaborative care strategies and resources, including HTCs, to improve care coordination for health plan patients with hemophilia
- Recommend hemophilia management policies and protocols to optimize patient outcomes in a managed care and/or specialty pharmacy setting
- Provide accurate and appropriate counsel as part of the treatment team

Faculty



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Faculty Disclosures

The **faculty** reported the following financial relationships or relationships they or their spouse/life partner have with commercial interests related to the content of this continuing education activity:

Name of Faculty or Presenter	Reported Financial Relationship
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Sue Geraghty, RN, MBA	Consulting Fees: Biogen Idec, Kedrion Biopharma, Inc., Novo Nordisk, Inc. Fees for Non-CME/CE Services: Biogen Idec, Novo Nordisk, Inc.
Marc Gilgannon, PT	No financial interest/relationships relating to the topic of this activity
Patrick Lynch	No financial interest/relationships relating to the topic of this activity
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Clinical Updates in Hemophilia Treatment

Michael D. Tarantino, MD

Professor, Department of Pediatrics and Department of Medicine University of Illinois College of Medicine at Peoria Medical Director Bleeding and Clotting Disorders Institute

Hemophilia: An Inherited Disorder

- X-linked recessive bleeding disorder leading to spontaneous bleeding and bleeding following trauma or surgery
 - Typically expressed in males; female carriers may have symptoms
 - Characterized by a deficiency of Factor VIII (hemophilia A) or Factor IX (hemophilia B)
- Current prevalence in the United States: ~20,000 males
 - Occurs in ~1 of every 5,000 live male births
 - 30% of cases are new mutations
 - Affects individuals from all racial and ethnic groups
- Hemophilia A is ~4X as common as hemophilia B

CDC. Hemophilia facts. http://www.cdc.gov/ncbddd/hemophilia/facts.html.

Detection/Diagnosis



- Identify carriers
- Pre-conception counseling
- Cord blood testing of males
- Low-level carriers should be identified early to prevent bleeding with surgery or injury

No Previous Family History

- Bleeding with birth or post-natal, circumcision, immunizations
- Excessive bleeding following trauma/injury
- Joint bleeds and hematomas

Clinical Manifestations



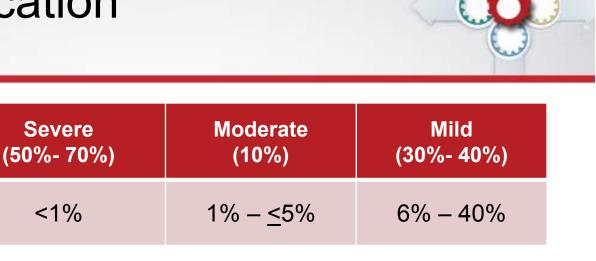
- Bleeding into joints (hemarthrosis), muscles, soft tissues, and other locations
- Interference with normal activities and ability to participate fully in school or work
- Long-term sequelae if bleeding not prevented
 - Flexion contractures
 - Arthritis/arthropathy
 - Chronic pain
 - Muscle atrophy
 - Loss of mobility
 - Neurologic impairment
- Inhibitor development represents severe sequelae occurring in ~30% of severe FVIII patients

Clinical Classification

Classification

(% of affected patients)

FVIII or FIX activity



Pattern of bleeding episodes	~2 – 4 per month	~4 – 6 per year	Uncommon
Cause of bleeding episodes	Spontaneous	Minor trauma	Major trauma, Surgery

Adapted from Henry's Clinical Diagnosis and Management by Laboratory Method. 21st edition; Table 38-4; Copyright Elsevier.

Treatment of Hemophilia



- Treatment goal
 - Rapid and effective replacement of missing coagulation factor
- Treatment approach
 - Comprehensive hemophilia treatment center (HTC) staffed by a multidisciplinary team of experts who care for patients with bleeding disorders
- Treatment strategies
 - Episodic or "on-demand" factor replacement
 - Prophylaxis

CDC. Hemophilia facts. http://www.cdc.gov/ncbddd/hemophilia/facts.html.

Prophylaxis

- Infused factor replacement before the occurrence of, and to prevent, bleeding^{1,2}
- Since the 1990s, prophylaxis supported by WHO, NHF, and WFH as first-line treatment for children with severe hemophilia^{2,3}
 - Use increasing for adult patients⁴
- Demonstrated benefits include
 - Prevention of chronic arthropathy and sequelae⁵
 - Prevention of intracranial and other serious bleeds¹
 - Prevention of pain⁶
 - Improvement in quality of life⁶
 - Reduction in long-term disability^{1,6}
- 1. Berntorp E, et al. *Haemophilia*. 2003;9(suppl1):1-4.
- 2. Carcao M, et al. Haemophilia. 2010;16(suppl2):4-9.
- 3. Rodriguez NI, et al. Hematol Oncol Clin North Am. 2010;24:181-198.
- 4. Collins PW, et al. J Thromb Haemost. 2010;8:269-275.
- 5. Manco-Johnson MJ, et al. *N Engl J Med*. 2007;357:535-544.
- 6. Shapiro AD, et al. The Role of Prophylaxis in Managing Hemophilia in Adult and Pediatric Populations. Available at: http://cme.medscape.com/viewarticle/703176_print.

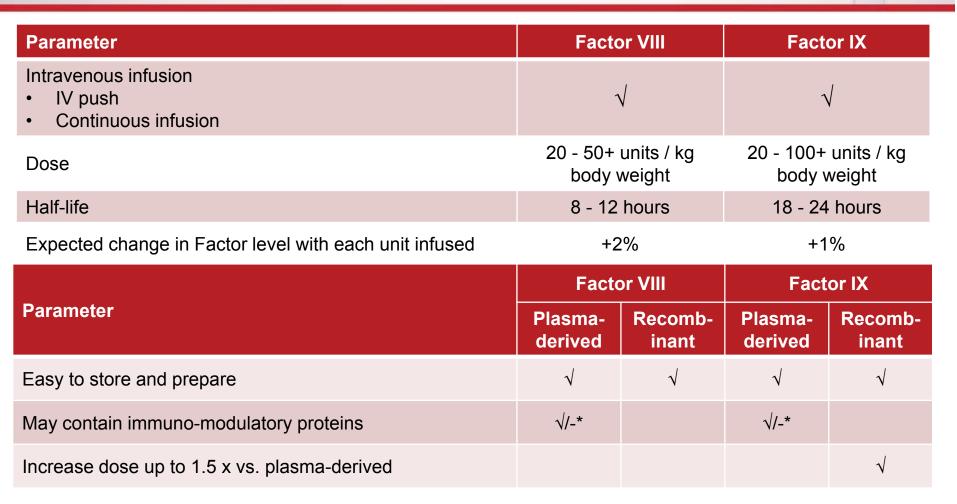
WHO=World Health Organization NHF=National Hemophilia Foundation WFH=World Federation of Hemophilia



Treatment Options

- Replacement of missing clotting protein
 - Factor VIII and IX
- Desmopressin acetate (IV, intranasal) in mild FVIII deficiency
- Adjunctive therapies
 - Antifibrinolytic agents
 - Aminocaproic acid
 - Tranexamic acid
 - Supportive measures
 - Icing
 - Immobilization
 - Rest

Factor VIII and IX Products



*variable depending on level of purity

NHF. http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=179&contentid=45&rptname=bleeding.

Inhibitors

- Infusion of exogenous clotting factor can trigger an immune response
- IgG antibodies (inhibitors) directed against Factor VIII or IX protein that neutralizes the procoagulant effect of the infused factor¹
- Incidence highest in patients with severe disease (Hemophilia A is 20-30%; Hemophilia B, 1-4%)
- Typically develop early in life (median age 1.7 3.3 years)
- Greatest risk for inhibitor development occurs within the first 50 days of exposure to infused product²

^{1.} CDC. Hemophilia facts. http://www.cdc.gov/ncbddd/hemophilia/facts.html.

^{2.} Bray GL, et al. *Blood*.1994;83:2428-2435.

Management of Inhibitors



- Bypassing agents
 - Activated prothrombin complex concentrates
 - Recombinant factor VIIa
- Bypassing agents have unpredictable efficacy (50 90%)
 - Patients often need access to both products
 - Surgery historically difficult to perform
- Immune Tolerance Therapy (ITT)
 - Methods to eradicate inhibitor
 - ~ 70% effective overall
- Overall cost of treating inhibitors is significant
 - More bleeding, more joint damage

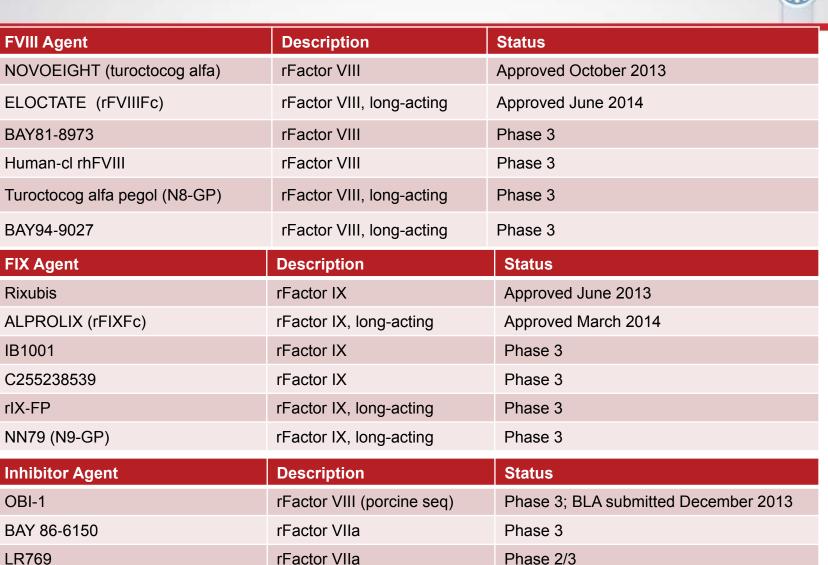
CDC. Hemophilia facts. http://www.cdc.gov/ncbddd/hemophilia/facts.html.

Promise of Long-Acting Hemophilia Therapeutics

- Half-life of standard hemophilia therapies results in frequent injections
 - Factor VIII three times per week to every other day
 - Factor IX two to three times per week
- Benefits of replacement product with a longer half-life include
 - Reduced frequency of administration
 - Ability to achieve higher trough levels in certain clinical situations
 - Potentially improved adherence
- The first long-acting rFVIII and rFIX recently obtained FDA approval
 - Several additional long-acting agents are currently in development

Franchini M, Mannucci PM. Orphanet J Rare Dis. 2012, 7:24. Available at: http://www.ojrd.com/content/7/1/24.

Late Phase Investigational and Recently Approved Treatments



Emerging Issues

- Prophylaxis
 - Target trough levels: Is 1% the best level?¹
 - Cost : benefit ratio of targeted higher levels
 - Impact on patient outcomes and QoL
 - Impact of peak levels²
 - Applicable age groups not just for pediatrics³⁻⁴
- Bleed treatment⁵⁻⁶
 - How long is hemostatic coverage required for healing & prevention of re-bleeding?
 - What is the best target peak level?
- What is the risk of CVD in hemophilia?⁷⁻⁹
 - How does level of severity impact risk?
 - FVIII versus IX deficiency
 - Will prophylaxis in older hemophilia population affect expression of underlying atherosclerotic disease?
- 1. Fischer K et al. Blood. 2013 Jun 18. [Epub ahead of print]
- 2. Lindvall K et al. Haemophilia. 2012 Nov;18(6):855-9. Epub 2012 Jun 11.
- 3. Manco-Johnson MJ et al. Haemophilia. 2013 Jun 11. Epub ahead of print.
- 4. Gringeri A et al. Haemophilia. 2012 Sep;18(5):722-8. Epub 2012 May 29.
- 5. Simpson ML & Valentino LA. Expert Rev Hematol. 2012 Aug;5(4):459-68.
- 6. Sørensen B et al. Haemophilia. 2012 Jul;18(4):598-606. Epub 2011 Dec 12.
- 7. Fransen van de Putte DE et al. Thromb Haemost. 2012 Oct;108(4):750-5. Epub 2012 Sep 5.
- 8. Alesci S et al. *Haemophilia*. 2012 Sep;18(5):e364-5. Epub 2012 Jul 3.
- 9. Konkle BA. Am J Hematol. 2012 May;87 Suppl 1:S27-32. Epub 2012 Mar 19

The HTC/Comprehensive Care Model

- A hemophilia treatment center (HTC) is a federally recognized comprehensive care facility featuring a multidisciplinary team expert in the care of patients with bleeding disorders and whose staff spends a majority of their time caring specifically for these patients
- Key features:
 - Expertise in coagulation disorders
 - Development and provision of individual treatment plans
 - Preventive medicine
 - Access to multiple health care disciplines
 - Optimization optimized care

Treatment via the HTC Model Results in More Comprehensive Care with Efficiencies that Drive Improved Outcomes

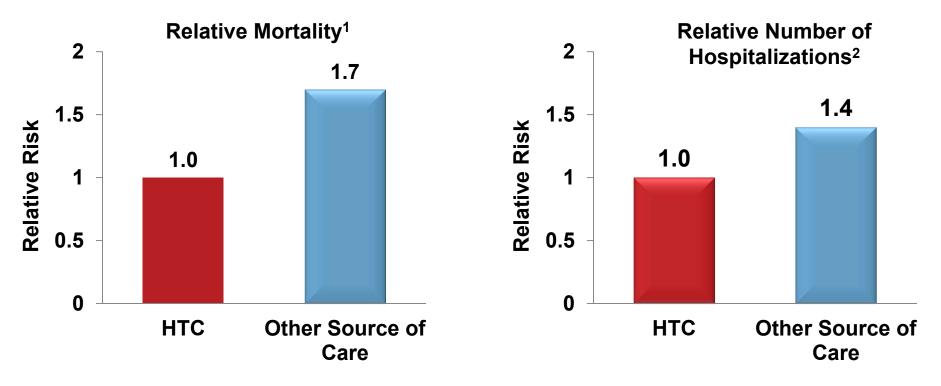
Outcome Data from 31 HTCs

Outcome Data	Year Before Program 1975	10 th Year of Program 1985	% Increased (+) % Decreased (-)
Number patients receiving regular comp care	1,333	5,683	+ 326%
Number patients on homecare	514	2,517	+ 390%
Average days/year lost from work/school	14.5	3.9	- 73%

Soucie JM, et al. *Blood*. 2000; 96:437-442.

Benefits of Care Delivered Through an HTC

For Patients Receiving Care Outside of an HTC: Mortality Rate Increases by 70% and Hospitalization Rate Rises by 40%



1. Soucie JM, et al. *Blood*. 2000; 96:437-442.

2. Soucie JM, et al. *Haemophilia*. 2001; 7:198-206.

Summary

- Hemophilia is an X-linked recessive bleeding disorder leading to spontaneous bleeding and bleeding following trauma or surgery
- Clinical manifestations include bleeding in the joints (hemarthrosis) and muscles
- Long-term complications include joint destruction, muscle atrophy, and decreased quality-of-life
- Inhibitor development is the most severe complication of hemophilia treatment and has significant clinical and economic consequences
- Prophylactic factor replacement may avoid or reduce musculoskeletal impairment from hemophilic arthropathy and enhances quality-of-life
- Introduction of longer-acting factor replacement products holds promise for patients
- The HTC model offers improved clinical and economic outcomes via multidisciplinary, comprehensive care

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Comprehensive Care Team Visit Patient Overview

Sue Geraghty, RN, MBA

Formerly: HTC Nurse Coordinator University of Colorado Hemophilia and Thrombosis Center University of Colorado Health Sciences Center

Pre-Comp Meeting



- 28-year-old male with severe (<1%) FVIII deficient hemophilia with a history of a high responding inhibitor, tolerized
- Past medical history
 - Diagnosed at birth by cord blood testing related to a maternal uncle with hemophilia
 - Developed inhibitor at 2 years of age with historical peak titer of 10 BU
 - Inhibitor eradicated after 18 months of immune tolerance-daily infusion
 - Transitioned to prophylactic treatment following immune tolerance
 - Developed target joint in right knee and left ankle in early childhood due to poorly controlled bleeding due to inhibitor
 - Immune Status
 - Hepatitis A immune
 - Hepatitis B core antibody positive
 - Hepatitis C positive
 - HIV negative

Pre-Comp Meeting

- Social History
 - Works as a software engineer, has a long-term girlfriend
 - Surgical History
 - Appendectomy 2000 without bleeding complications
 - Synovectomy of left ankle 2010

Pre-Comp Meeting

- Contact with comp team in the past year
 - 1 Hospitalization
 - Following MVA, hit head on windshield, Head CT negative, observed overnight
 - Coordination of a wisdom teeth extraction with oral surgeon
 - 2 office visits including laboratory factor levels, discussion of breakthrough bleeding
 - Nursing: 10 telephone contacts
 - Related to bleeding episodes in right knee, prior authorizations, follow up from hospitalization, questions related to new hepatitis C treatment
 - PT: 2 encounters related to recommendations for stretching and strengthening exercise
 - SW: 2 encounters related to FMLA paperwork & insurance



Hemophilia Nurse's Perspective

Hemophilia & Thrombosis Nurse

- Nursing assessment and recording of general health and bleeding-related issues
 - Sites and types of bleeds
 - Factor utilization, including dosing and frequency
 - Maximum factor quantity storage at home
 - Factor log
 - Other health concerns
- Patient education
 - Dosing, prophylaxis, avoidance of bleeding events/ED visits
 - Expectations for potential synovectomy
- Care plan and evaluation of home therapy regimen
- Immunization status and administration as needed



Physical Therapist's Perspective

Physical Therapist

- Assessment of musculoskeletal and functional status
- Individually designed exercise programs and activity guidelines
- Synovectomy and potential rehabilitation program
- Value of HTC-trained PT to improve patient outcomes and reduce cost of care
 - Coordinate referral to outpatient clinic for physical therapy if needed
 - Resource for community based services



Social Worker's Perspective

Social Worker

- Psychosocial Assessment:
 - Established adult patient updates on demographics, employment status, family concerns, financial and insurance matters, emotional issues, etc.
- Identification of challenges and barriers to patient's physical and emotional well-being:
 - Problems that may interfere with hemophilia-related treatment and life routine, i.e., change in insurance, increased copays, loss of income, inability to cope with condition, lack of support system, etc.
- Surgery: concerns and needs for potential surgery
- Cooperative Plan:
 - Calls and/or visits in preparation for future surgery and activities of daily living until next visit
 - Assistance with financial/insurance concerns
 - Necessary documentation (prior authorization, work leave/disability forms, etc.)
 - Coverage and insurance-related issues—prior authorizations, benefit determination (medical vs. SPP), site of care (HTC, home care, SPP, etc.)



Hematologist's Perspective

Hematologist

- Factor use, increasing dose for prophylaxis (medical necessity, potential complications averted, etc.)
- Potential management of infection, including screening for liver damage, hepatitis, and HIV
- Further discussion of overall care plan
- Exploring potential synovectomy
 - Benefits and disadvantages
 - Alternatives via physical therapy, etc.
- Consider referral to any of the following specialists on an as-needed basis:
 - Chronic pain specialist
 - Dentist
 - Geneticist
 - Hepatologist/infectious disease specialist
 - Immunologist
 - Orthopedic surgeon

Closing Conference

- Multidisciplinary team regroups
 - Each specialist provides feedback
 - Consensus on individual plan of action
- Unique value-added approach by HTC
 - Efficient patient care to improve outcomes and control costs

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Comprehensive Hemophilia Management: Leveraging Collaborative Care Strategies and Resources

Vanita Pindolia, PharmD, BCPS

Vice President, Ambulatory Clinical Pharmacy Programs Henry Ford Health System/Health Alliance Plan of Michigan Hemophilia: High Aggregate Cost of Care Despite a Low Incidence

- Hemophilia is a rare disorder affecting ~24,000 individuals in the US
- Variables in the cost of care include
 - Disease severity
 - Frequency of bleeding
 - Development of inhibitors
 - Cost of factor replacement products
- Mean healthcare expenditures per patient in a commercial population: \$155,000/year
- Mean healthcare expenditures per patient in a commercial population with inhibitors: \$697,000/year

8

Cost of Care: Hemophilia Services

- Prevalence Rate per 100,000 males for Hemophilia A and B is very low
 - Commercial: 11 (A), 1.8 (B)
 - Medicaid: 21.2 (A), 3 (B)
- Prevalence rate of inhibitors (more serious complications with treatment) is 2%-9% for Hemophilia A and 1%-4% for Hemophilia B

Average Annual Allowed Claim Costs by Hemophilia Type for Commercial and Medicaid (2008-2011):

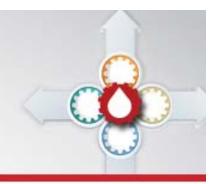
Service	Avg Mbr Claims	Hemo A	Hemo B
Hospital Facility	\$1,065 (C) / \$1,488 (M)	\$9,661(C) / \$13,900 (M)	\$5,384 (C) / \$24,009 (M)
Professional	\$2,394 (C) / \$1,217 (M)	\$7,433 (C) / \$3,905 (M)	\$7,062 (C) / \$11,033(M)
Drugs (non-hemo)	\$740 (C) / \$404 (M)	\$3,492 (C) / \$1,700 (M)	\$1,491 (C) / \$3,608 (M)
Hemophilia Drug	N/A	\$64,153(C) / \$121,335 (M)	\$33,237 (C) / \$36,043 (M)

C = Commercial; M = Medicaid

Milliman Client Report: An Actuarial Study of Hemophilia (Oct 2013); Prepared for Baxter Healthcare Corporation

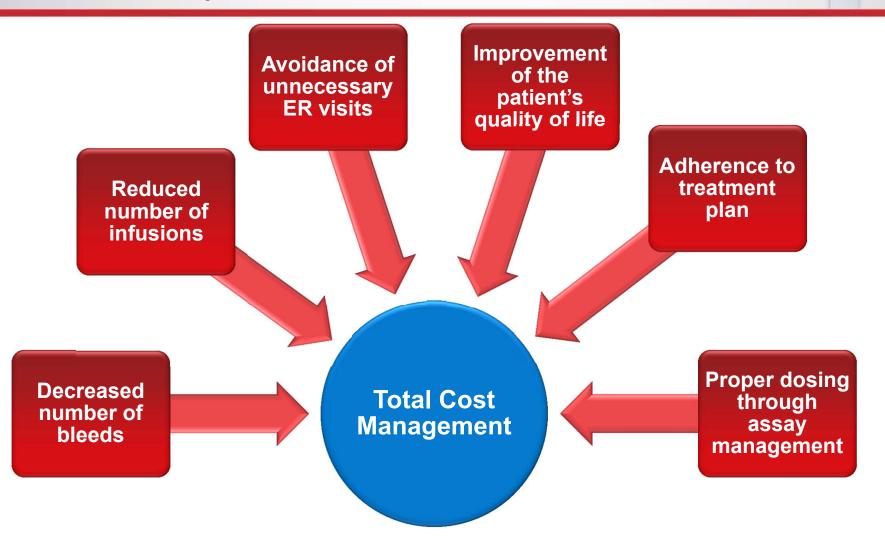
- Hemophilia A: Drug costs are 76% and 86% of total Claims cost for Commercial and Medicaid, respectively
- Hemophilia B: Drug costs are 70% and 48% of total Claims cost for Commercial and Medicaid, respectively

Challenges of Hemophilia Care Management in Managed Care



Challenge	Approach
Treatment access and quality	 Integrate hemophilia care in network management and medical management strategies Establish relationships with HTCs, specialty pharmacy, and specialized medical providers
Care management	 Consider how to coordinate multi-disciplinary outpatient and home-based services
Cost management	Consider cost-effective approaches for administration of factor replacement while keeping in mind the individualized treatment needs of each patient
Pharmacy management	 Evaluate all services required to manage hemophilia Secure cost-effective and timely factor replacement services for routine and emergency needs
Risk management	 Identify financing solutions (eg, risk adjustment or carve outs) to ensure member access to care
Patient involvement	 Include members in decisions impacting their care Support member involvement in self-management and facilitate social support networks

Effective Hemophilia Management Can Improve Outcomes and Avoidance of Unnecessary ED Visits and Hospitalizations



Hemophilia Drug Management

- Specialty Pharmacies
 - Discounted pricing through purchasing power
 - Case management
 - Drug dispensing/administration in close collaboration with patient/caregiver/treatment center
- Drug dosing
 - Prophylaxis vs. on-demand factor use
 - Starting dose range
 - Patients with inhibitors

Opportunities Exist for Health Plans to Improve Outcomes through Collaboration

- Coordination with Providers
 - Physicians
 - Overall patient wellbeing/care
 - Comorbid conditions
 - Anticipation of change in care needs
 - Hemophilia Treatment Centers (HTCs)
 - Provide high level care coordination and supportive care with Health Plan
 - Assure clinical care/support for accurate assay testing
 - Compliance and adherence
 - Specialty Pharmacy Providers (SPPs)
 - Coordination with HTC and Provider
 - Coordination of PA and billing
 - Compliance and adherence

Opportunities for Improvement



- Capitalizing on the capabilities of, and enhancing relationships with contracted Specialty Pharmacies, HTCs, and the National Hemophilia Foundation (NHF)
- Encouraging care that is consistent with best clinical practices
- Examine the potential of investment in care today to achieve or enhance long-term clinical outcomes and cost savings in the future
- Considerations regarding patient cost-sharing (eg, deductibles, coinsurance and annual out-of-pocket maximums) and maximum annual patient financial responsibility

Willey VJ, et al. Health Aff. 2008;27:824-834.

Opportunities for Improvement (cont.)

- Potential role of specialty pharmacy providers and coordination with HTCs where both organizations are involved
- Utilization and sharing of data available from HTC annual patient evaluation reports (as available) subject to addressing administrative and financial implications
- Payer's support for telemedicine
 - Encourage better communication between HTCs, hematologists, and patients
 - Encourage care that is consistent with best clinical practices that might yield cost savings
- Improved understanding of needs and coordination of care between HTCs, community hematologists, specialty pharmacy providers, and payers

Strategies to Improve Collaboration Between Specialty Pharmacy and Payers

- Understand the needs of each stakeholder
 - HTCs are concerned with medical care of patient
 - Specialty pharmacy is concerned with the timely and accurate filling of prescriptions to meet the clinical needs of patient
 - Payers need to be assured that the dispensed factor and patient care is appropriate and cost-effective

Methods to Improve Collaboration Between Specialty Pharmacy and Payers

- Proactively calls to check on bleed activity and inventory on hand
- Proactively implements steps to avoid ER visits
- No shipments when patient has adequate supply of factor and supplies on hand
- Information gathering on bleed log history
- Communicate expected changes in costs to payer
 - Planned surgeries and procedures
 - Significant changes in utilization
 - Identify barriers to optimal patient outcomes
 - Establish communication with case managers

HTC Collaboration with Specialty Pharmacy Provider (SPP)

- Points of contact/interaction between the HTC and SPP
 - Initial prescription
 - Changes in treatment plan
 - Some pharmacies require prior authorization for each shipment
- Having a dedicated, knowledgeable contact at each payer is very helpful
- Ability to share data between payers, HTC, and SPPs is limited due to lack of technical compatibility

Methods for Facilitating Collaboration Between the SPP and HTC

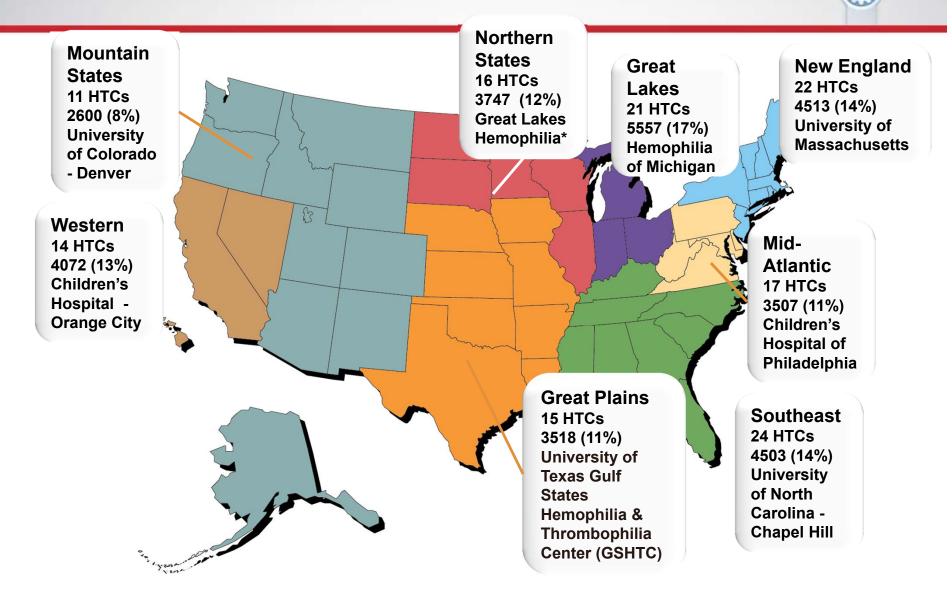
- Use a case manager who is familiar with hemophilia, HTCs, and hemophilia patient needs, factor administration, need for ancillary supplies, and treatment challenges
- Provide a consistent contact person who is familiar with the HTC staff and patients
- Provide paperwork needed to fulfill a prescription in advance
 - Prior authorization, prescription, how often, etc.
 - Send paperwork at the time of the request

Improving the Management of Hemophilia with HTC Care

- Every patient should be followed by an HTC
 - HTCs offer multidisciplinary team approach to care
 - 40% reduction in mortality among those who receive HTC care vs. those who do not
 - However, ~30% of hemophilia patients in the US receive care outside of an HTC
 - Patients, providers, and managed care organizations need to be educated about the benefits of HTC care

Centers for Disease Control. Hemophilia. http://www.cdc.gov/ncbddd/hemophilia/data.html. Accessed April 22, 2104. Soucie JM, et al. *Blood*. 2000; 96:437-42.

Regional Hemophilia Treatment Center Network



Collaborative Care: Multidisciplinary Patient Management Team

Core Team

- Patient / Family
- Hematologist
- Nurse
- Social worker
- Physical therapist

Extended Team

- Other physicians
 - Primary care
 - Orthopedics
 - Infectious disease
 - Obstetrics-gynecology
 - Hepatology
- Geneticist
- Pharmacist
- Dental
- Educational/vocational counselors
- Research coordinator
- Nutritionist
- Risk reduction coordinator
- Clinical data manager

Ruiz-Saez A. *Hematology.* 2012;17(supp1):S141-143.

Value of Hemophilia Care Administered Through an HTC

Features of HTC Care

- Relatively stable and predictable annualized costs over time
- Committed physician and patient advocacy
- Complete medical care and wellness programs
- Reduced overall costs
- Decrease in hospital admissions
- Reduced patient morbidity and mortality

Implications for Managed Care

- Comprehensive care
- Benefits include:
 - Continuity of care
 - Access to specialists and treatments
 - Reduced number of days hospitalized per year
 - Reduced frequency of hospital visits
 - Reduced average length of stay
 - Early identification/treatment of inhibitors

Centers for Disease Control. Hemophilia. http://www.cdc.gov/ncbddd/hemophilia/htc.html. Accessed April 22, 2104. Soucie JM, et al. *Blood*. 2000; 96:437-42. Smith PS, Levine PH. *Am J Public Health*. 1984;74:616-17.

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