Wednesday, June 8, 2011

The 40th meeting of the Advisory Committee on Blood Safety and Availability convened at The National Institute of Health, Building 31 6C Room 6, 9000 Rockville Pike, Bethesda, MD 20892 with Jerry A. Holmberg, PhD, Executive Secretary, Designated Federal Official, Chair presiding.

Call to Order:

Dr. Holmberg called the meeting to order and advised everyone that Dr. Ison left early to go to Geneva. He stated that as the Designated Federal Official he was permitted to sit in his place.

Roll Call/Conflict of Interest:

Dr. Holmberg took the Roll Call and the following members indicated they were present: Dr. John Arnold, Dr. Charles Haley, Dr. Ravindra Sarode, Dr. Aryeh Shander, Mr. Edward Burke, Dr. Andra James, Dr. Gregory Pomper, Ms. Alissia Cofer, Dr. Ileana Lopez-Plaza, Dr. Karen Quillen, Mr. Richard Vogel, Dr. Laurence Corash, Dr. Frederick Axelrod, Dr. Jay Menitove, Ms. Mary Gustafson, Dr. Matthew Kuehnert, Dr. Jay Epstein, Dr. Harvey Klein, Dr. Monique Hollis-Perry, and Dr. Laura St. Martin. The following members were absent: Dr. Michael Ison, Dr. Roslyn Yomtovian, Mr. Klaus Nether, Dr. Sheila Roman and Dr. Jim Bowman.

Dr. Holmberg noted that the Department of Health and Human Services is convening the June 7th and 8th meeting of the Advisory Committee on Blood Safety and Availability under the authority of the Federal Advisory Committee Act (FACA) of 1972. He stated that with the exception of the industry representatives all participants of the committee are special government employees or regular federal employees. Federal employees of various operating divisions of the department are subject to the federal conflict of interest laws and regulations. The federal employees are non-voting members of the committee. The Secretary is responsible under section 301, 351, 361 of the Public Health Service Act as amended and various provisions of the Federal Food Drug and Cosmetic Act for issuing and enforcing regulations concerning the collection, preparation and distribution of blood, blood products, human tissues and human organs. For issuing and enforcing regulations related to the transmission of communicable diseases and for carrying out research in health fields including diseases involving these products. The Advisory Committee on Blood Safety and Availability shall advise, assist, consult with and make policy recommendations to the Secretary and the Assistant-Secretary regarding these broad responsibilities. The Department has determined that all the members of the Advisory Committee are in compliance with the Federal Ethics and Conflict of Interest laws. We would like to remind members and participants that if there is a personal or financial interest on a topic being discussed the conflict of interest should be disclosed. Dr. Holmberg asked if there were any disclosures that anyone would like to make. No members responded.
Dr. Holmberg noted that copies had been made of the recommendation discussed on June 7th. He asked if they could be distributed. He noted there had been some comments made concerning ethical consideration. He stated that the department would have the transcripts and would look at the comments made during the discussion. He asked that if anyone wanted to amend the recommendation to include an ethical point of view they could entertain that. There was an involved discussion with suggestions and Dr. Holmberg asked as there was still a recommendation on the floor. He asked if there was a motion to amend the recommendation. The motion was moved and seconded. The recommendation reads:

Whereas:
1. DHHS endorses WHA Resolution 63.22.
2. The U.S. is the largest user of organ transplantation.
3. Global leadership is needed to:
   a. promote best practices in organ transplantation
   b. Eliminate human rights abuses related to organ trafficking and transplant tourism.
4. U.S. participation in transplant tourism may undermine global objectives for safety, availability and ethical conduct of organ transplantation.

The Committee recommends the Secretary establish a task force to:
1. Identify mechanisms to obtain data on U.S. participation in transplant tourism and utilization of U.S. organs by foreign nationals to inform efforts to resolve practical and ethical dilemmas.
2. Take steps to increase the availability of organs in the U.S. and to lower patient transplantation costs.
3. Promote research on organ failure prevention, organ regeneration and xenotransplantation.
4. Establish standardized systems (e.g. ISBT – 128) for identification and codification of all organ transplants (including country of origin for those acquired abroad) to facilitate tracking and traceability.
5. Coordinate with established biovigilance efforts to ensure reporting, tracking and monitoring of transplantation related adverse events to improve outcomes.

Dr. Holberg asked if they had a call for the question. He asked all in favor to raise their hands. It passed by one additional vote from June 7th. There were 0 'no' votes and no abstentions.

**WHA Resolution 63.12 – Overview of WHO Secretariat Report and WHA Resolution**

Dr. Holmberg stated that WHA63.12 called for the establishment or strengthening of systems for a safe and rational use of blood products. He stated that the questions they had been asked were the following: Does the U.S. have a system for a safe and rational use of blood products? If yes, what are some areas of needed improvement in light of patient blood management? If no, what does the committee recommend to establish safe and rational use of blood products in light of patient blood management? Does data support guidelines or performance measures for the
rational use of blood in patient blood management? And then in review of the WHA63.12 are there areas of safety and sustainability of blood and blood products that should be addressed?

Dr. Holmberg introduced a committee member, Dr. Klein who is the chief of the Department of Transfusion Medicine at the NIH. He stated that the idea behind the resolution initially was support for the WHO to upgrade the blood collection facilities in developing countries. Dr. Klein stated that the WHA was the decision-making body of the WHO, it set policies and created resolutions. A review of the background of WHO with its record of issuing standards and guidelines and the many initiatives concerning blood and transfusion, was given. He stated that according to Resolution 63.12 "blood products" were defined as "Any therapeutic substances derived from human blood, including whole blood, labile blood components and plasma-derived medicinal products". He described the WHO standard setting functions and described how the WHO set out guidelines on good manufacturing practices for blood establishments which were directed toward the developing world.

Dr. Klein began a review of the WHO Secretariat Report published in March of 2010 on the availability, safety and quality of blood products. Specific issues addressed were: 1. increasing needs, blood shortage, and wastage of blood 2. wastage of plasma 3. inappropriate usage of blood products 4. risk of transfusion transmissible infections 5. emerging and re-emerging threats and 6. poor quality systems, lack of GMP (Good Manufacturing Practices) and regulation of blood products in developing countries. He noted the goals of WHA63.12 which were: 1. make safe blood products available 2. raise quality standards in blood establishments 3. reduce risk of transmission of infectious diseases and 4. enforce implementation of blood products regulations.

Dr. Klein provided a definition of patient blood management. "Evidence-based medical and surgical practice designed to manage anemia, optimize hemostasis, restore hematologic function, minimize blood loss, improve patient outcomes." He stressed the importance of the blood centers and hospitals in blood management.

Dr. Corash asked him to clarify the issue of plasma wastage in the developing world. He asked if that implied that they are collecting whole blood and separating red cells from plasma. Dr. Klein said yes it did. He added a small amount of the plasma is used for transfusion. He added most developing countries don't have fractionation capability. They collected plasma as whole blood and the plasma was inadequately tested. It was not collected under GMP conditions so it could not be sent to commercial fractionators so it was discarded.

Dr. Holmberg introduced Ms. Harriet Gammon of the Joint Commission. She is the Associate Project Director, Division of Healthcare Quality and Evaluation at the Joint Commission. The measures represent a first-step to tracking metrics relating to national blood use at the unit and patient level. She explained that the Joint Commission uses core measure sets and these are standardized and used nationally. They are used to fulfill a hospital's accreditation requirements.
In 2006 the Joint Commission was approached by Bayer to consider developing a set of measures for blood use. In 2007 a stakeholder meeting was held with organizations associated with blood use to provide input. They recommended that the Joint Commission move forward to develop measures and this began in 2008. She described the development of how the measures were compiled. Seven measures went forward for pilot testing and these were described with statistics. She described pilot measures using retrospectively abstracted – sample, two sub-populations and three levels of abstraction. She outlined measures specifications. A first measure discussed was transfusion consent, procedures and feedback. She described RBC (Red Blood Cell) data collection and feedback. Similar information was reviewed for plasma and platelets. Another measure reviewed was blood administration documentation.

Patient blood management measures were detailed as: PBM-01 Transfusion Consent, PBM-02 RBC Transfusion Indication, PBM-03 Plasma Transfusion Indication, PBM-04 Platelet Transfusion Indication, PBM-05 Blood Administration Documentation, PBM-06 Preoperative Anemia Screening and PBM-07 Preoperative Blood Type Screening and Antibody Testing. She noted that in November 2010 the technical advisory panel met and recommended that seven measures move forward. They were submitted to the National Quality Forum Surgical Endorsement Steering Committee for consideration. The committee did not support endorsement based on certain criteria. She noted that the Joint Commission remained committed to improving patient blood management.

Dr. Corash asked her to define what she meant by rate. Ms. Gammon replied that the rate is the denominator. The numerator is the subset of the denominator. As an example she said when they look at all the people that received red blood cells the rate would be the number of patients that had a pre-transfusion lab and a clinical indication.

Economics of Blood Transfusion

Dr. Holmberg introduced the next speaker as Axel Hofmann who is an economist from Vienna, Austria who is with the Medical Society for Blood Management. He disclosed his conflicts of interest. He noted that he wanted to put transfusion and patient blood management into perspective because it becomes important in the economic analysis. He defined it as follows: Patient blood management is the application of evidence based medical and surgical concepts aimed at relying on a patient's own blood rather than on donor blood and achieving better patient outcomes. He discussed the health-economic context. In the U.S. in 2008 $16 out of $100 was spent for health-related issues. In other developed countries it ranges between 8 and 9.5 percent. By 2050 in the U.S. it is expected to rise to be larger than 30 percent. He described five economic cost drivers that are currently shifting the paradigm and they are: supply issues (reviewed age and various countries), cost (all elements including institutions), inherent transfusion risk (on the product itself), adverse transfusion outcome (literature search was completed) and efficacy/effectiveness.

He discussed the current transfusion practice in a health-economic perspective. He noted the formula used called the incremental cost effectiveness ratio and it showed that the cost of
transfusions was much higher than previously assumed. He discussed PBM on national levels and stated Australia was taking the lead and they have detailed guidelines with the first module, "Critical Bleeding Massive Transfusion" recently published.

Dr. Kuehnert asked about adverse outcomes and whether they had been put into the model adverse events associated with transfusions, things like allergic reactions. He wondered if a hospital might think this is costing more money than the blood. Mr. Hofmann stated it was the case.

Dr. Sarode asked if he had ever done a cost analysis for plasma. Mr. Hofmann said no, the next thing they were doing was platelets. Dr. Sarode expressed an interest in doing a study with him for plasma.

Dr. Klein stated that he thought they should be cautious in making statements about blood efficacy or toxicity. He stated for example that chemotherapy was associated with many deaths and toxicity but it was the appropriate use of chemotherapy which is more toxic than blood transfusions, so he said the inappropriate use of blood associated with excess toxicity and lack of efficacy. Mr. Hofmann discussed blood transfusions and the circumstances they are given and stated that PBM was pro-active.

**Break**

**Blood Component Utilization at the Hospital Level: Guidelines, Education and Enforcement**

Dr. Holmberg introduced the next speaker as Dr. Joseph Sweeney from the Roger Williams Hospital in Providence, Rhode Island. He stated he was a transfusion medicine physician and directed three blood banks in Rhode Island and collectively oversaw 60 to 65 percent of all red cells and probably 85 to 90 percent of all platelets transfused the state of Rhode Island. He suggested there were three important questions: How much blood is transfused? Who are the recipients of the transfused blood? Why is the blood transfused? He thought the last question extremely important. To the first question he said it can be described at various levels: national, regional, state, municipal, system (hospital networks) all commonly referred to as "blood utilization". For the question how much is transfused he said data at the national or state level can be expressed as units transfused/1,000 population and in the United States the figure is 53 units of red cells per 1,000 population, in Europe in the low 40s and in Western Australia the number is 28. For the question of who are the recipients? It can be grouped by age, gender, type of patient, disease grouping, by service, by physician or by hospital location. He addressed his last question of why is blood transfused? He noted that blood is transfused because the physician prescribes it. Physicians' judgment is fashioned by previous experience and training. Factors as to why blood is transfused were reviewed and it was noted that it should be possible to analyze and develop guidelines to help standardize the practice. He suggested guidelines could be developed by international organizations, national or regional organizations, hospitals or groups. He described the obstacles and opportunities to developing prescribing practices. He described the steps for a practical approach to changing such practices. He presented in-depth data and
statistics on plasma and Vitamin K. He presented conclusions and his '4Cs' of hospital blood management.

Dr. Shander said that he felt that there should be a distinction between blood conservation and patient blood management. He said now we're hearing a lot about blood conservation and improving patient outcomes. He felt that patient blood management is where patients were not candidates for transfusions but were candidates for other interventions.

Dr. Epstein felt that there had been a lot of progress in the last few decades in establishing an evidence base for transfusion practices. He thought that there were however large domains of uncertainty. He thought that communication to physicians about blood transfusion practices should also include information about where those uncertainties lie. Following up on that, he thought that the uncertainties should be linked to trials.

**Overview and Implementation of a Patient Blood Management Program**

Dr. Holmberg introduced Dr. Irwin Gross. Dr. Gross is from the Eastern Main Medical Center in Bangor, Maine. He indicated that he wanted to present their experience in implementing a comprehensive patient blood management. First he described Eastern Main Medical Center, a rural-based hospital that does tertiary care, not an academic center. He said they have a large number of hospital-based internists who do not have an out-patient practice and they care for three quarters of the patients. He stated they did high-risk obstetrics, had a trauma center, a dialysis center, family practice residency, cardiac surgery program, and an active hematology/oncology service. He noted that in 2006 they had a $3.2 million blood acquisition budget, the year prior to implementing patient blood management. He described the challenges of changing transfusion practice. He stated that they used an organizational change model.

He reviewed the steps to setting up the PBM program with goals of decreasing blood acquisition costs and improving patient safety and quality of care. He discussed resources, education, partnering, role of information technology and their computerized physician order entry (CPOE) system. Two patient screens were reviewed in which he illustrated how physicians would order blood noting how the programs does and does now allow them to make certain choices, something that was written as a program to assist the physicians to make better decisions for the patient and harder to make inappropriate orders. He noted that provider specific transfusion practice reports were generated by the system and sent to providers and service chiefs. In addition different kinds of reports are also generated from the system. They created an electronic process to enroll the patients in anemia management through a scheduling event in their EMR as they found that insufficient attention was given to older patients especially by PCP (Primary Care Providers). He described their perioperative blood collection program. The impacts of the program were reviewed including financial savings. Some of the conclusions were: significant variation in blood use in the U.S., over-utilization is common, changes in transfusion practice can occur quickly and be “hard-wired” to last and the EMMC data suggests a 30-50 percent reduction in blood use nationally is a realistic goal with associated savings in costs.

Dr. Menitove asked about the yield on the preoperative or admission anemia workups, and of whom the intervention actually had an impact. Dr. Gross said that they saw anemia as defined as
a hemoglobin <13 and they used the same threshold for women as for men and about 35 percent
of their patients had hemoglobin <13. He said they treated about 20 percent so they captured one
third, looking at different factors and then treated about one patient in five. He said as far as an
increase in hemoglobin that they considered significant, they defined as an increase of least gram
per decile.

Dr. Klein commented that with the electronic medical record he thought it underlined what Dr.
Epstein said about comparative effectiveness research because outcomes are critical but other
things change.

Dr. Pomper asked about the outcomes data. He asked if he had any linking of the DRG-based
outcomes and the DRG-based transfusion rates, for example orthopedics. He said they did but it
was not included in the presentation. He said that when they looked at outcome measures their
most robust data analysis had been in cardiac surgery because their data was collected over a
long period of time. He noted the outcome measures they looked at were length of stay, cost of
care, and surgical site infections among others. He said for the two areas, elective hip and knee
and open-heart surgery all of the outcome measures were at least the same or better over the
years of the program. Dr. Pomper asked if it was just red cells for the transfusion rate on the
cardiac data. Dr. Gross replied that they had data on red cells and they also had platelet and
plasma data.

**Understanding the Past and Predicting the Future of Blood Requirements**

Dr. Holmberg introduced Dr. Richard Benjamin. He is the chief medical officer of the American
Red Cross and he oversees the donor and patient safety issues related to blood collection and
transfusion. Dr. Benjamin gave a quick overview of the American Red Cross saying they are
about 40 percent of the blood supply in the U.S. and are committed to the safety of donors and
patients and to meet the best interests of the public they serve. They distribute about six million
units of red cells and 1.7 million units of plasma products.

Dr. Benjamin summarized some issues he considered important as follows: 1. the fact that we
have a poor understanding of past blood use practices 2. the current downturn in blood utilization
has been accompanied by an unsustainable abuse of type O- RBC and AB plasma 3. blood
demand associated with the Baby Boomer generation was likely to threaten the blood supply in
the future. 4. a desperate need for better patient-level blood utilization data to understand blood
demand and avoid supply/demand mismatches (i.e. shortages and discards). He stated that they
are interested in supply chain management and balancing supply and demand. They want this
data to be able to react and to anticipate changes, to predict future situations. He discussed
reasons why blood use has gone up in the past including waste and excess surgeries and
utilization disparity

He asked how well do we understand who uses red cells and how well do we understand the
influencers on red cell use? He noted they needed more data of real time demographics of
transfused patients such as age, gender, race, location etc. He described several international
studies collecting data and outlined potential U.S. data sources such as AIM2 based on the
He discussed the overuse of Group O blood by hospitals in the country as poor blood management. A similar situation exists for Group AB male plasma. He noted that they have a poor understanding of the past and what will happen in the future. He described the influences on red cell use, population changes from the 2010 census, Baby Boomer issue, changes in U.S. population and donor groups, and predictions of RBC collections and transfusions. His conclusions were: 1. in the prior decade RBC growth was driven by changes in medical practice 2. there was a utilization boom and waste 3. there are critical shortages of type O, Rh neg RBC and AB plasma 4. the Baby Boomer generation will increase RBC needs by 2 to 2.5 percent 5. these conditions may be balanced by economic drivers and healthcare reform 6. indications are that there is a strong need for data so blood centers can plan, avoid waste and control costs.

Dr. Klein brought up the issue of the O neg and said he would like to propose an alternative interpretation. He said that all of them in hospitals had routinely given O positive blood to O neg patients due to shortages and they define that as a shortage. Dr. Klein suggested that you would have less of that kind of shortage because you have collected more O neg. Dr. Benjamin said that they would have to go back to where they were before if they were going to meet the needs of the Baby Boomers.

Dr. Pomper said there was a paper published in January 2007 and there was a consensus that included just about every academic trauma surgeon in the U.S. The conclusion of that consensus meeting was a national paradigm change. So he felt it was conceivable that the explosion of publications and the advancement of the 1:1:1 trauma protocol has. In fact, it was predicted at that time that the demand of O neg and AB plasma was going escalate and it would have to escalate and there was a challenge put out to the transfusion medicine community to respond. Dr. Benjamin responded that in the 2008 NBCUS database trauma was 15 percent of red cells so he said he didn't know if there was enough there to cause the dramatic increase they've seen. Dr. Holmberg said the distribution of where the blood went and if it was the first time the data had been collected might prove difficult when patients moved from one service to another service to be able to capture this. He noted it was problematic but he thanked Dr. Klein for suggesting that that data went into the NBCUS.

Dr. Holmberg introduced Dr. Rana Samuel from the Department of Veterans Affairs, Buffalo, New York. He advised that she is the medical director and chief of the Department of Pathology and Laboratory Medicine. Dr. Samuel described the risks of red cell transfusions, both early and late risks. She stated that it was her view that "non-emergent red cell transfusion offers no benefit to most patients, and may cause serious harm" and she reviewed the evidence and some statistics for trials outcomes. She confirmed as per the studies that withholding blood did no harm whereas giving blood sometimes did harm. She reviewed some of the myths associated with blood transfusions. She noted the concept of "first do no harm" as the approach but discussed guidelines for transfusions as physicians often had to deal with very sick patients. She reviewed red blood cell transfusion guidelines and discussed chronic anemia. She did an education and utilization review noting improved patient safety and improved healthcare
delivery. Under suggested national monitors she noted 1. a percentage of RBCs transfused at Hb > 7 g/dl and 2. a percentage of non-single unit RBC transfusions.

Dr. Corash noted that there was a lot of data about adverse reactions to blood transfusions but he said that they had been poor about measuring the benefits of red cell blood transfusions. He related a conversation with another doctor who he had asked the question, why did he transfuse patients? The doctor responded that he needed to improve their functional capacity because I need to get them out of the hospital and walking and into cardiac rehab. He then discussed the 'six-minute walk test' which showed what a patient could do. Dr. Corash stated therefore that when he sees oxygen extraction data that is usually done at bed rest, he would think that would not be the reason that I am transfusing somebody. He noted that he would want them up and walking. He suggested that they think about that. Dr. Samuel agreed but said that where is the data showing that if you transfuse a patient so they can get into physical rehab earlier that they will have better outcomes? She said we know that patients do better if they are in rehab but transfusion as the answer to get them there, she did not see that risk/benefit ratio.

Dr. Sarode discussed both anemia and the number of excess tests done on patients and the reasons why some tests would show the physical decline or poor response of the patient due to not eating well or they could be vitamin K deficient. He thought that there were a number of things that could be done to prevent unnecessary transfusions of plasma and red blood cells.

Dr. Klein asked to be respectfully confrontational. He agreed with Dr. Corash and stated perhaps they had treated too many very sick patients with conditions such as sickle cell disease requiring chronic transfusions and if they had been treated by giving one unit at a time every three weeks it would have been an enormous frustration. He thought some of the data on trials discussed could be correct but it was fatally flawed. He noted that he had published extensively on that. He thought before they call for national standards we need more data on efficacy before worrying too much about hurting people with blood transfusions.

Dr. Kuehner asked about informed consent. He noted that she had done a lot of work educating physicians. What did she tell her patients concerning the risks of transfusions? Dr. Samuel noted that it took a lot of energy to get physicians to change their practice so she took little steps. The transfusion informed consent she did not have a lot of faith in and stated it was a form developed about a decade ago. Dr. Samuel noted the communication of this information with patients could be seen as a gap in their process. She said she tried to improve it little bits at a time taking into account limited resources and time. Dr. Holmberg stated his appreciation for her inclusion of the savings made on healthcare workers because this aspect had not been addressed.

**Open Public Comments**

Dr. Holmberg noted the beginning of the public comment period and Ms. Teresa Wegman from AABB was presenting.

Ms. Wegman distributed a written statement and she proceeded to summarize it. She thanked the committee for dealing with PBM which fitted into the role of the AABB. She noted that they thought that PBM should encompass all aspects of patient evaluation and clinical management
surrounding the transfusion decision-making process. She stressed that they believed in the importance of making decisions that are evidence-based and demonstrated to improve patient outcomes. They thought that PBM programs should be multi-disciplinary. She noted that AABB was offering a number of programs to try to advance PBM. They offered educational materials and programs at the annual meeting. They set standards at blood banks and transfusion services for over 50 years. They were working on producing additional materials for hospitals. She noted that they had been working on developing clinical guidelines. In 2010 they issued guidelines on plasma and in 2011 on red blood cell indications. She said it was critical to get the guidelines into the hospitals, provide education and have them implemented.

Dr. Quillen asked if AABB would consider producing some patient education material. Dr. Shander noted that AABB and SABM (Society for the Advancement of Blood Management) worked together and produced patient information in terms of choices available to patients who are to receive transfusions. He advised there was a patient pamphlet available on the website.

**Break**

**Committee Discussion**

Dr. Holmberg advised he wanted to go through some of the questions they were asked to address. He stated WHA63.12 called for the establishment or strengthening of systems for the safe and rational use of blood products. The question is, "Does the U.S. have a system for the safe and rational use of blood products?" He said if the answer was yes, then what are some areas of needed improvement in light of PBM and if no, what did the committee recommend to establish safe and rational use of blood products in light of PBM? He opened it for discussion.

Dr. Epstein stated that there was the product and optimizing the safety, efficacy and consistency of the product. He thought that the WHA resolution was drawing attention to the issue but he felt that they had not discussed during the meetings how the product itself could be improved and he thought that they needed to concede that whereas scientific advancements are possible that the need in the U.S. had more to do with practices of blood management. He said that they should acknowledge that there were some safety issues but the main issue of the day should be blood management. He stated that there should be a critical review but that he had not seen the guidelines issued by AABB.

Dr. Shander made some comments with regard to 'rational use'. He thought they needed to ask certain questions. He thought the question was where do red cells fit in the treatment or the algorithm of treatment of anemia and who are the patients or patient groups who will benefit from a transfusion of red cells under those circumstances? He noted the literature if used to answer that, would be large trials.

Dr. Sarode thought that they needed some national guidelines. He thought the guidelines of AABB would not be easy for hospitals to work with. He thought there should be comprehensive guidelines easily implemented at all hospitals.
Dr. Holmberg added to comments by Drs. Menitove and Klein regarding comparative research. He noted that the committee did a whole session on comparative effectiveness and many patient groups became concerned that they were going to move in a direction where they would not receive their products. Dr. Holmberg agreed that there were some great opportunities with the comparative effectiveness but he thought that some of the studies were not successful because they were too complex.

Dr. Benjamin brought up the issue of evidence with regard to the efficacy of transfusions. He stated the issue is the level of evidence. He confirmed there was expert opinion but noted that they were waiting for level one evidence so he expressed concern when hearing negative comments about transfusions in public forums. He said that evidence at the moment for good and bad was weak evidence. He thought that they should wait until they have level-one evidence before making judgments.

Dr. Epstein discussed advocating for the principal role of transfusion experts in transfusion decisions in hospitals. He said he was troubled by the call for national guidelines when there was one out there. He asked if it was a question of HHS advocating one of these or was it a call for a synthesis of the two. He agreed that they needed to make a set of findings as a committee and that the findings go along the lines that current practices project demands for blood that may exceed supply with a projected timeline. A statement should be issued that the situation is not sustainable and appears to be due to excessive and inappropriate use of transfusions and that the situation could be remedied by patient-oriented blood management. He thought the statement though needed to be framed in such a way as to reflect what HHS was expected to do.

Dr. Pomper agreed that a set of national guidelines would be good. He stated that hospitals at their highest level of administration could set up a protocol to allow experts to review requests for blood transfusions.

Dr. Epstein suggested that the findings would be: that blood transfusion carries serious risk that may exceed the benefits in some settings, that data indicate that there is excessive and inappropriate use of blood transfusion in the U.S., that medical advances in aging of the population are expected to drive demand that could exceed supply in the next one to two decades, that improvements in rational use of blood have lagged behind improvements in products per se, that programs of patient-oriented blood management at some hospitals have demonstrated decreased blood use without increased harm to patients through optimization of patient coagulation status hemoglobin minimizing blood loss and conservative use of transfusion. That the committee therefore recommends: that the Secretary first of all promulgate national standards on blood use recognizing the value of patient management, blood conservation, conservative use of transfusion etc., that the Secretary take steps to establish transfusion expertise as integral to transfusion practice within hospitals, that the Secretary establish metrics for good practice of blood use in hospitals, that there be integration of the patient electronic health record with blood management and something about the education of clinical practitioners and starting at medical school.

Dr. Holmberg asked if they wanted to say in the findings something about the blood measurements that the Joint Commission had already established.
Dr. Menitove stated that he would include mention about costs. He also stated under action items to recommend to the Secretary to evaluate the role of professional societies.

Dr. Klein under findings suggested that geographic variability of transfusion practice across the U.S. be noted.

Dr. Holmberg said the reason that he brought in the AHRQ is that they have centers of excellence and he wondered if they might be able to provide the data for the performance measures.

Dr. Haley said they do have centers but also a budget. He noted the comparative effectiveness budget is substantial and he said they are willing to study anything. He thought it would be legitimate to ask the Secretary to ask AHRQ to study all of the guidelines and evidence bases for the guidelines and produce a report.

Dr. Holmberg asked them to go ahead with the recommendation:

Recognizing the significant role of transfusion practices in the quality of healthcare and its costs, the committee finds that:

1. Blood transfusion carries significant risk that may outweigh its benefits in some settings and add unnecessary costs.
2. Wide variability in use of transfusions indicates that there is both excessive and inappropriate use of blood transfusions in the U.S.
3. Medical advances and ageing of the population are expected to drive demands for transfusions that could exceed supplies in one to two decades.
4. Improvements in rational use of blood have lagged behind improvements in the quality and safety of the products.
5. Additional data on blood utilization and clinical outcomes are needed to identify gaps in knowledge in order to effectively manage transfusions and support evidence-based practices.
6. Programs of patient oriented blood management at some hospitals have demonstrated significant reduction in blood use without increase in patient harm based on expert decision making. (Methods have included correction of anemia, coagulopathy, blood conservation including minimizing blood loss, and conservative use of blood products).

Therefore the Committee recommends that the Secretary:

1. Identify mechanisms to obtain data on patient blood management, utilization of transfusion and clinical outcomes.
2. Support development and promulgation of national standards for blood use recognizing the value of patient management, blood conservation and conservative blood use.
   a. Consider a consensus development conference
b. Ask AHRQ to evaluate available clinical guidelines and to sponsor comparative effectiveness research in patient blood management and transfusion.
c. Acknowledge the role and leverage the efforts of professional organizations.
d. Improve the quality of health for Medicare beneficiaries by monitoring transfusion practices and outcomes.

3. Take steps to establish transfusion expertise as integral to transfusion practices in hospitals and other patient care settings.
4. Establish metrics for good practices of blood use and patient blood management.
5. Advise the ONCHIT on the need to integrate patient blood management and blood utilization into electronic health records.
6. Promote education of medical students and practitioners on optimizing patient blood management and use of transfusion and elevate awareness of the essential role of blood management in the quality and cost efficiency of clinical care.
7. Promote patient education about the risks, benefits and alternatives of transfusion to promote their empowerment in transfusion decision making.
8. Support demonstration projects on patient blood management.
9. Support research on non-invasive clinical measures to define indications for transfusion for example ischemia and hemostasis.

A motion was made to approve the recommendation. It was seconded. Dr. Holmberg took a vote and stated there were 12 'yes' votes, 0 'no' votes and no abstentions.

Dr. Holmberg announced that it was the last meeting for Dr. Haley and he thanked him for all his work and contributions.

Dr. Holmberg adjourned the meeting of the Advisory Committee for Blood Safety and Availability at 5:00 p.m.