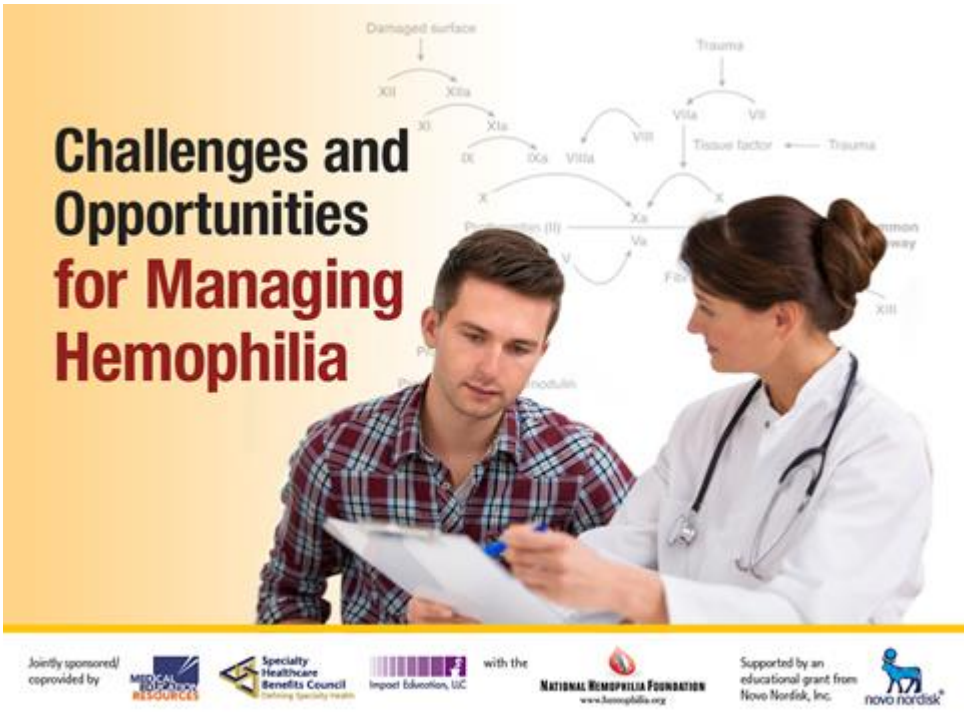
Challenges and Opportunities for Managing Hemophilia 2014

Track 2: Care Management Strategies

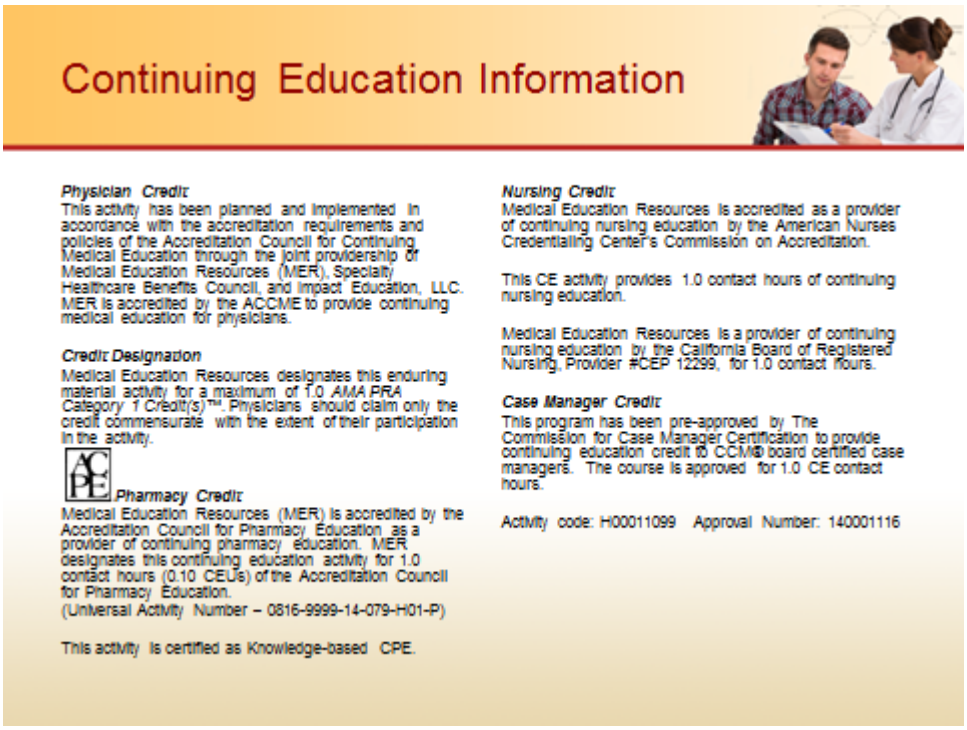


Slide 1: Challenges and Opportunities for Managing Hemophilia

Welcome to Challenges and Opportunities for Managing Hemophilia 2014 Continuing Education Series.

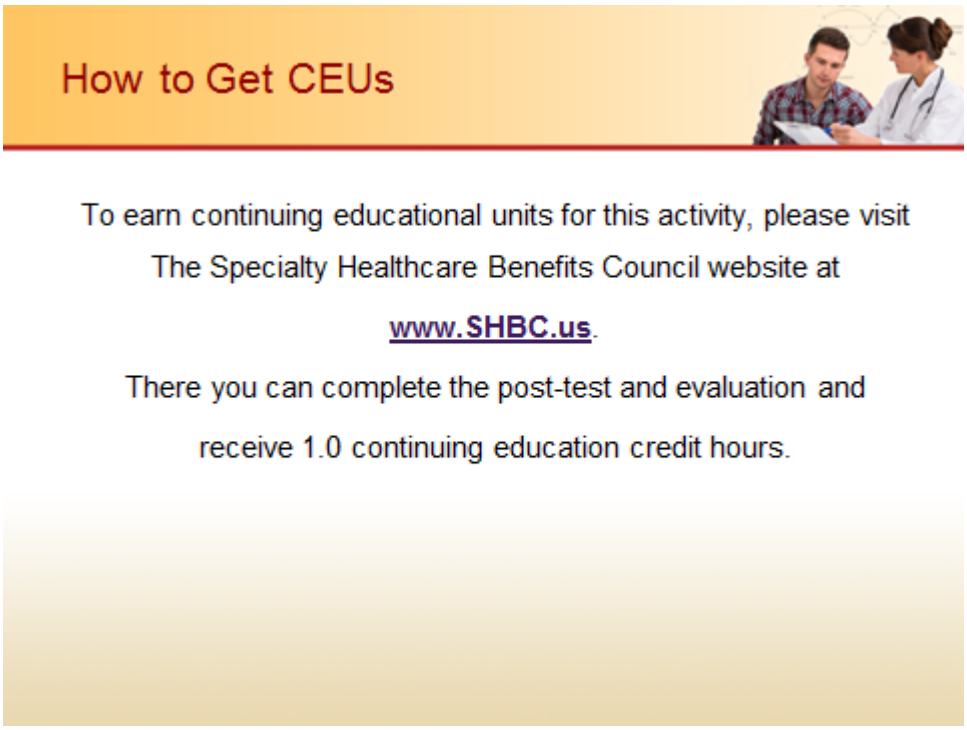
This series of three tracks is jointly sponsored by Medical Education Resources, the Specialty Healthcare Benefits Council, and Impact Education, LLC, in collaboration with the National Hemophilia Foundation.

This activity is supported by an educational grant from Novo Nordisk, Inc. and we would like to thank them for their support.



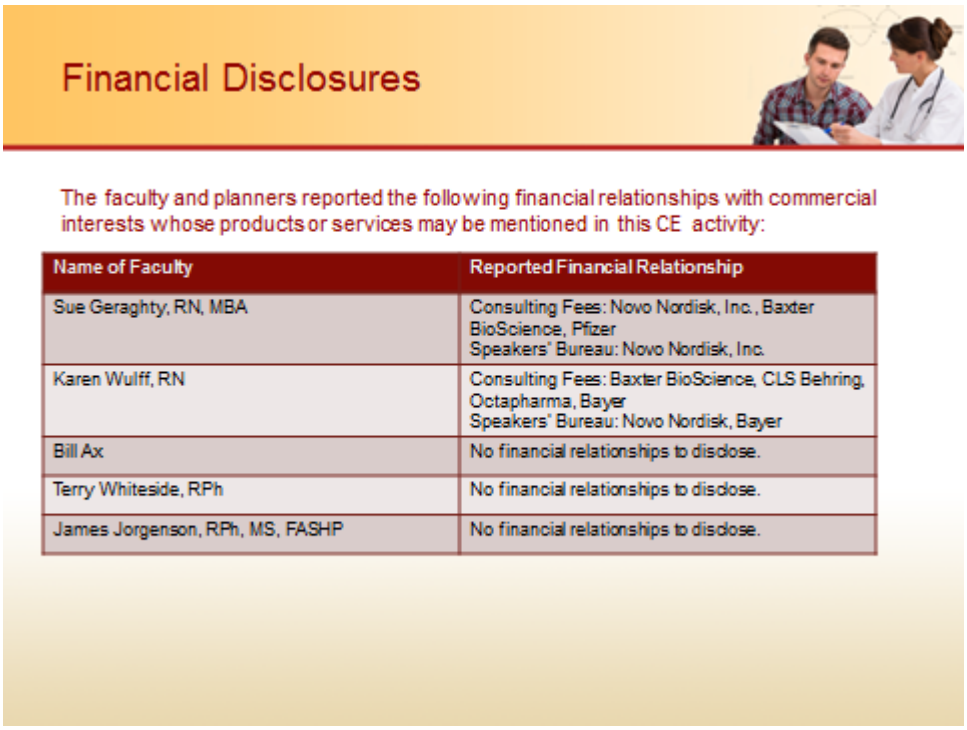
Slide 2: Continuing Education Information

Continuing education for this activity is provided by Medical Education Resources, or MER. They have designated this activity for one (1) credit hour for each track, or a potential total of three (3) hours if all three tracks are completed. This credit is for physicians, pharmacists, nurses, and case managers.



Slide 3: How to Get CEUs

To earn continuing educational units for this activity, please visit The Specialty Healthcare Benefits Council website at www.SHBC.us. There you can complete the post-test and evaluation and receive 1.0 continuing education credit hour.



Slide 4: Financial Disclosures

The faculty and planners reported the following financial relationships with commercial interests whose products or services may be mentioned in this continuing education activity.

Slide 5: Financial Disclosures **(continued)**

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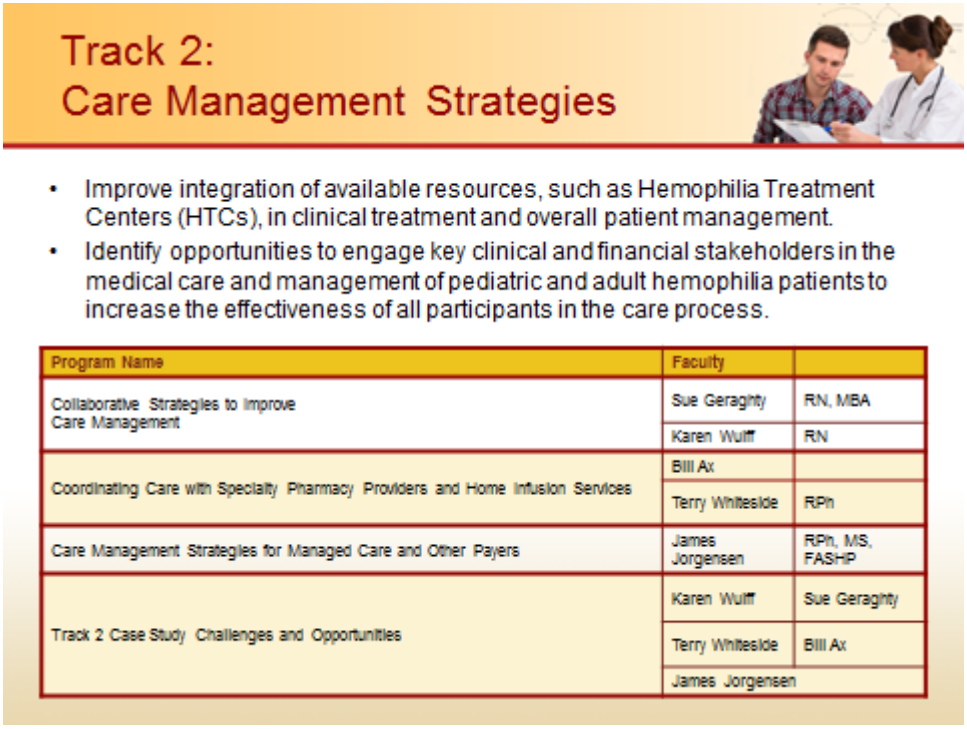


Slide 6: Track 2: Care Management Strategies

Welcome to Track 2 of a three part series. This track, entitled Care Management Strategies, will focus on the care and management strategies for managing hemophilia within a managed care setting.

Upon completion of this learning track, the learner will be able to:

1. Improve integration of available resources, such as Hemophilia Treatment Centers (HTCs), in clinical treatment and overall patient management.
2. Identify opportunities to engage key clinical and financial stakeholders in the medical care and management of pediatric and adult hemophilia patients to increase the effectiveness of all participants in the care process.

Program 1:

Collaborative Strategies to Improve Care Management

Slide 7: Collaborative Strategies to Improve Care Management

This program is entitled Collaborative Strategies to Improve Care Management, and represents the hemophilia nurse coordinator perspective.

Slide 8: Program Faculty

The faculty for this program includes two Hemophilia Treatment Center nurses: Sue Geraghty, retired nurse from the University of Colorado Denver Hemophilia and Thrombosis Center; and Karen Wulff, Hemophilia Nurse Coordinator at the Louisiana Comprehensive Hemophilia Care Center, Tulane University Medical School. Support staff for this presentation includes Joe Eichenholz, Executive Director of the Specialty Healthcare Benefits Council, and Marla Feinstein and Michelle Rice, from the National Hemophilia Foundation's Public Policy Team.

Slide 9: Hemophilia Treatment Centers

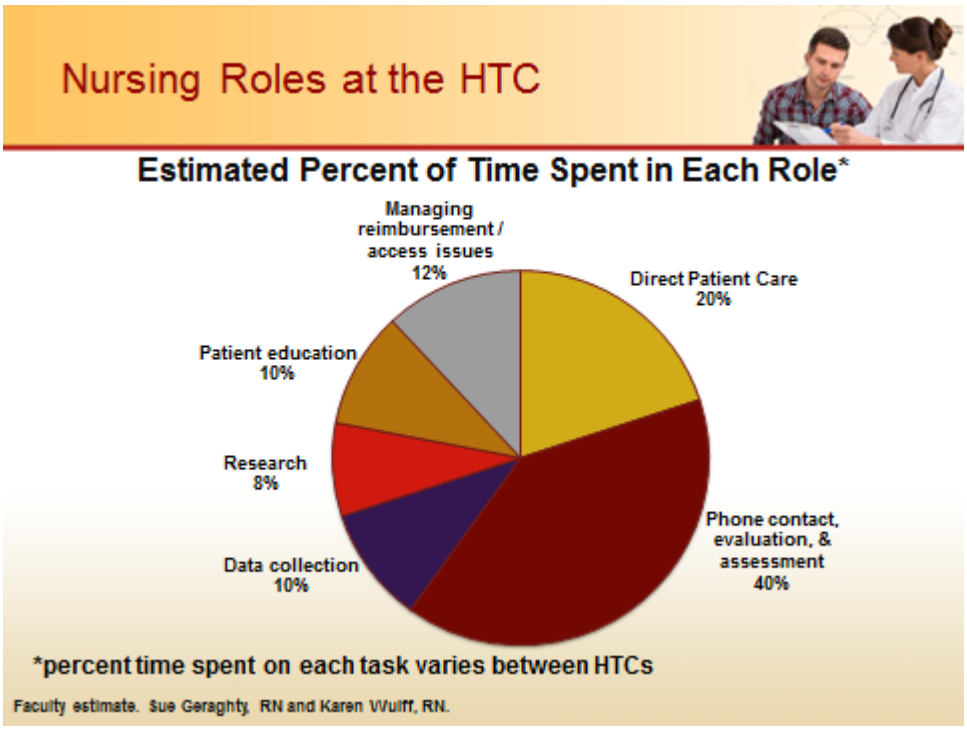
The topic of this program is the Hemophilia Treatment Center, or HTC, care environment. The primary responsibility of HTCs is to dispense factor and provide services when requested for individuals with hemophilia and their caregivers.

HTC services include state-of-the-art care management across the lifespan of each patient, patient education, research, and outreach, and provision of ancillary supplies for home infusion.

Slide 10: Comprehensive HTC Care Team

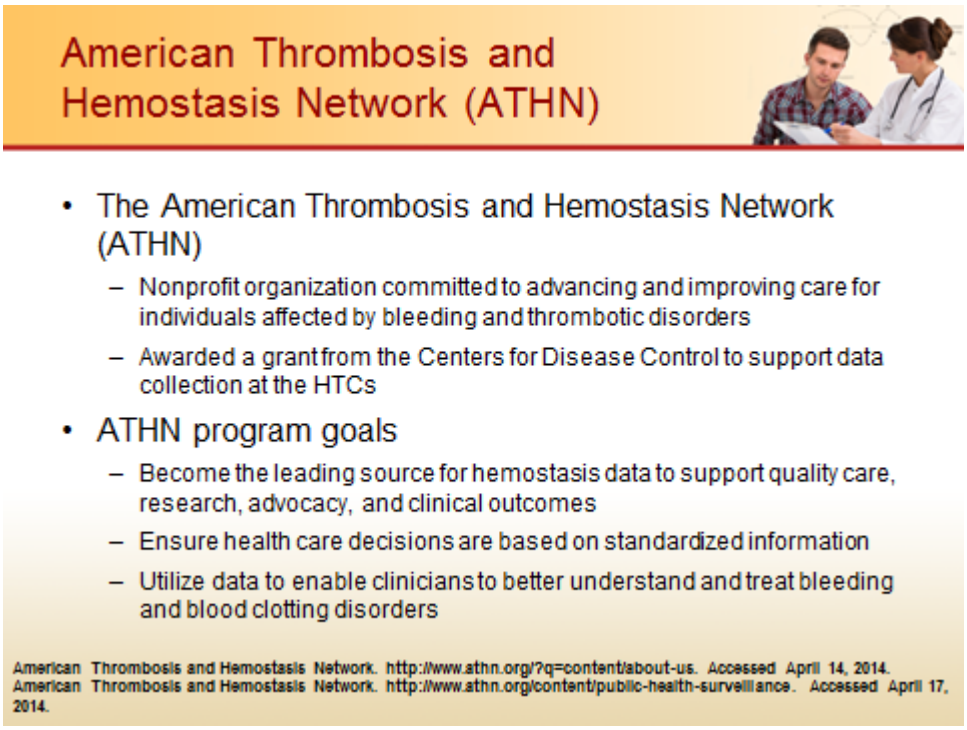
The comprehensive HTC care team is family-centered, with the patient and family being the most important members of the team. The hematologist and nurse work primarily with the patient to provide hemophilia education. The team also includes a social worker, physical therapist, and at some centers, an orthopedist. The pharmacy plays a critical role in patient home care. The coagulation laboratory ensures that clotting factor activity levels can be measured in a timely manner.

Over time, HTCs have added other specialists, to address comorbidities such as HIV or hepatitis infection. A geneticist is important to help patients understand the family inheritance of the hemophilia genetic mutation. Many HTCs have a dental care service because in some cases patients cannot get care in their local community due to the concern about their bleeding disorder. Nutrition services help ensure that patients maintain a healthy BMI. Most HTCs do ongoing research and surveillance; patients are receptive to this and understand that it may help them and others with hemophilia. Finally, the patient's primary care provider, or PCP, is kept abreast of all changes related to the patient's hemophilia and co-morbidities, as well as any other clinical observations made during the course of care at the HTC.



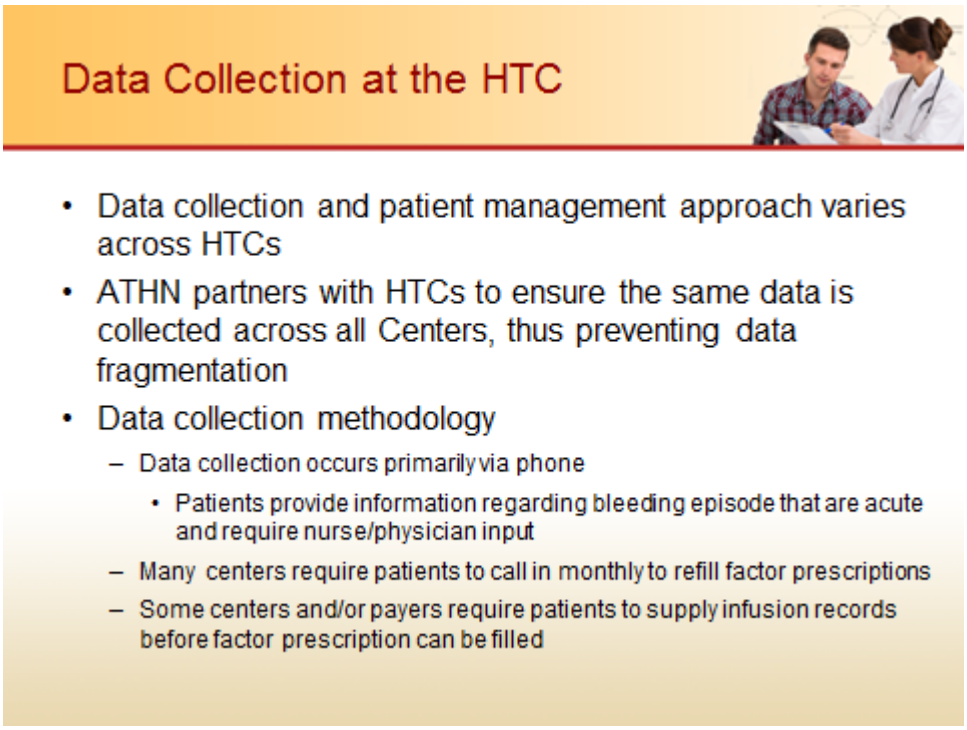
Slide 11: Nursing Roles at the HTC

Sixty-percent of an HTC nurse's time is spent on phone triage and direct patient care. Managing reimbursement or insurance access issues and performing data collection are also a reality of the nursing climate now. Additional activities include patient education and research.



Slide 12: American Thrombosis and Hemostasis Network (ATHN)

The American Thrombosis and Hemostasis Network, or ATHN, is a nonprofit organization committed to advancing and improving care for individuals affected by bleeding and thrombotic disorders. ATHN was awarded a grant from the Centers for Disease Control and Prevention, or CDC, to support data collection at the HTCs. As its organizational goals, ATHN aims to become the leading source for hemostasis data to support quality care, research, advocacy, and clinical outcomes. It also aspires to ensure health care decisions are based on standardized information. Finally, ATHN seeks to utilize data to enable clinicians to better understand and treat bleeding and blood clotting disorders.



Slide 13: Data Collection at the HTC

Data collection and patient management approaches vary across HTCs. ATHN partners with HTCs to ensure the same data is collected across all HTCs, thus preventing data fragmentation.

Data collection occurs primarily via telephone. Patients provide information regarding bleeding episodes that are acute and require nurse or physician input. Many centers also require patients to call in monthly to refill factor prescriptions, rather than providing automated refills. Many HTCs use this monthly call as an opportunity to check in with patients utilizing prophylaxis, to encourage treatment adherence, and to verify that the treatment is working for them at the current dose and interval. Finally, some centers and/or payers require patients to supply infusion records before factor prescriptions can be filled.

Slide 14: Why Use Logs

Most HTCs ask patients to keep infusion records, writing down or recording every treatment including bleeding events and prophylactic infusions. It is a challenge when HTCs see patients only once or twice per year to rely on the patient's recollection of every bleeding event when evaluating his history, so having a written record is vital.

Having a written record helps to determine whether a target joint is developing. A target joint is a joint that bleeds more than twice in a six month period of time; a target joint can cause significant complications including pain, range of motion limitations, and eventual disability.

A written record also allows the HTC to monitor factor use and possible misuse. As an expensive resource, clotting factor concentrate misuse should be corrected as early as possible.

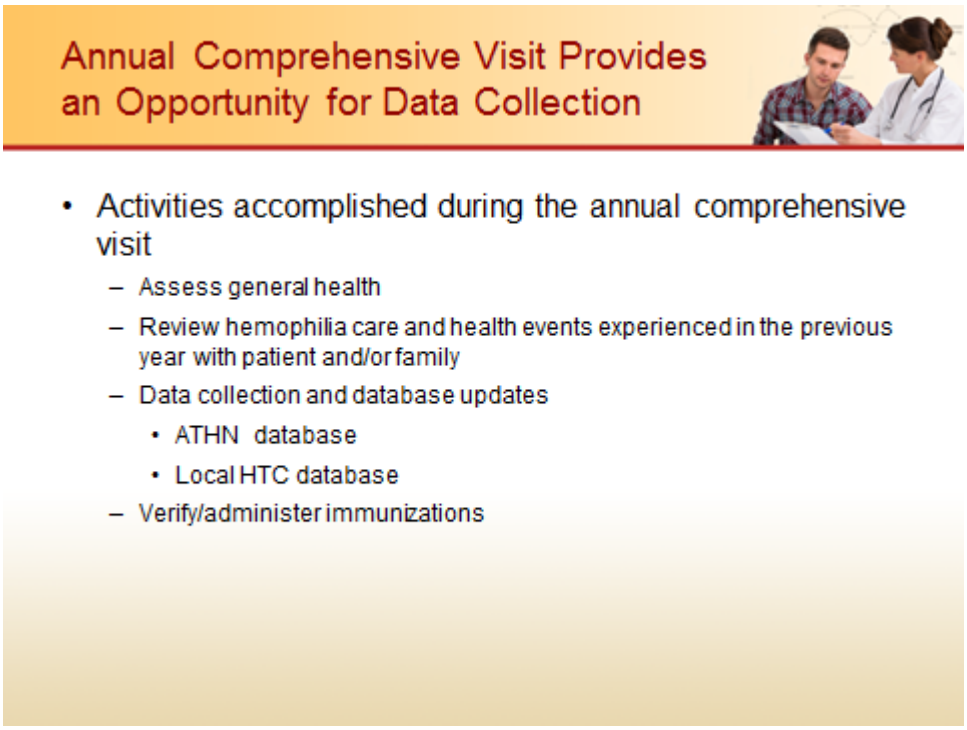
Infusion logs can signal the need for dosage adjustments. It is important not to over-utilize factor concentrates, but by the same token, to make adjustments when children grow or when people have breakthrough bleeding events.

Finally, some insurance companies are now asking for these records as a condition of providing coverage for clotting factor concentrates. They want to document appropriate utilization of this very expensive medication.

Widespread availability of smart phone and web-based technology makes keeping infusion records easier for patients.

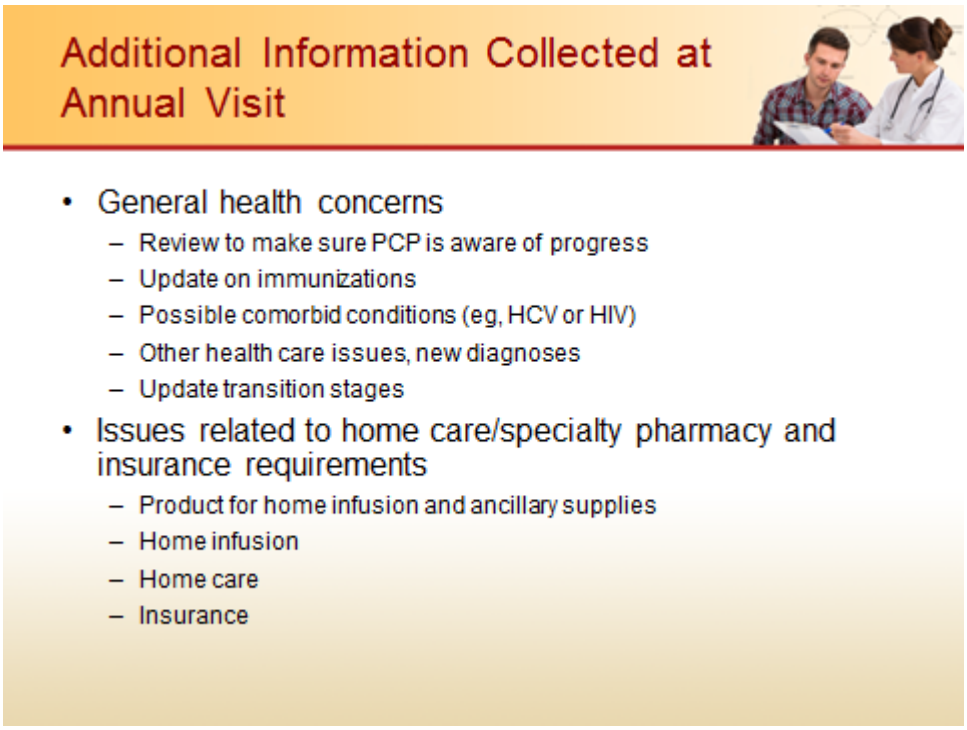
Slide 15: A Variety of Logging Apps Are Available

Young patients with hemophilia tend to prefer electronic logging applications over paper logs. Some of these electronic apps are creative and simple to use, with a body image that the patient simply touches to denote where a bleeding event occurred. It is important for the logging app to have an interface for HTC staff to access the logs or for patients to be able to email the logs to the HTC staff of their choice.



Slide 16: Annual Comprehensive Visit Provides an Opportunity for Data Collection

The annual comprehensive visit is often the one opportunity per year for HTC staff to interact "live" with the patient and review the events of the past year. During this visit, the multidisciplinary team must assess general health and review hemophilia care and health events experienced in the previous year with the patient and/or his family. Data collection and database updates are also conducted, including updates of the ATHN database and the local HTC database. Finally, this is the opportunity to verify or administer immunizations.



Slide 17: Additional Information Collected at Annual Visit

During the annual visit, HTC staff review general health concerns and then send a letter to the patient's PCP to ensure they are aware of the patient's progress.

The update on immunizations includes the critical review of hepatitis A and B immunization status as well as a review of childhood immunizations to verify they are current.

Many HTC patients continue to have comorbid conditions such as hepatitis C virus or HIV that they acquired from contaminated blood products in the 1980s. The HTC's risk management specialist or hepatologist evaluates these patients during the annual visit and provides any updates on available treatments.

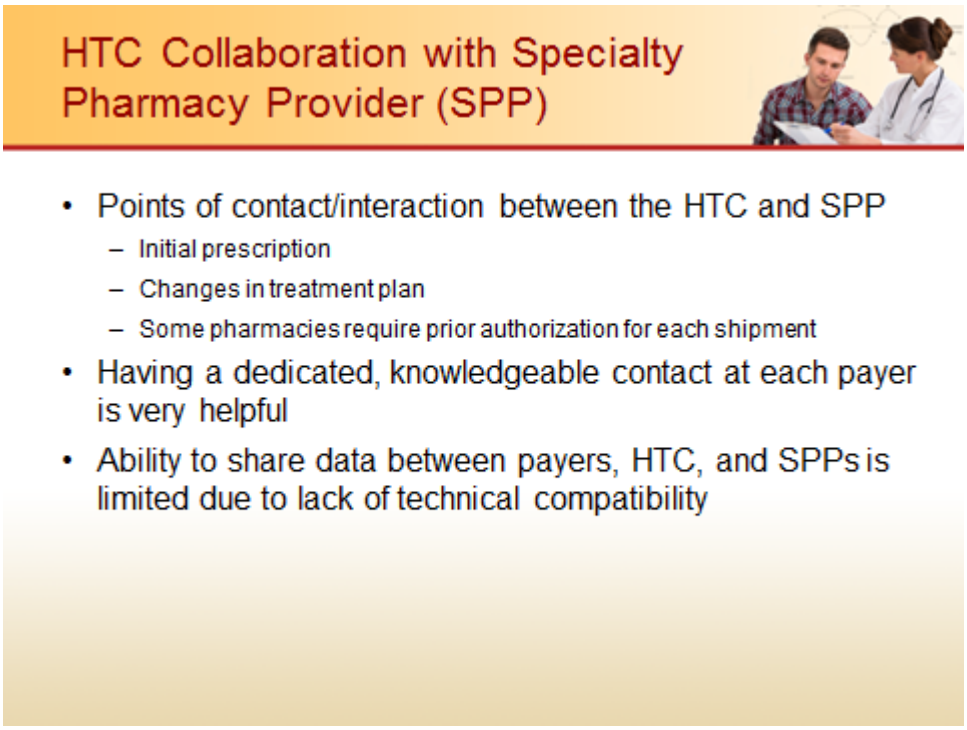
Finally, HTCs are increasing their focus on patients' transition stages, putting increased attention on patients' needs at changing stages in life, such as when they become adolescents, college students, full-time employees, etc.

When working with specialty pharmacies and insurance companies, HTCs must be able to provide necessary and accurate information, such as product for home infusion and ancillary supplies. .

HTCs do home infusion training, and then work with the home care company that supplies the product and the insurance company as well, to see if prior authorization is needed for a certain type of therapy. The prior authorization process may need to be repeated at every refill or when dosage, treatment interval, or treatment product are changed.

Slide 18: Long-Acting Therapeutics May Impact Patient Management Strategies

New and emerging long-acting agents may help patients reduce the number of regular infusions needed to prevent bleeding or manage prophylaxis. These replacement therapies will likely require changes to hemophilia management plans including those for acute bleeding episodes, prophylaxis, and surgical interventions.

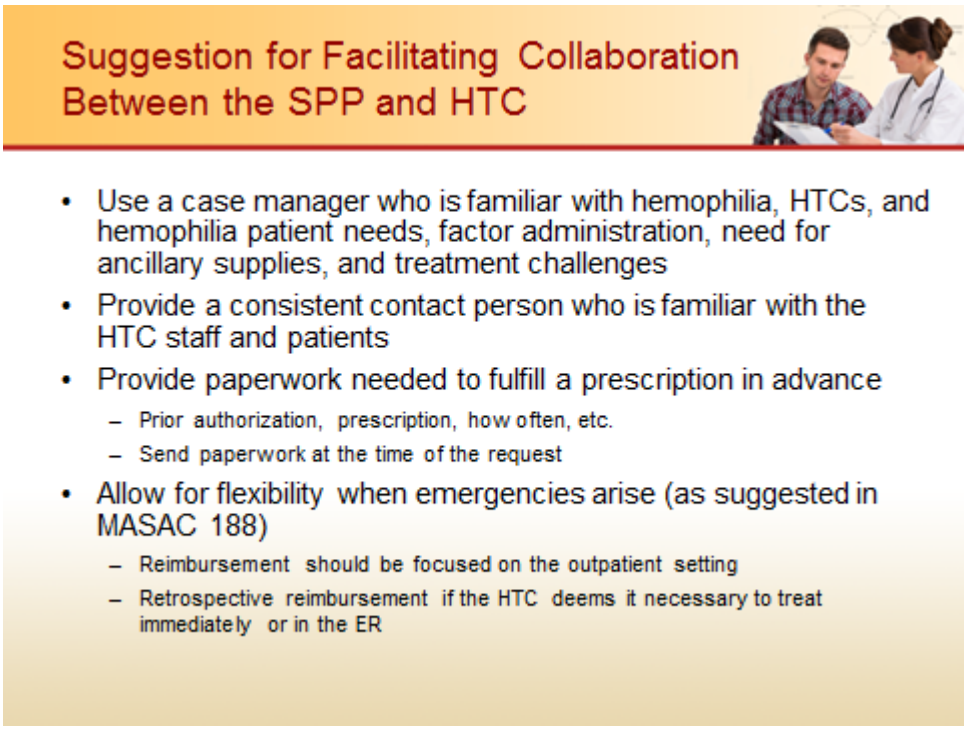


Slide 19: HTC Collaboration with Specialty Pharmacy Provider (SPP)

The HTC and specialty pharmacy provider interact at the time of the initial prescription of clotting factor concentrate and when there are changes in the treatment plan. Some pharmacies require prior authorization for each shipment.

It is beneficial for HTC nurses to keep abreast of who is working at the hemophilia desk at the specialty pharmacy; it is very helpful for the nurses to have a dedicated, knowledgeable contact at each payer, rather than go through a new phone tree and speak to people who are unfamiliar with hemophilia during each call.

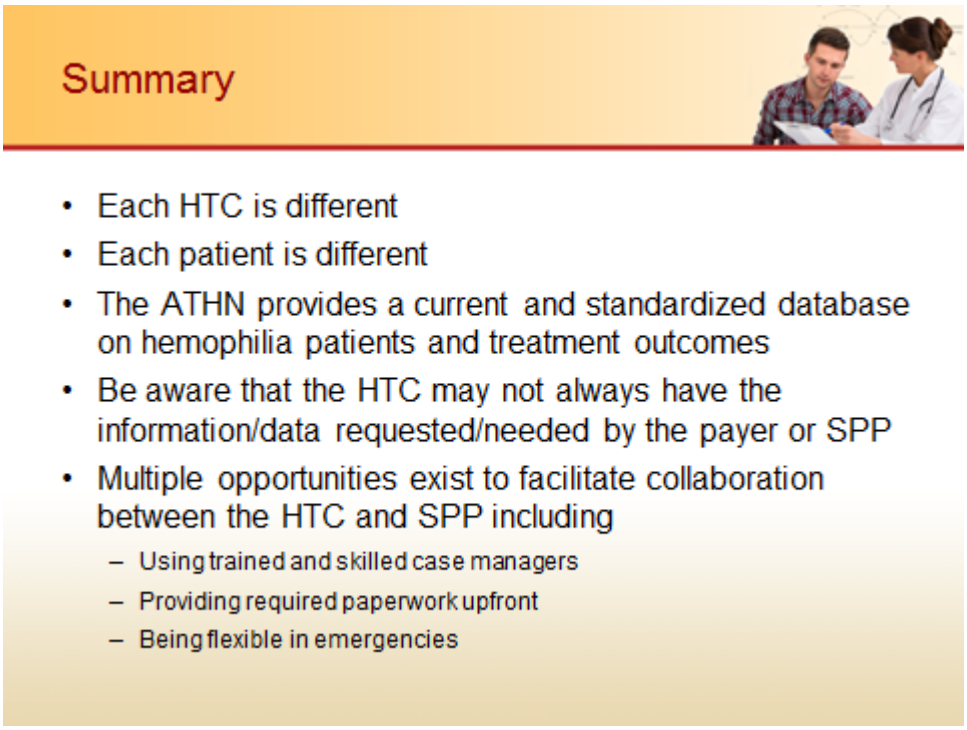
HTCs and specialty pharmacies share information as efficiently as possible; however, data sharing is often limited due to lack of technical compatibility on one end or the other. Specifically, electronic methods do not always synchronize and sometimes the HTC or specialty pharmacy must still work with paper records.



Slide 20: Suggestion for Facilitating Collaboration between the SPP and HTC

An HTC nurse would say that the ideal case manager would be familiar with hemophilia, factor administration, the need for the supplies, and the reasons for treatment challenges from time to time. It would be most helpful for the specialty pharmacy to provide a consistent contact person who is very familiar with HTCs and hemophilia patients' needs. Moreover, it would be helpful to solidify in advance what is necessary for a prescription so that the HTC could send that in a timely manner and allow time for authorization if needed.

In 2013, the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation recommended the need for pharmacies to allow for flexibility when emergencies arise, including the focus of reimbursement on the outpatient setting and on retrospective reimbursement if the HTC deems it necessary to treat immediately or in the emergency room.



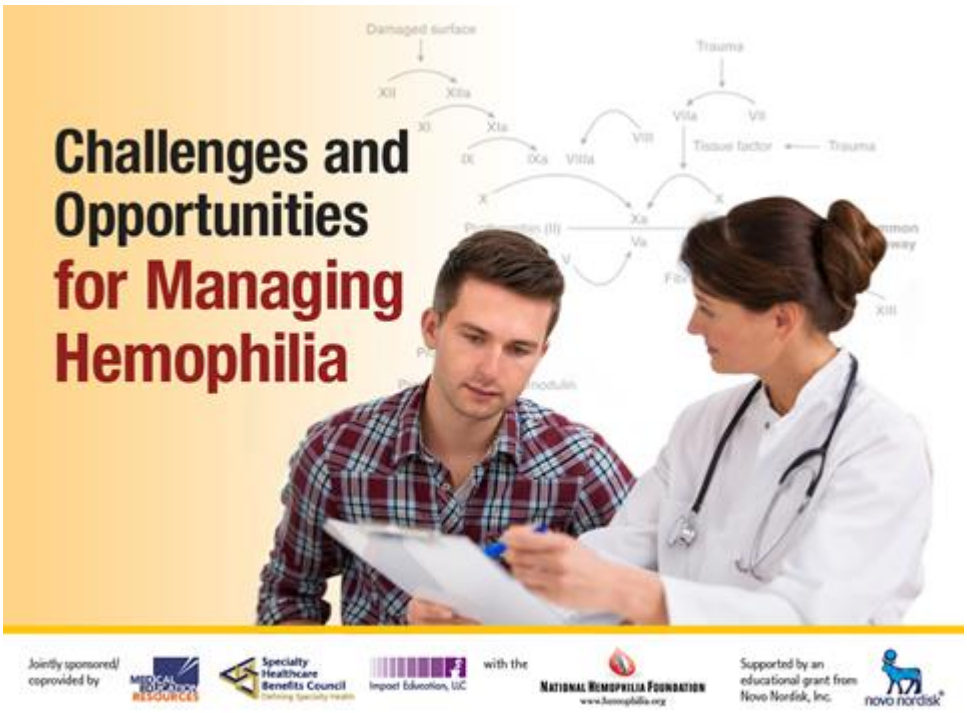
Slide 21: Summary

In summary, each HTC is different and each patient is different.

The ATHN data set provides a current and standardized database on hemophilia patients and treatment outcomes. This may help in identifying trends among HTCs and coming to agreements regarding therapies that are being offered.

It is important for the specialty pharmacy provider to be aware that the HTC may not always have the information or data requested or needed.

Multiple opportunities exist to facilitate collaboration between the HTC and the specialty pharmacy provider, including the use of trained and skilled case managers, providing required paperwork upfront, and being flexible in emergencies.



Slide 22: Challenges and Opportunities for Managing Hemophilia

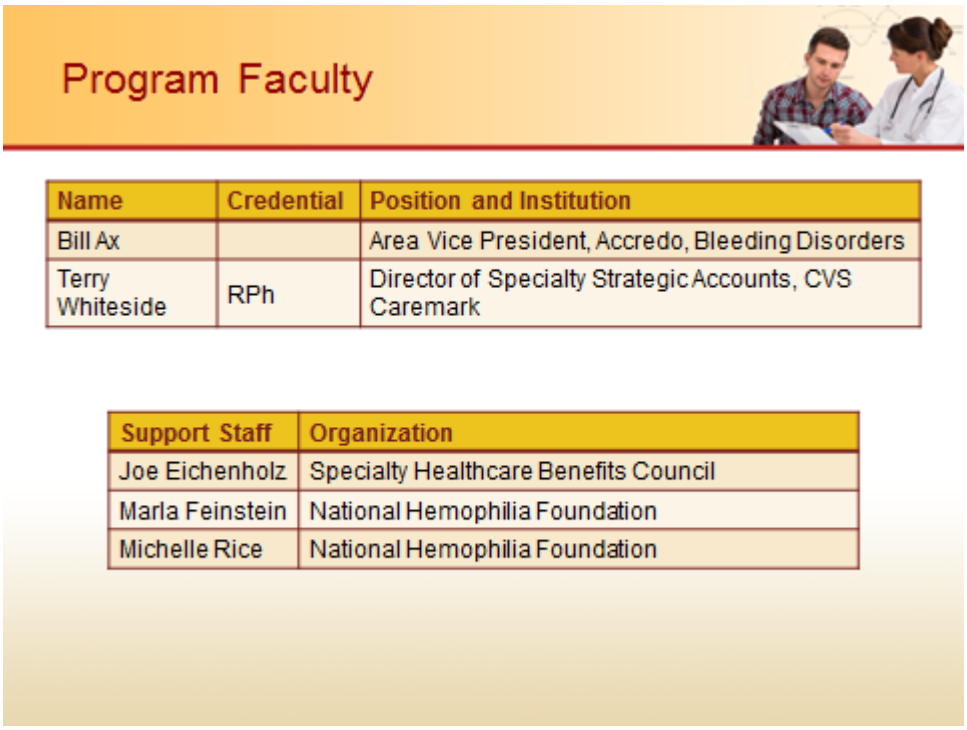
This concludes Program 1 of Track 2, entitled Collaborative Strategies to Improve Care Management.

Program 2:

Coordinating Care with Specialty Pharmacy Providers and Home Infusion Services

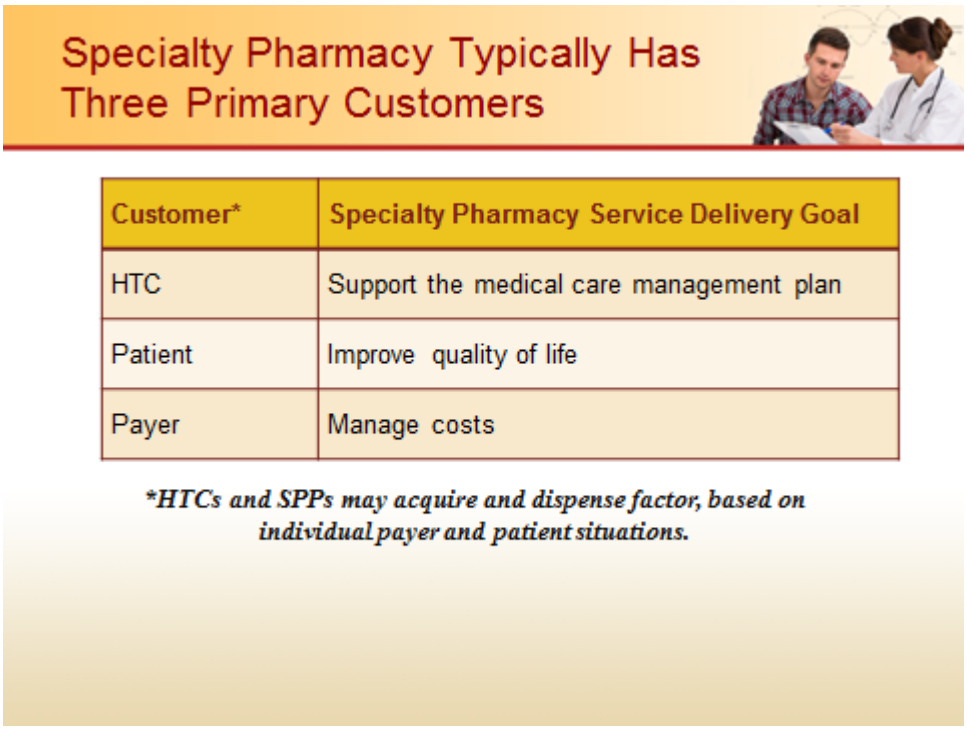
Slide 23: Program 2: Coordinating Care with Specialty Pharmacy Providers and Home Infusion Services

The second presentation of Track 2 is entitled Coordinating Care with Specialty Pharmacy Providers and Home Infusion Services, and represents the specialty pharmacy provider perspective on hemophilia management.



Slide 24: Program Faculty

The faculty for this presentation is Bill Ax, Area Vice President of Accredo, Bleeding Disorders; and Terry Whiteside, Registered Pharmacist, Director of Specialty Strategic Accounts, CVS Caremark. Support staff for this presentation includes Joe Eichenholz, Executive Director of the Specialty Healthcare Benefits Council, and Marla Feinstein and Michelle Rice, from the National Hemophilia Foundation's Public Policy Team.



Slide 25: Specialty Pharmacy Typically Has Three Primary Customers

Specialty pharmacies typically have three primary customers. The first is the Hemophilia Treatment Center, or HTC, where the hemophilia patient is evaluated and optimal therapy is determined by experienced treatment staff. A specialty pharmacy's goal with the HTC is to provide support to the medical care management plan that is determined by the HTC, as well as to provide information pertinent to the patient's clinical outcomes. An example of this would be a patient who was having an increased number of bleeds over time.

The second customer is the patient. A specialty pharmacy's goal with the patient is to improve his quality of life by providing education to the families, again in coordination with the HTC. A specialty pharmacy works very hard to anticipate any product and supply needs the patient may have, and also to closely monitor his care for any signs and symptoms of potential complications.

The third customer is the payer. Here it is important to keep in mind that clotting factor concentrate is expensive. In fact, it accounts for 85% or more of the total cost for this particular therapy. An average claim that one would dispense would be $20,000 or more depending on the severity level, the diagnosis, the treatment regimen, the patient's weight, and other variables. So

with the payer, a specialty pharmacy aims to minimize waste and any unnecessary costs that would be associated with lack of factor, such as emergency room visits.

Slide 26: Role of Specialty Pharmacy in Hemophilia Patient Management

For the pharmacy that specializes in hemophilia, it is essential to have experience and proficiency not only with hemophilia, but also with some of the other bleeding disorders and rare blood disorders. They must be knowledgeable in the different diagnoses, factor products, differences between products, U.S. Food and Drug Administration, or FDA indications for products, factor reconstitution and stability once reconstituted, potential drug interactions and side effects.

The pharmacy must know about temperature and storage requirements. A worst case scenario is for a patient to have product that expires or that is left out and not stored properly and must be thrown away.

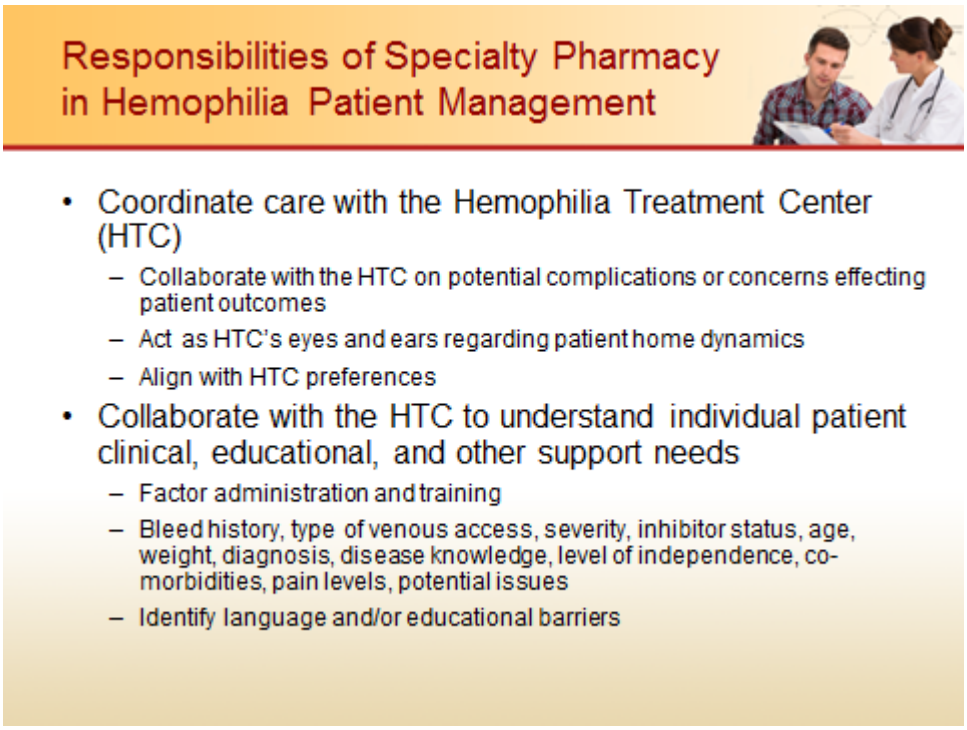
The pharmacy must know enough to dispense factor products according to prescribed therapy. This leads us to the topic of assay matching. Due to the manufacturing processes for factor products, the number of units is listed on the vials and is often not a round number. For example,

a vial may contain 528 international units, or 1,489 international units, or any other number, according to lot. Physicians understand that there is going to be a variance in the units contained in those vials. When a hemophilia physician prescribes clotting factor, he or she usually provides a +/-10% range of the prescribed dose within which the pharmacy can dispense. The reason for that is to allow flexibility in combining the different vial sizes. The pharmacies' goal then is to combine vials into a combination that is as close as possible to what is prescribed for that particular patient. Industry standards are about a 2% variance, which takes some skill and learning on behalf of the pharmacist combining the assays.

Finally, the specialty pharmacy provider must know what the dosing regimens and appropriate doses are. There are generally two ways that clotting factor concentrate is prescribed: one is to treat a bleed, called episodic or on-demand treatment; and the other is to prevent bleed, called prophylactic treatment. The pharmacists must be familiar with the recommendations of the Medical and Scientific Advisory Council, or MASAC, of the National Hemophilia Foundation, which is a leadership body comprised of prominent hematologists throughout the United States who make treatment recommendations for hemophilia.

The pharmacist should also be aware of some of the protocols that would be important to treat patients who develop complications such as inhibitors.

Finally, as discussed in Track 1, new long-acting products are beginning to emerge in the market. While this is an exciting time in the treatment of hemophilia, it is going to be important for specialty pharmacies to understand the doses and frequency for these new products. The pharmacists will have a role in educating families so that they know how to properly use the products at home.



Slide 27: Responsibilities of Specialty Pharmacy in Hemophilia Patient Management

A specialty pharmacy has two main responsibilities. One is to coordinate care with the HTC by building on the information that the HTC provides. The goal of this care coordination is to anticipate any potential complications for the patient and ensure that measures are taken to avoid complications as services are performed for the patient.

Most specialty pharmacies will contact patients on a monthly basis. During these contacts, the pharmacist ascertains how many bleeds the patient has had in the past month and whether the patient is having any issues with his infusion products. The pharmacy acts as the eyes and ears for the HTC and can report back to the HTC any patient home dynamics or other concerns that have been identified during discussion with the patient.

The specialty pharmacy also aims to align with the HTC preferences. Some of the HTCs want their patients to contact them before each shipment of factor and to report the occurrence of any bleeding events. It is the specialty pharmacy provider's responsibility to support that to the extent possible.

The second responsibility of the specialty pharmacy provider is to collaborate with the HTC to understand individual patient's clinical, educational, and other support needs. The pharmacy will conduct an initial assessment as well as ongoing assessments with the patient during which the following are assessed: bleed history, type of venous access, hemophilia severity, inhibitor status, age, weight, diagnosis, disease knowledge, level of independence, co-morbidities, pain levels, and potential issues. If the assessment indicates that the patient is not infusion-independent and does need nursing, then the specialty pharmacy provider will often coordinate nursing, either with their own nurse or with an agency that is skilled in treating hemophilia patients. The initial assessment also identifies any language and/or educational barriers.

Slide 28: Responsibilities of Specialty Pharmacy in Hemophilia Patient Management (cont'd)

One goal of the specialty pharmacy for the patient is to manage the clotting factor concentrate inventory that is in the home. This is done by calls to the patient's home. Alternatively, if a nurse happens to be in the home, the nurse takes an inventory of the factor supply.

During inventory management calls with the patient, the specialty pharmacy provider inquires whether the patient is currently having an active bleed; and if so, whether he has an adequate supply of product on-hand for his next dose. If the patient is not having an active bleed, then the

pharmacist asks how many doses the patient has on-hand and how many and what type of bleeds the patient has experienced since the last call. This information is compared to the prescription and number of doses that were sent out in the last shipment of product.

These calls serve two primary purposes. They allow the specialty pharmacist to assess adherence as well as to verify that the patient has a minimal amount of clotting factor concentrate on-hand at all times, which is critical to prevent emergency room visits.

Most specialty pharmacies have 24/7 access to both nurses and pharmacists that are trained in hemophilia.

Patients are educated on treatment adherence, drug storage, product rotation, after hour's point-of-contact, and adjunctive therapies.

Slide 29: Responsibilities of Specialty Pharmacy in Hemophilia Patient Management **(cont'd)**

With regard to the payer, it is very important for the specialty pharmacy provider to understand the payer requirements. Most payers have a prior authorization, but it is not for the purpose of determining whether or not the patient needs clotting factor. That is the determination of the

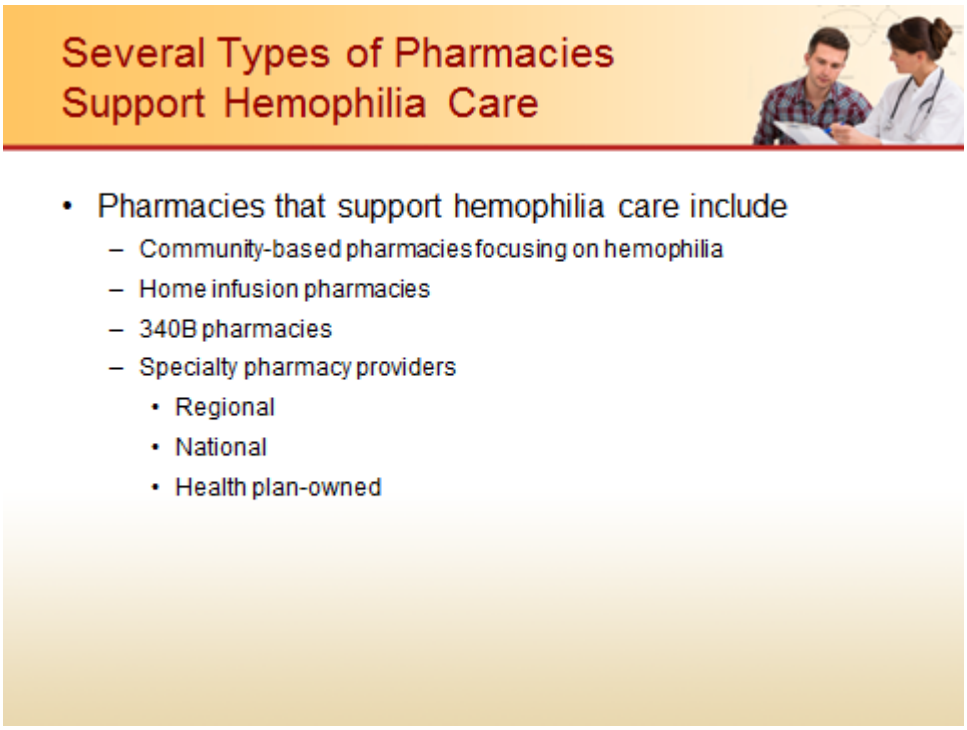
physician. The prior authorization is in place to authorize the shipment of product. It is essential for the pharmacy to know when prior authorizations expire, any basis for supply management and any other reporting that must be made, such as assay management performance.

It is very helpful for the pharmacy to have a case manager or a pharmacy contact at the payer because there will always be unusual circumstances that require discussion and case management.

The specialty pharmacy must also be aware of any bleed log requirements that the payer might have.

Hemophilia claims are unique. As discussed earlier, clotting factor is dispensed in vials, but it is actually billed based on the number of international units of clotting factor in each vial. It is critical for billing to understand that point.

Additionally, many patients have two prescriptions: their PRN doses for breakthrough bleeding events, as well as a prescription for the prophylactic treatment. The specialty pharmacy must navigate payers' different ways of handling the two prescriptions.



Slide 30: Several Types of Pharmacies Support Hemophilia Care

There are several different types of pharmacies that support hemophilia care. One is a community-based pharmacy that focuses primarily on hemophilia. In this case, they may only provide services to hemophilia patients, and they may only have a few patients that they manage.

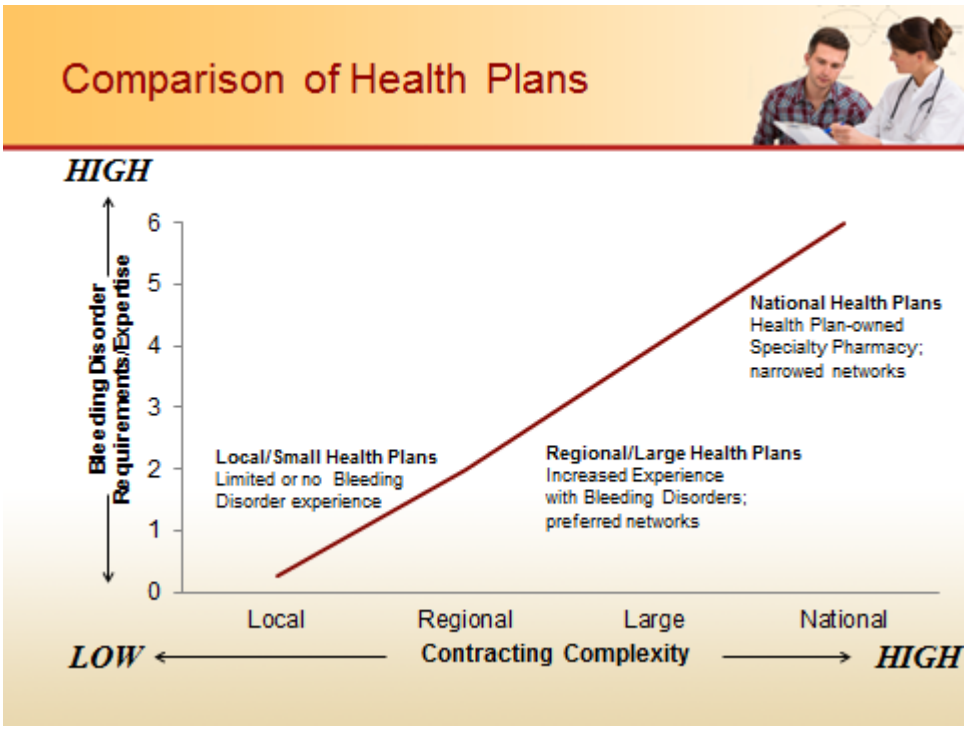
Next is a home infusion pharmacy. These pharmacies typically have other therapies that they provide which are infused therapies, such as intravenous, or IV, antibiotics, total parenteral nutrition, or TPN, and pain management. Home infusion pharmacies will always have nurses that are proficient in starting IVs. They often have pediatric nurses and staff as well. Moreover, they usually have experience with central venous access devices, or ports, so they are helpful in training patients to administer clotting factor through ports.

340B pharmacies are another type of specialty pharmacy. These are typically associated with the HTC. 340B pharmacies can only dispense the 340B product to patients of the HTC affiliated with the pharmacy.

There are specialty pharmacies that are typically larger and have services for other specialty medications. These pharmacies almost always have a team of people dedicated to hemophilia.

The regional pharmacies may have a limited number of pharmacies. The national pharmacies would be larger and they often have multiple sites with different pharmacies that can service people from across the country. National pharmacies typically provide care to a number of hemophilia patients.

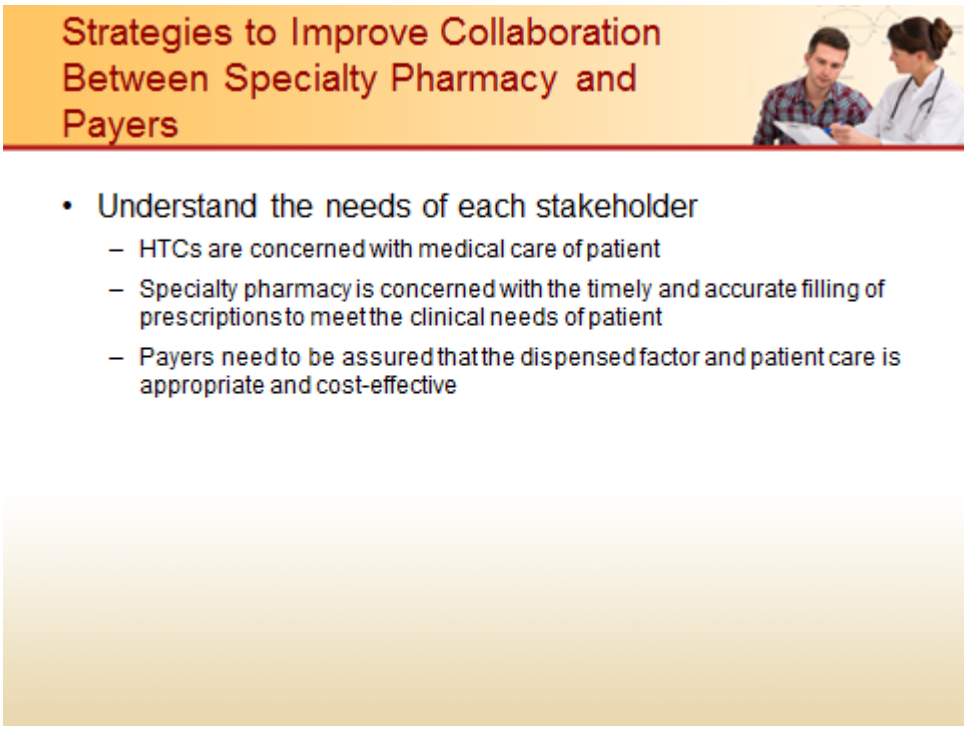
Finally, some of the health plans that are very large have specialty pharmacies that they actually own. Examples of these are United Healthcare, Humana, and Cigna. Health plan-owned pharmacies usually do not have a nurse on staff and are not able to make home visits. Unlike the other types of pharmacies, health plan-owned pharmacies also do not get involved with the community.



Slide 31: Comparison of Health Plans

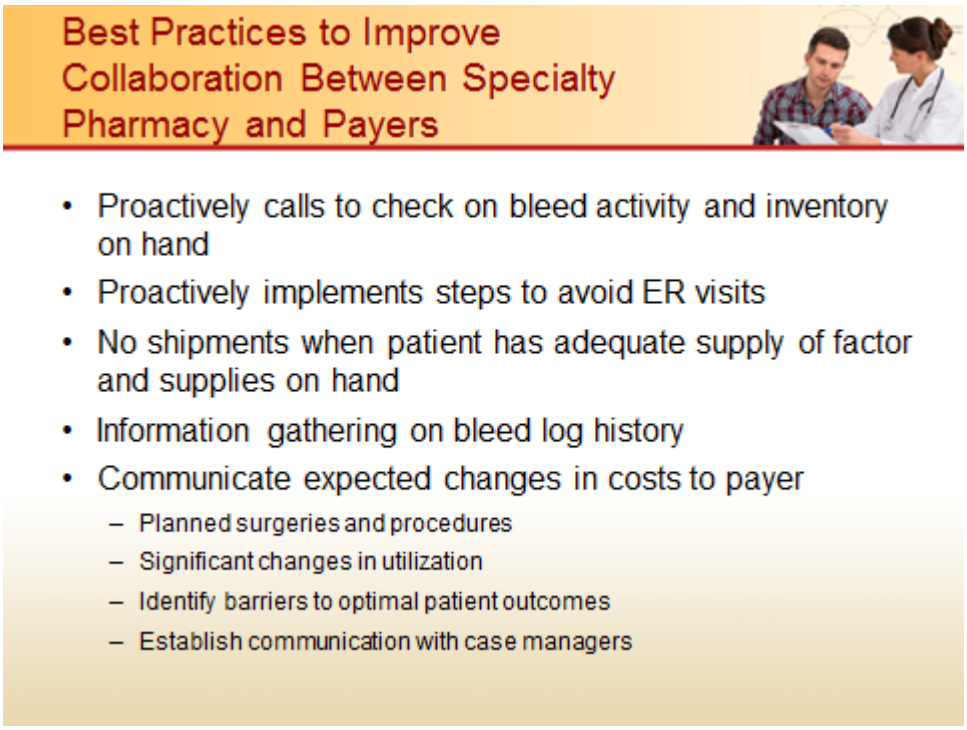
Just as there are different types of pharmacies, there are also different types of health plans. In some of the smaller health plans, such as a managed Medicaid plan, there are not very many hemophilia patients. These plans may require a bit of education on hemophilia.

Moving up the scale to larger numbers of patients and larger health plans, there are increasing levels of complexity in the contracting and some of the performance and reporting requirements that are associated with the larger contracts.



Slide 32: Strategies to Improve Collaboration Between Specialty Pharmacy and Payers

The primary strategy to improve collaboration between specialty pharmacy and payers is to understand the needs of each stakeholder. HTCs are concerned with the medical care of the patient. A specialty pharmacy is concerned with the timely and accurate filling of prescriptions to meet the clinical needs of patients. Payers need to be assured that the dispensed factor and patient care is appropriate and cost-effective. Understanding the needs of each stakeholder and fostering open communication are key to assuring the very best patient outcomes.



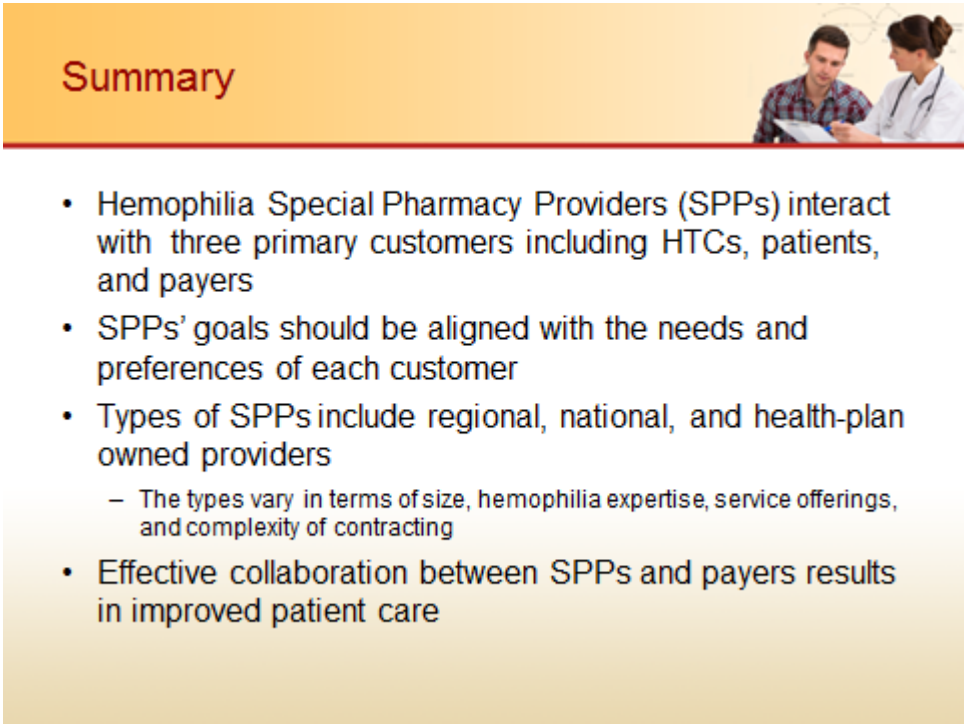
Slide 33: Best Practices to Improve Collaboration Between Specialty Pharmacy and Payers

Being proactive is the first best practice to improve collaboration between specialty pharmacy and payers. The specialty pharmacy can make proactive calls to check on bleed activity and factor inventory as well as to implement steps to avoid emergency room visits. If the patient has an adequate supply of factor and supplies on hand, the shipment should be moved to a later date. A hemophilia patient should not have an excess supply of clotting factor on hand that risks expiring before use.

Best practices should include information gathering about bleed activity and infusion log history. Of increasing importance, specialty pharmacies should make the appropriate documentation and encourage patients to record all clotting factor utilized. This will provide the necessary documentation for payers to see that factor shipments are valid and clotting factor is being used responsibly.

Finally, the specialty pharmacy provider should communicate any expected changes in costs to the payer. Examples of this scenario include planned surgeries and procedures or significant changes in factor utilization. It is also important to discuss with the payer any barriers to optimal

patient outcomes. It is a best practice for the specialty pharmacy provider to establish communication with a case manager from the payer.



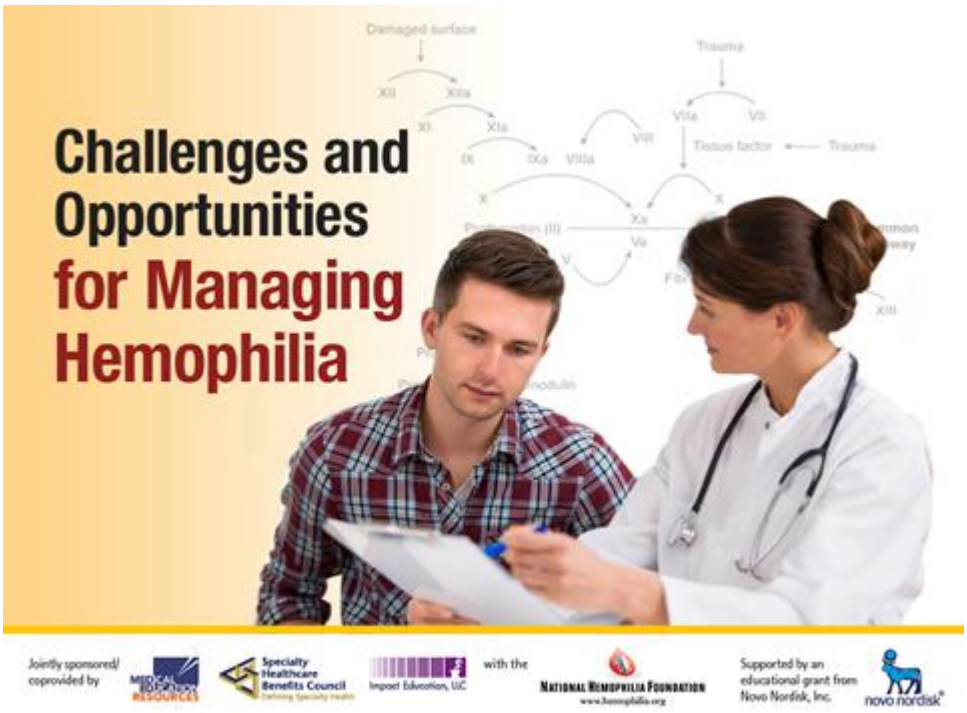
Slide 34: Summary

To summarize this presentation, hemophilia specialty pharmacy providers interact with three primary customers including HTCs, patients, and payers.

Specialty pharmacy providers' goals should be aligned with the needs and preferences of each customer.

Types of specialty pharmacy providers include regional, national, and health plan-owned providers. These types vary in terms of size, hemophilia expertise, service offerings, and complexity of contracting.

Effective collaboration between specialty pharmacy providers and payers results in improved care.

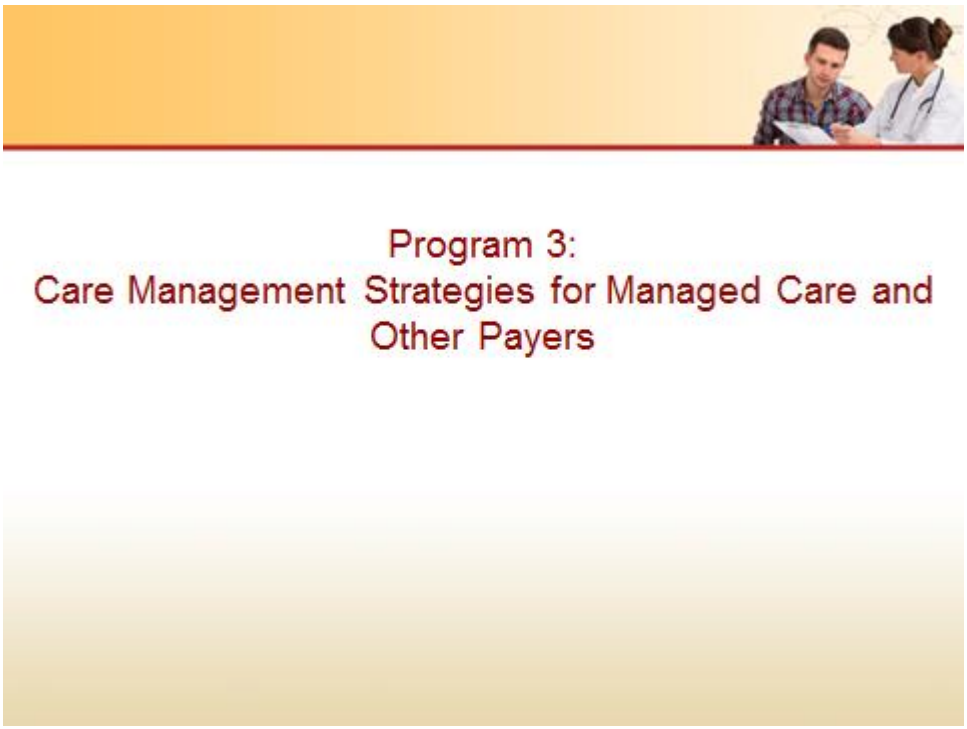


Slide 35: Challenges and Opportunities for Managing Hemophilia

This concludes Program 2 of Track 2, entitled Coordinating Care with Specialty Pharmacy Providers and Home Infusion Services.

Program 3:

Care Management Strategies for Managed Care and Other Payers



Slide 36: Program 3: Care Management Strategies for Managed Care and Other Payers

The third program of Track 2 is entitled Care Management Strategies for Managed Care and Other Payers, and represents the managed care perspective of hemophilia management.

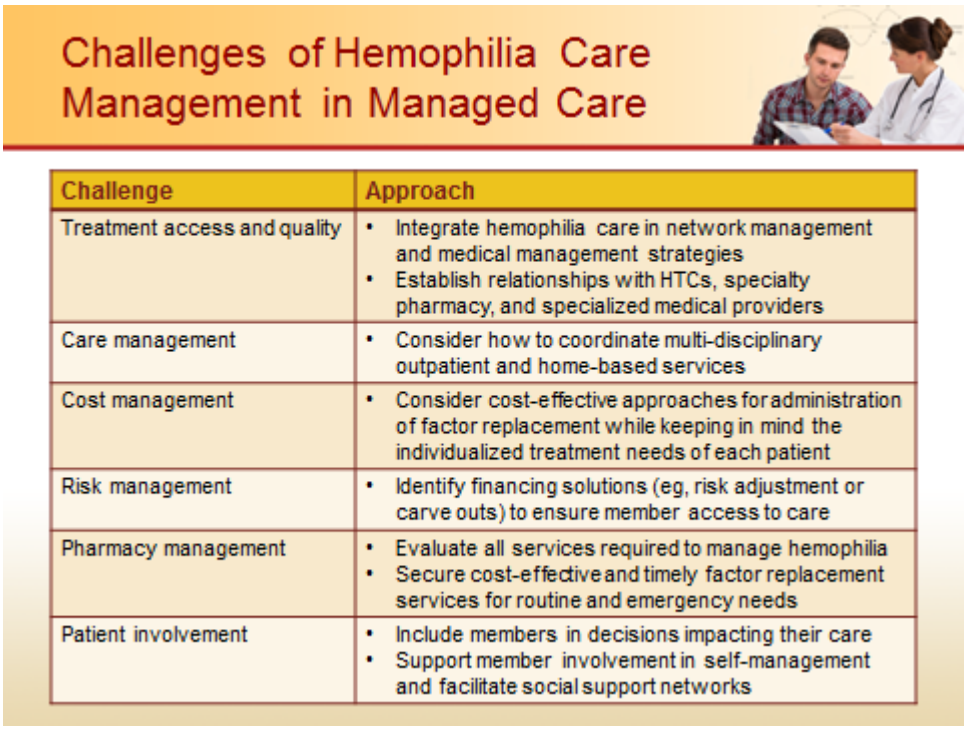
Slide 37: Program Faculty

The faculty for this program is James Jorgensen, registered pharmacist, Chief Executive Officer of Visante, Inc. Support staff for this presentation includes Joe Eichenholz, Executive Director of the Specialty Healthcare Benefits Council, and Marla Feinstein and Michelle Rice, from the National Hemophilia Foundation's Public Policy Team.

Slide 38: Hemophilia: High Aggregate Cost of Care Despite a Low Incidence

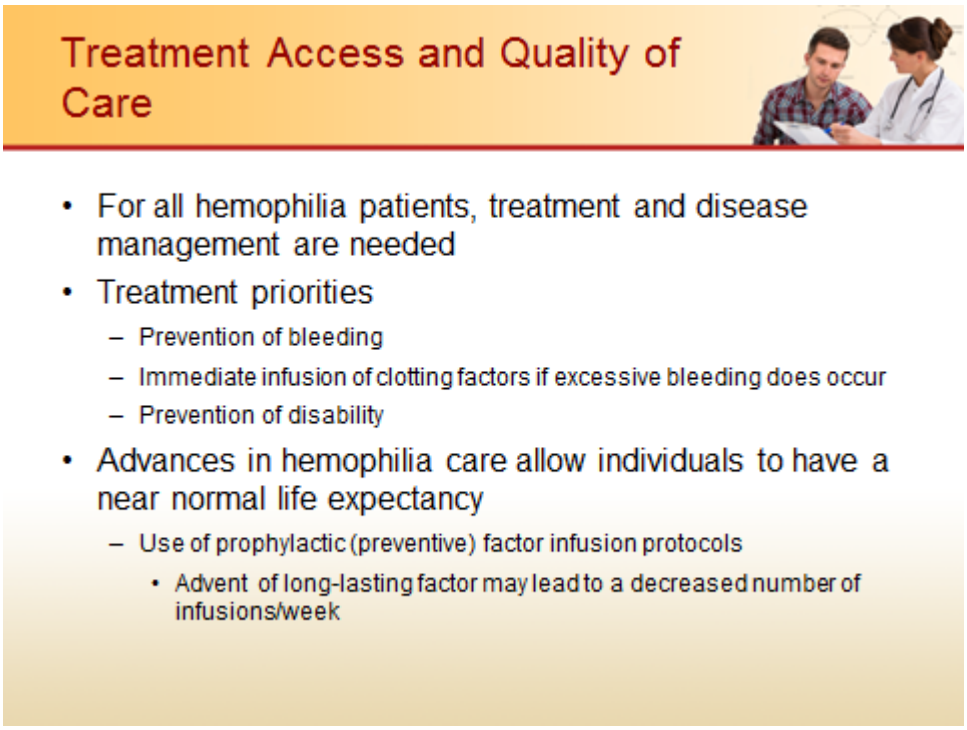
One of the most important points about hemophilia that we have seen in Track 2 of the Challenges and Opportunities for Managing Hemophilia 2014 online learning series is that it is a chronic condition that involves ongoing costly care but overall affects a small number of patients. As a result, managed care companies are generally not experts at managing complex diseases with several key variables that can dramatically affect the cost of care.

Currently, the mean cost of care for a patient without inhibitors is running around $155,000 per year. This figure leaps to $697,000 for a patient with inhibitors. Clearly, cost for managed care entities can add up very quickly in this patient population.



Slide 39: Challenges of Hemophilia Care Management in Managed Care

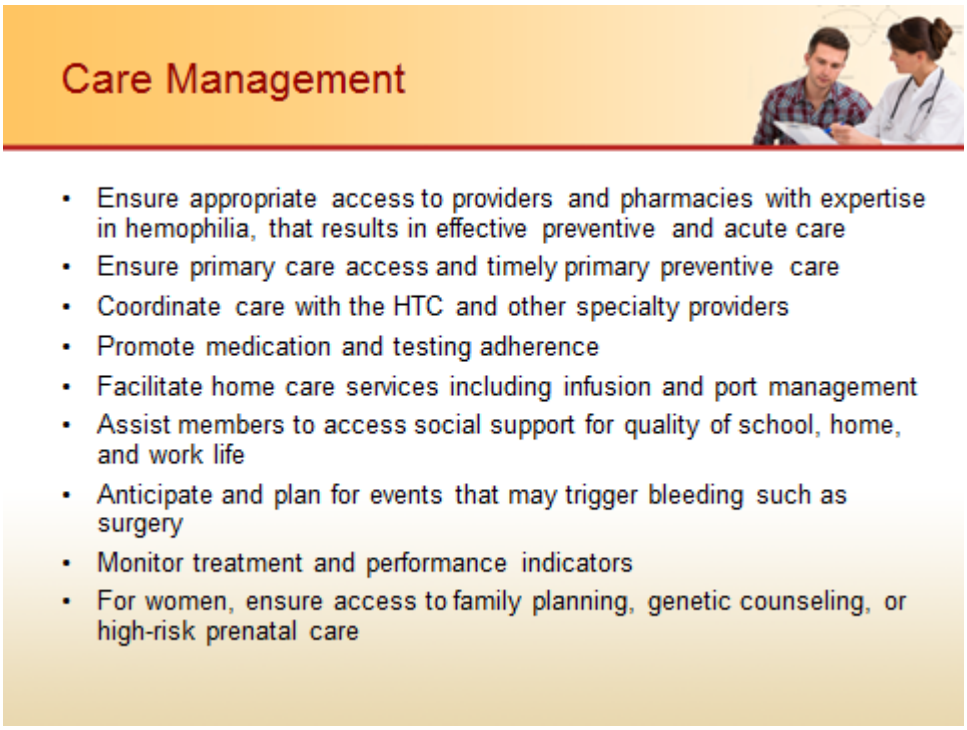
Hemophilia patients present some significant challenges for managed care. There are challenges with treatment access and the quality of treatment provided as well as with coordination of care between different providers. There are substantial cost management challenges. In addition to cost challenges for patients, there are financial issues for managed care related to plan risk associated with this population. There are challenges with the timely provision of factor support from the pharmacy providers. And finally, there are challenges in how best to involve patients and their families in the care process and decision-making. Let us take a closer look at each of these challenges from a managed care perspective.



Slide 40: Treatment Access and Quality of Care

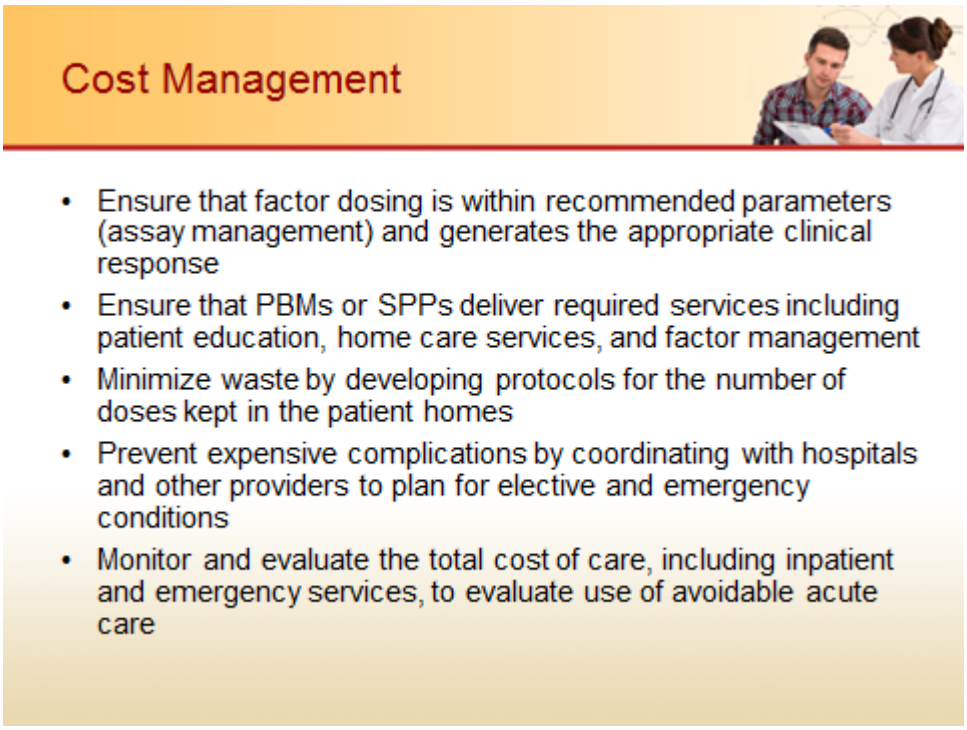
For hemophilia patients, there is a significant need for treatment and disease management. On the acute front, the obvious aim is to prevent bleeding episodes and all of the associated complications. Failing that, should a bleed occur, the timely infusion of clotting factor to prevent further progression is the immediate goal, with the long term goal being to prevent disability and enable the patient to live a near-normal life. One alternative to managing bleeding episodes is the appropriate use of prophylactic clotting factor infusion protocols.

This is an area that managed care often struggles with in terms of cost. Giving regular prophylaxis can increase the cost for these products, but overall, prophylactic protocols are superior in terms of total cost and outcomes and the ability to prevent disability and achieve the goal of a near-normal life.



Slide 41: Care Management

As we have seen in this Track, provision of care for hemophilia patients really needs to be a team effort. There are roles for providers and pharmacies with expertise in hemophilia that result in effective preventive and acute care, as well as for primary care providers, or PCPs, and timely primary care. There is a need for coordination of care with the HTC and other specialty providers. Promotion of medication and testing adherence is important as is facilitation of home care services including infusion and port management. There is a role for care managers to assist members with access to social support for quality school, home, and work life. The entire care team, including the patient and family, can help anticipate and plan for events that may trigger bleeding such as surgery, as well as monitor treatment and performance indicators. Finally, for women, it is important to ensure access to family planning, genetic counseling, and high-risk prenatal care.



Slide 42: Cost Management

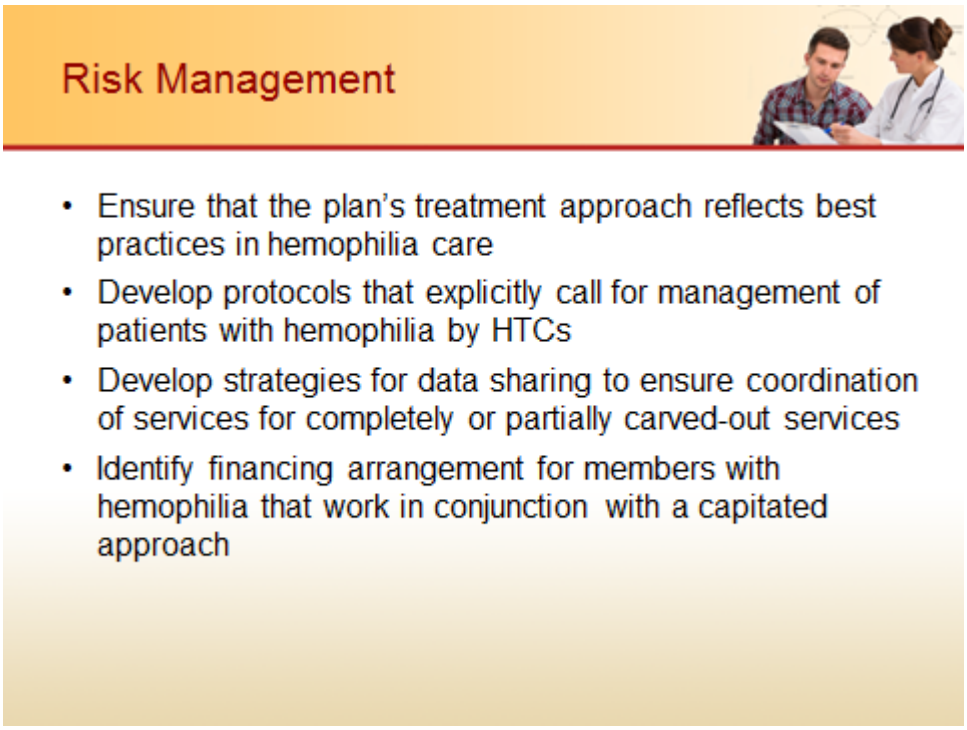
Without question, the effort to support hemophilia is expensive, and it is in the best interest of both the patient and managed care to control these costs as much as possible while still providing optimal treatment. There are several proven strategies in this regard to consider.

One of these strategies is the regular review of clotting factor dosing to verify it is within recommended parameters and that the patient is experiencing the appropriate clinical response. Another strategy is to ensure that the specialty pharmacy is delivering the required services including patient education, home care services, and factor management. A third strategy is to minimize waste by developing protocols for the number of doses kept in the patient's home. Yet another strategy is to prevent expensive complications by coordinating with hospitals and other providers to plan for elective and emergency conditions. A final strategy is to monitor and evaluate the total cost of care, including inpatient and emergency services, to evaluate use of avoidable acute care.

Slide 43: Pharmacy Management

With the effective use of factor as the key therapeutic intervention in hemophilia patients, the selection of the pharmacy provider is a paramount decision. The care of hemophilia is highly specialized and it is extremely important to work with an experienced hemophilia pharmacy provider. Managed care providers should ensure that pharmacy providers can consistently meet patient needs for timely services and delivery of factor and infusion supplies. Managed care providers should also ensure that any vendor manages factor cost through appropriate assay testing and product inventory management; and develop policies to ensure practice of correct dosing and stock for at-home use. Finally, managed care providers should monitor quality and accountability of pharmacy providers for this patient population and, when necessary, should be willing to narrow the network by excluding pharmacies that perform poorly.

With regard to the narrowing of networks, it is the National Hemophilia Foundation's position on network adequacy that there should be more than one qualified in-network pharmacy provider per health plan.



Slide 44: Risk Management

In terms of risk to a health plan, as we have seen, small numbers of patients can have a big impact. There are several strategies available to help mitigate the risk. First, it is crucial to ensure that the health plan's treatment approach reflects best practices in hemophilia care. Whenever possible, the payer should develop a relationship with a Hemophilia Treatment Center, or HTC, to access the expert care and best practices available through those entities. Managed care should take advantage of the expertise available from the various team members engaged in the care of these patients by data sharing to ensure coordination of services for completely or partially carved-out services.

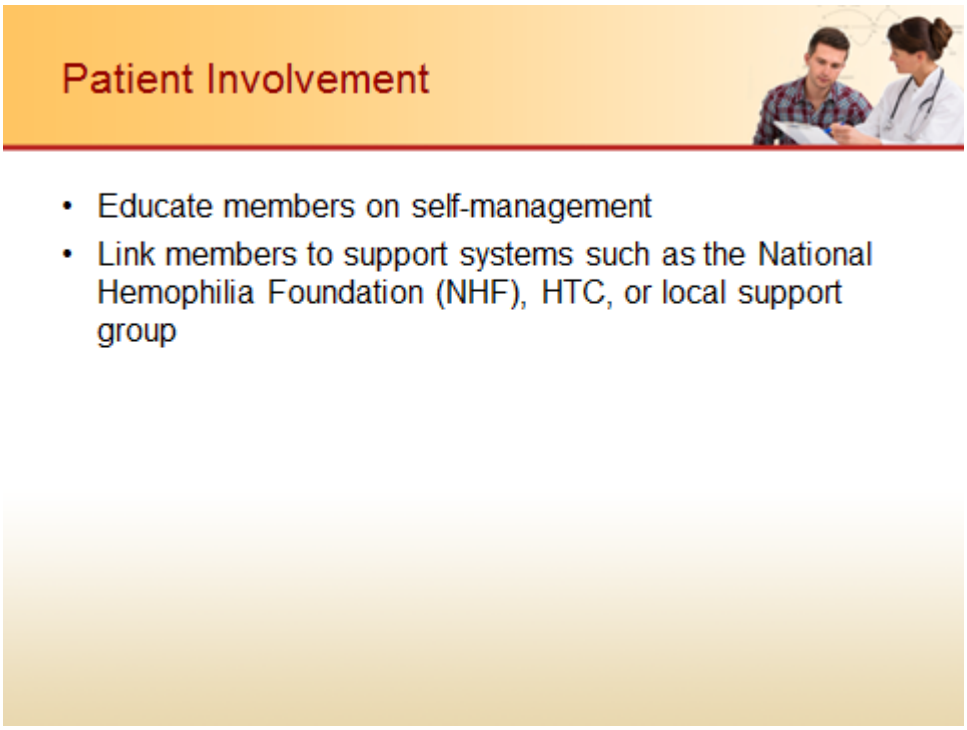
It is also important to verify that financing arrangements work for patients. Oftentimes, the cost of care is not that large if there are only a few hemophilia patients in one specific insurance plan, but the cost rises substantially if multiple patients are on the same plan. Some insurance issues arise from the fact that the patient may not be part of a large insurance pool. The size of the insurance pool has been addressed in health care reform where everyone is encouraged to be ensured because the more people in the pool, the more the health plan is able to spread the costs over a large number of people.

Over time, all of a health plan's members generally access a significant amount of health care, but at any one time, only a small number of plan members access a significant amount of health care. Therefore, a larger pool makes it easier to fund care for everyone. That is the reason why we are seeing lifetime caps removed. As lifetime caps are removed and as health plans provide improved case management services, it is likely that fewer hemophilia patients will change plans, and those that do may change less frequently. That will translate into the opportunity for health plans to manage these patients over extended periods of time.

We also have to recognize that cost-sharing is a serious issue and it has increased significantly over the past few years as health care costs continue to rise. Cost-sharing, in the form of co-pays, coinsurance or other out-of-pocket expenses are ways for overall premiums to be held down, but patients need to meet their cost-sharing obligations, which may present a financial burden.

It is important for the health plan to be able to help move the patient in the right direction towards those entities and organizations that can help with cost-sharing. There is also a role for employers in this process by ensuring quality of care for these patients. Employers need to work with health plans to ensure that factor products and other pharmaceuticals are covered under the medical benefit, the pharmacy benefit, or both. Patients have to be able to afford these products to drive adherence and ultimately better quality outcomes and overall cost reductions.

In addition, employers should consider limits on out-of-pocket expenses and ensure that the nearest HTC is included in the network. Good benefit design to encourage wellness management and appropriate treatment adherence is in everyone's best interest to reduce costs and improve outcomes.

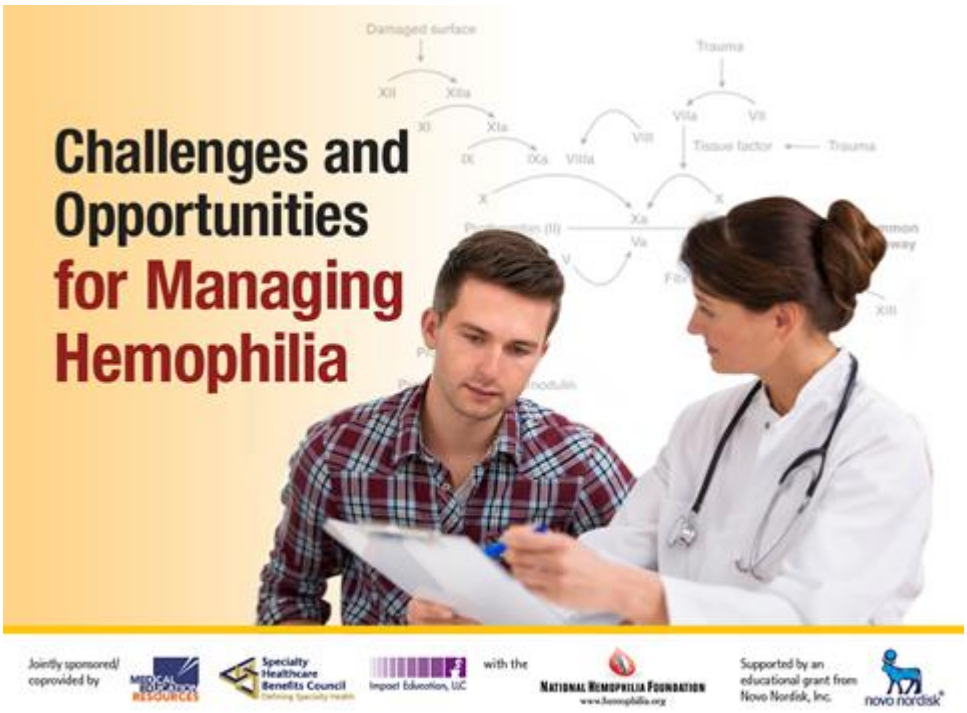


Slide 45: Patient Involvement

With many current disease states, we are seeing a definite shift in the social contract between patients and providers. The advent of social media, telemedicine, smart phone apps, sensors, advanced data collection and reporting technologies have opened up the opportunity for patients and their families to be more actively engaged in their disease management and associated decision-making than ever before.

For hemophilia patients, this is certainly true, and it is to be encouraged. Instead of trying to get patients to buy into therapy regimens given to them by their providers, more of an effort should be made to include them in the decision-making process and educate them through support groups like the National Hemophilia Foundation resulting in a sense of ownership of their disease management process.

We continue to make impressive strides in caring for hemophilia patients. As new and better factor products come onto the market, such as the longer acting products, along with advances in technology and education, a normal life expectancy is within our grasp for these patients. Achieving that goal will require the combined efforts of providers, payers, and patients.

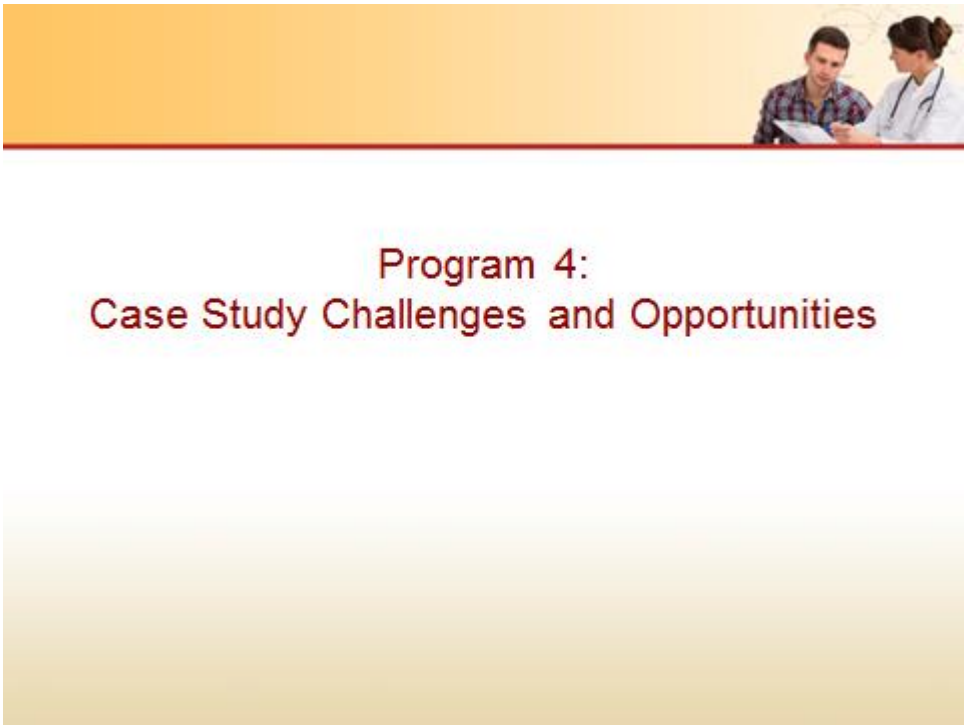


Slide 46: Challenges and Opportunities for Managing Hemophilia

This concludes Program 3 of Track 2, entitled Care Management Strategies for Managed Care and Other Payers.

Program 4:

Track 2 Case Study Challenges and Opportunities



Slide 47: Track 2 Case Studies Challenges and Opportunities

Now that we have had an update of important care management strategies for hemophilia, let us apply this to real world patient scenarios.

Program Faculty

Name	Credential	Position and Institution
Karen Wulff	RN	Hemophilia Nurse Coordinator, Louisiana Comprehensive Hemophilia Care Center, Tulane University Medical School
Sue Geraghty	RN, MBA	Retired, University of Colorado Denver Hemophilia and Thrombosis Center
Terry Whiteside	RPh	Director of Specialty Strategic Accounts, CVS Caremark
Bill Ax		Area Vice President, Accredo, Bleeding Disorders
James Jorgensen	RPh, MS, FASHP	Chief Executive Officer, Visante, Inc.

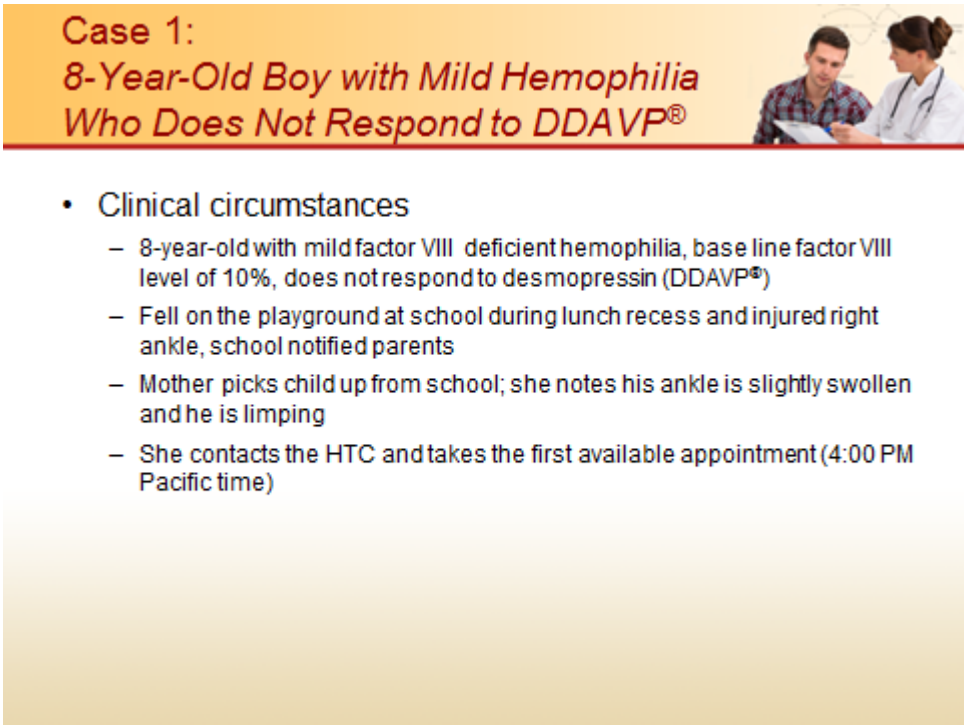
Program Faculty (continued)

Support Staff	Organization
Joe Eichenholz	Specialty Healthcare Benefits Council
Marla Feinstein	National Hemophilia Foundation
Michelle Rice	National Hemophilia Foundation

Slides 48 and Slide 49: Program Faculty

The faculty of this presentation includes Karen Wulff, Hemophilia Nurse Coordinator at the Louisiana Comprehensive Hemophilia Care Center, Tulane University Medical School; Sue Geraghty, retired nurse from the University of Colorado Denver Hemophilia and Thrombosis

Center; Terry Whiteside, Registered Pharmacist, Director of Specialty Strategic Accounts, CVS Caremark; Bill Ax, Area Vice President of Accredo, Bleeding Disorders; and James Jorgensen, registered pharmacist, Chief Executive Officer of Visante, Inc. Support staff for this presentation includes Joe Eichenholz, Executive Director of the Specialty Healthcare Benefits Council, and Marla Feinstein and Michelle Rice, from the National Hemophilia Foundation's Public Policy Team.

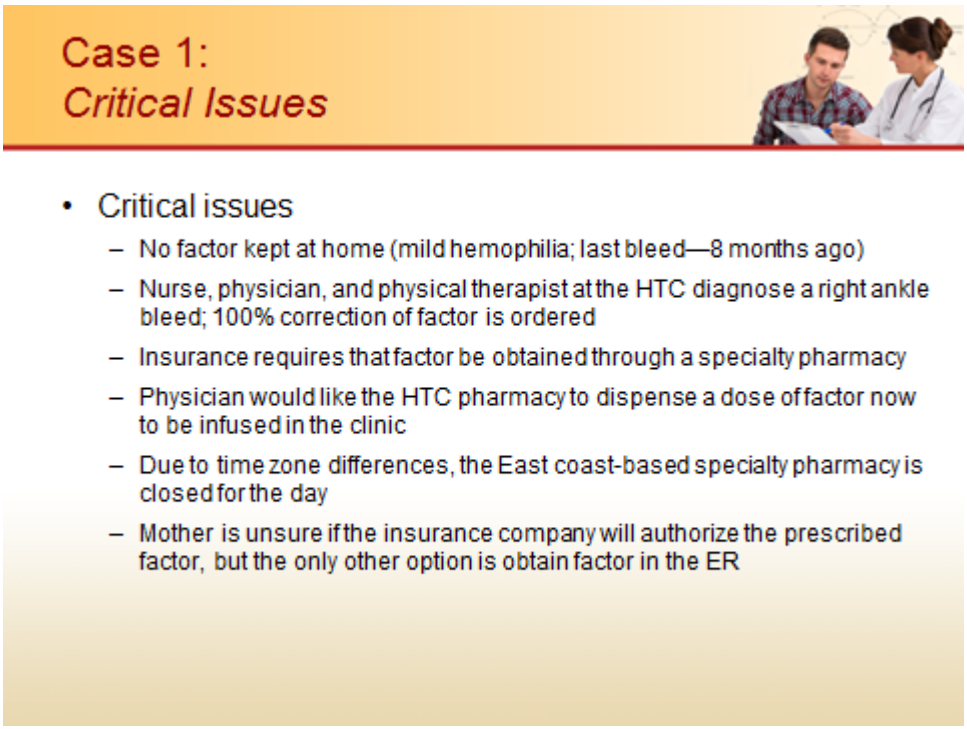


Slide 50: Case 1: *8-Year-Old Boy with Mild Hemophilia Who Does Not Respond to DDAVP®*

The first case is an 8-year-old boy with mild factor 8 deficiency with a base line factor 8 level of 10 percent who does not respond to the drug desmopressin acetate, or DDAVP®. This is a medication that was not intended for hemophilia but has the side effect of drawing out factor 8 stores from the endothelium and essentially flushing it into the circulation to increase a person's own factor 8 level. Some people respond very well to the drug and have a two to four fold increase in factor 8 levels. Others, as with this child, do not respond at all and therefore cannot use the drug.

The boy fell on the playground at school during lunch recess and injured his right ankle. The school notified the parents, which was the appropriate action to take. The mother picks the child

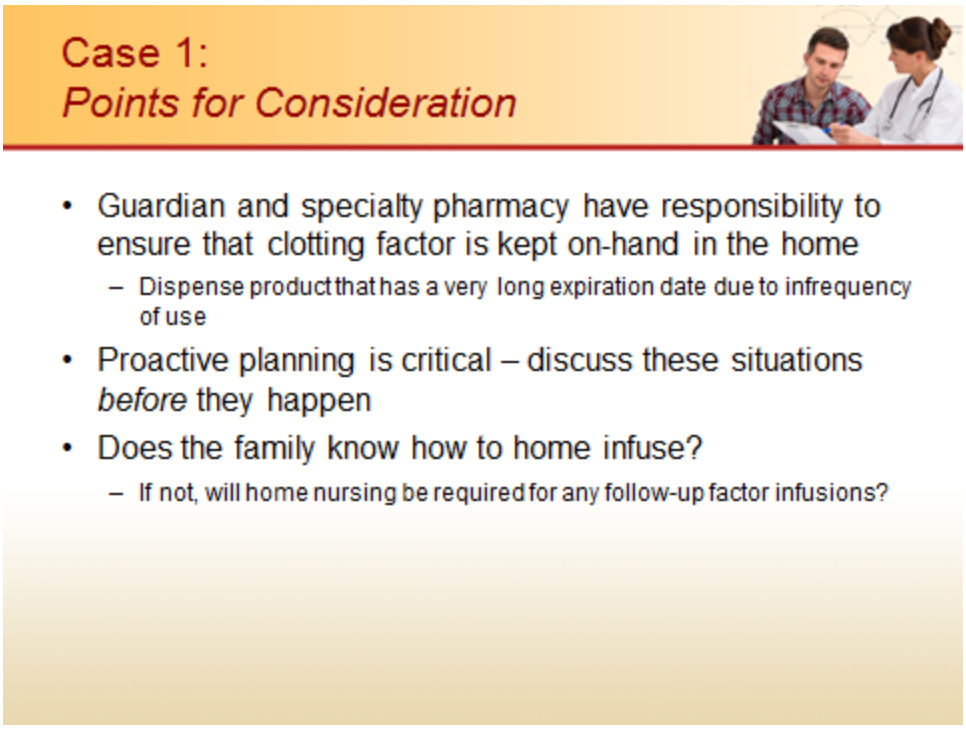
up from school and notes that his ankle is slightly swollen and that he is limping; she contacts the Hemophilia Treatment Center, or HTC, and takes the first available appointment, which is 4 o'clock p.m. Pacific time.



Slide 51: Case 1: *Critical Issues*

Unfortunately, the family does not have any factor product at home, mainly because the boy has mild hemophilia and rarely needs clotting factor.

The nurse, hematologist, and physical therapist who examine the boy at the HTC diagnose a right ankle bleed and a 100% factor correction is ordered. His insurance carrier requires that factor be obtained through a specialty pharmacy, but because of the immediate need, the HTC physician would like the HTC pharmacy to dispense a dose of factor immediately to be infused in clinic. Due to time zone differences, the East coast-based specialty pharmacy is closed for the day. The mother is unsure if the insurance company will authorize the prescribed clotting factor, but the only other option is to obtain factor in the emergency room.

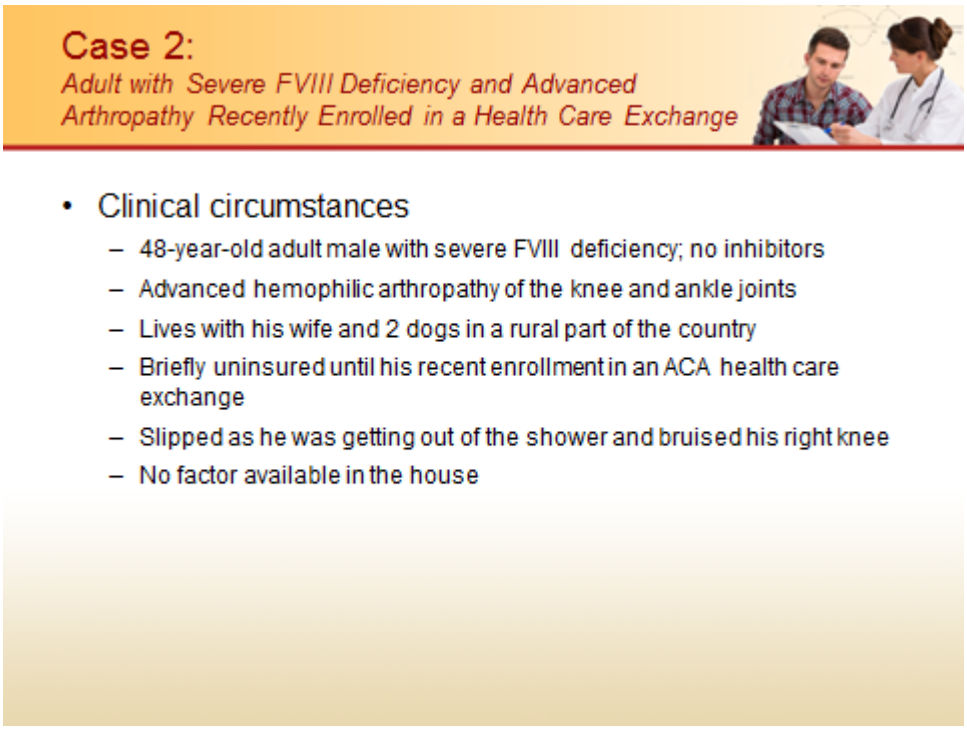


Slide 52: Case 1: *Points for Consideration*

This case study raises a number of important points for consideration. First, the mother and the specialty pharmacy share a responsibility to ensure that one or two doses of clotting factor are kept on-hand in the home. Because this patient has had minimal bleeds in the past, it would be wise to dispense product that has a very long expiration date so that the product would not expire before it is used.

It is also critical that the patient or guardian and specialty pharmacy take a proactive approach and discuss these situations with the payer in advance. In this case, the mother is facing a ten-to-twenty-thousand dollar dose of factor for which coverage is uncertain. When facing that magnitude of financial commitment, it is important for patients and/or their guardians as well as the provider to be aware of the impending financial obligation.

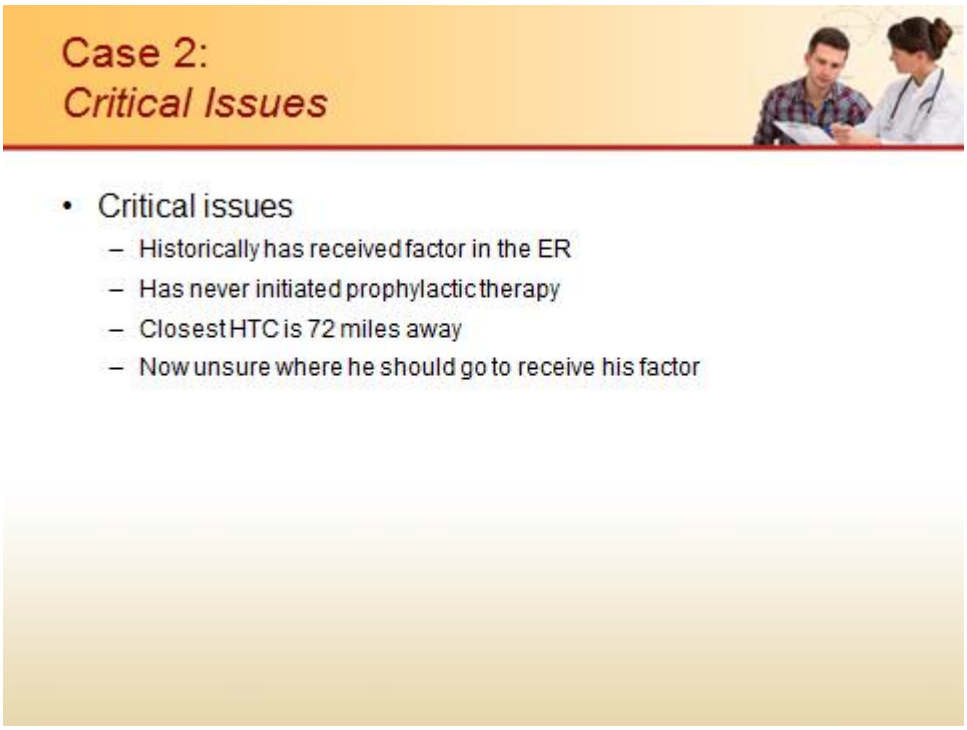
Another consideration is whether or not the patient's plan authorizes home nursing services. If this is a patient with mild hemophilia who is 8 years old and has not had many bleeding episodes, the family may not be trained or proficient in home infusion. In case they are not, they may need home nursing service available to them for any follow-up clotting factor infusions that are prescribed.



Slide 53: Case 2: ***Adult with Severe FVIII Deficiency and Advanced Arthropathy Recently Enrolled in a Health Care Exchange***

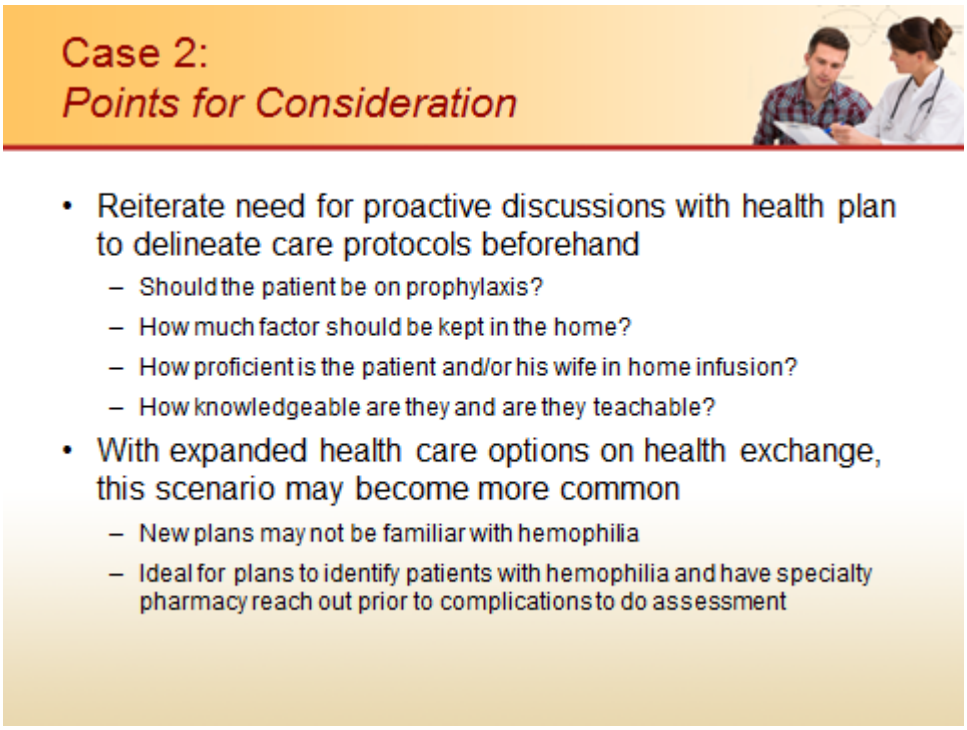
The second case is a 48-year-old who has severe FVIII deficiency with no inhibitors. He has advanced hemophilic arthropathy of the knee and ankle joints. He lives with his wife and two dogs in a remote part of the country. He had a period of time when he was uninsured but he recently enrolled in an Affordable Care Act health care exchange and now has coverage.

He slipped and fell as he was getting out of the shower and bruised his right knee. He has no factor available in the house.



Slide 54: Case 2: *Critical Issues*

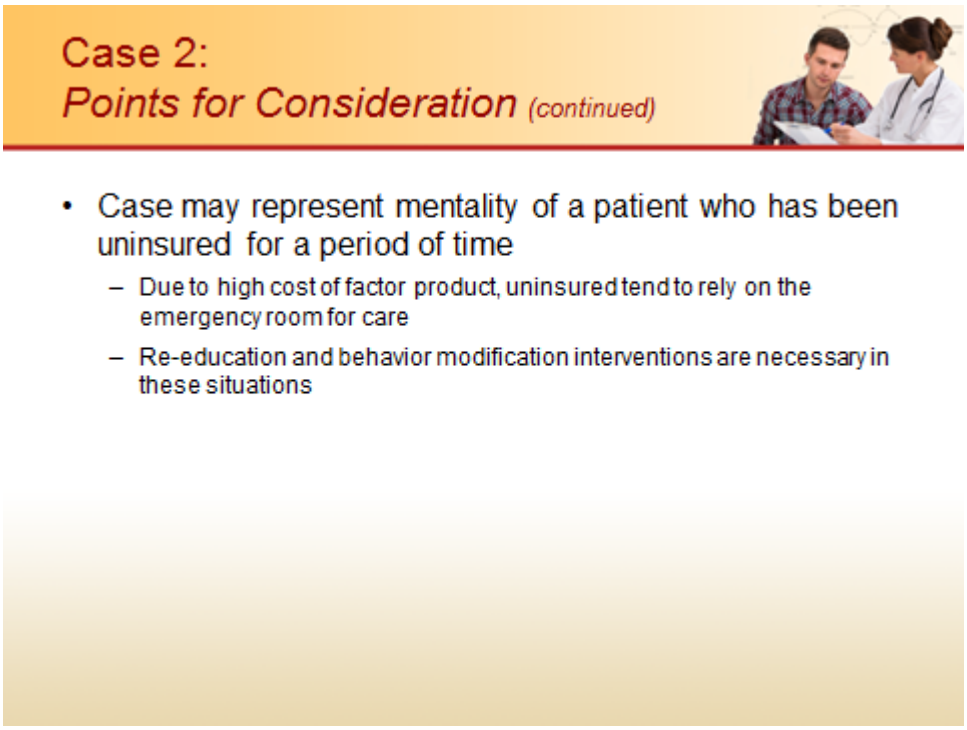
Historically, this man has received clotting factor in the emergency room. He has never initiated prophylactic therapy. His closest HTC is 72 miles away. He is now unsure where he should go to receive factor for his bruised right knee.



Slide 55: Case 2: *Points for Consideration*

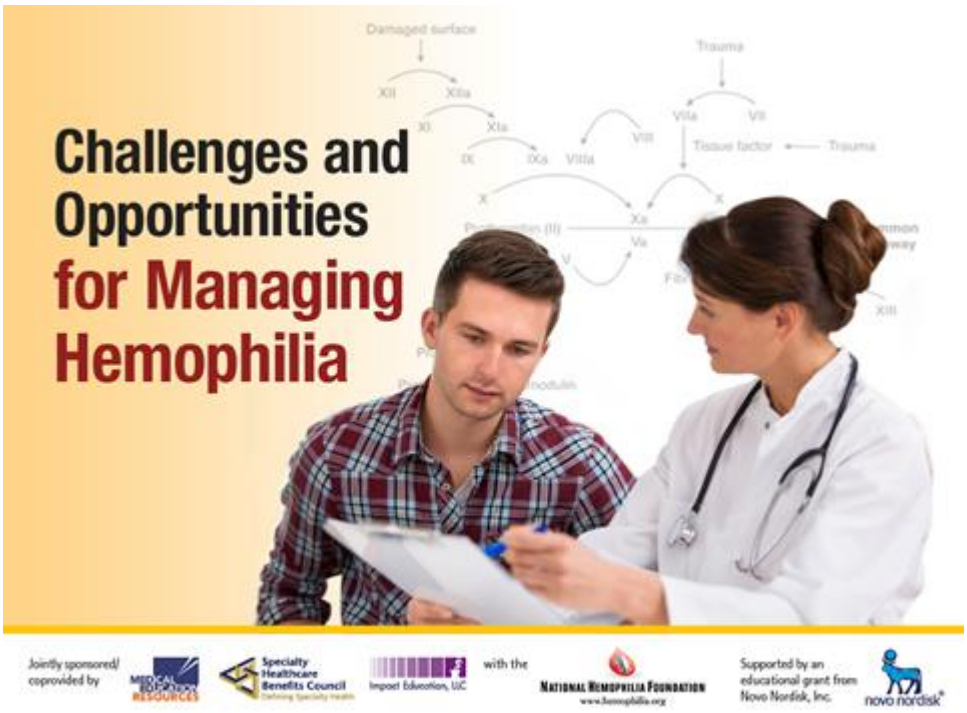
This case brings to light a few points for consideration. First, it reiterates the need for proactive discussions with the health plan to delineate care protocols beforehand. Important questions must be asked such as: Should the patient be on prophylaxis? How much factor should be kept in the home? How proficient is the patient and/or his wife in home infusion? How knowledgeable are they and are they willing to learn?

Secondly, with expanded health care options on the health care exchange, this scenario may become more common as new plans may not be familiar with hemophilia. It is ideal for these plans to try to identify patients with hemophilia and have their specialty pharmacy provider reach out prior to complications to do an assessment.



Slide 56: Case 2: *Points for Consideration* *(continued)*

Due to the high cost of factor product, patients who have experienced a gap in insurance coverage may be more likely to access the emergency room for care. In such cases, re-education and behavior modification interventions may be necessary.



Slide 57: Challenges and Opportunities for Managing Hemophilia

This concludes Track 2, Care Management Strategies, of the Challenges and Opportunities for Managing Hemophilia 2014 Continuing Education Series. Please continue to the next track or visit the Specialty Healthcare Benefits Council at www.SHBC.us to complete the Track 2 post-test and evaluation and receive the appropriate amount of continuing education credit hours. Thank you for your time and attention.