The Feasibility of Implementing the ACP-215 at the Dayton Community Blood Center: A Cost-Benefit Analysis

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Angela Albrecht

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Acknowledgment

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Abstract

The community blood supply is a limited resource with a relatively short shelf-life. To ensure an adequate supply, a balance must be maintained between the numbers of donors providing blood and blood products required by hospitals to meet patient needs. Any change in the number of blood donors or in the volume of blood required by hospitals can create a blood shortage. During times of disaster, a blood shortage may be inevitable. Additional strategies must be in place to ensure availability of blood for essential transfusions across the community.

Cryopreservation of red blood cells to build and maintain a blood product reserve has been considered a possible strategy for many years. However, red blood cell products prepared by the traditional process expired 24 hours after thawing, allowing only that time for successful transfusion. This was not practical from an emergency preparedness perspective. Haemonetics Corporation has developed an Automated Cell Processor (ACP-215) that both freezes and thaws a red blood cell product in a system that allows for long-term storage of the blood product and extends the shelf-life of this thawed product to 14 days. This research conducted a cost-benefit analysis of the ACP-215 to determine the feasibility of implementation of this instrument by the Dayton Community Blood Center to establish a frozen red blood cell reserve and improve its emergency preparedness efforts.

Keywords: ACP-215, red blood cell cryopreservation, strategic blood supply, transfusion
The Feasibility of Implementing the ACP-215 at the Dayton Community Blood Center: A Cost-Benefit Analysis

Transfusion medicine is a medical specialty that focuses on the transfusion of blood and blood components for patients who are in need of this medical procedure for various reasons. The majority of these blood products are acquired by hospitals from local community blood centers (Erickson et al., 2008). The Dayton Community Blood Center (DCBC), located in Dayton, Ohio, is the single provider of transfusion blood products for 25 hospitals in the Greater Dayton Area. During normal routine operations, the DCBC cost-effectively manages its own blood component inventory using strategies that maximize efficiency and minimize wastage (DCBC Inventory Senior Staff, 1 March 2013). However, what if blood supplies were suddenly insufficient or depleted during an ongoing emergency or disaster situation, creating a critical shortage of blood products?

Disaster or emergency situations refer to any crisis that temporarily restricts or eliminates the ability of a blood transfusion service to maintain its supply of blood products or to meet the sudden increase in demand for these blood products as a result of the particular crisis. Specific disaster or emergency scenarios include destructive acts of terrorism, mass casualties, major storms, floods, earthquakes, epidemic infectious disease outbreaks, or seasonal shortages limiting the number of available donors. These situations can create a challenging impact on the supply of blood donors, blood service staff, blood center volunteers, and blood products, as well as on patients, hospitals and the general public (Kuruppu, 2010; Erickson et al., 2008; Ramsey, 2008).

The solution to this dilemma is the establishment of a reserve strategic blood supply so that the demand for blood products is always met under any circumstances, without the need to spend a large amount of money to acquire blood products from outside sources. This is done by
having a reserve of frozen red blood cells, which can then be stored for 10 years, with at least the same, if not better, efficacy and safety as fresh liquid red blood cells (DCBC Transfusion Services Senior Staff, 12 February 2013; Erickson et al., 2008; Ramsey, 2008).

However, red blood cell (RBC) products prepared by the traditional process expired 24 hours after thawing, allowing only that time for successful transfusion. This is not ideal from an emergency preparedness perspective. Therefore, in 1998, the Haemonetics Corporation developed an Automated Cell Processor named the ACP-215 that both freezes and thaws products in a closed system that allows for long-term storage and extends the shelf-life of a thawed product to 14 days (DCBC Transfusion Services Senior Staff, 12 February 2013; Chaudhari, 2009; Erickson et al., 2008; Ramsey, 2008; Bandarenko et al., 2007; Valeri & Ragno, 2006). A closed system uses sterile techniques during the freezing and thawing processes to lower potential bacterial contamination of the final RBC product and extends the post-thaw shelf-life of this product (DCBC Transfusion Technician, 7 March 2013; Haemonetics Sales Representative, 25 February 2013).

Currently, the United States military and large community hospitals are the primary consumers of the ACP-215 as blood transfusions are highly demanded in these locations. The ACP-215 is used by only 2 to 3 small local community blood centers with little published data discussing the benefits or potential cost-savings with implementation of this instrument by these community blood collection centers (Haemonetics Sales Representative, 25 February 2013). As stated previously, the DCBC is the sole provider of transfusion blood products for 25 hospitals in the Greater Dayton Area (DCBC Inventory Senior Staff, 1 March 2013). The establishment of a strategic frozen RBC reserve is a potential solution to cost-effectively meeting the community’s
blood product needs at all times and improving the Greater Dayton Area’s emergency preparedness efforts.

This research, designed as a case study, performed a cost-benefit analysis on the ACP-215 instrument. It determined the feasibility of the not-for-profit DCBC to employ this medical device in its daily operations, based on the operational advantages and disadvantages and the overall annual costs and savings afforded to the DCBC with implementation of the ACP-215. The primary investigator hypothesized that ACP-215 implementation would benefit the DCBC from a cost-savings and emergency preparedness perspective.

**Literature Review**

**Blood Transfusion**

Blood transfusion is one of the top 5 hospital procedures and expenses. Every year, approximately 4.5 million Americans require a blood transfusion, as someone needs blood every two seconds. These transfusion requirements use 43,000 pints of donated blood every day in the United States and Canada (DCBC Transfusion Services Senior Staff, 12 February 2013; America’s Blood Centers [ABC], 2013). There are four main red blood cell groups: A, B, AB and O. Each group can be positive or negative for the Rh factor. AB is the universal recipient and O negative is the universal donor of red blood cells. The demand is greatest for O negative blood because it is commonly transfused in trauma cases and other emergency cases when the blood type of the recipient is not immediately known (ABC, 2013; James, Hillyer, & Shaz, 2012).

**Blood Product Supply and Demand**

The transfusion process demonstrates the classic supply and demand model, in which the demand for blood products from hospitals, transfusion services, and the public significantly
influences the supply of blood products, or needed blood donations. A lack of blood occurs when the supply, or number of blood donations, is unable to meet the demand, or transfusion needs, of patients and hospitals (Sacchini et al., 2013).

The demand for blood products is rising, as blood transfusions continue to increase approximately five to seven percent (5-7%) per year without a similar boost in donations (James et al., 2012; Pittoco & Sexton, 2012). The aging population, the increase in medical technology such as organ transplantations and cancer chemotherapy treatments, and the rise of other surgical procedures contribute to the rising demand. This phenomenon mandates a mutual growth in blood collections from the suppliers by approximately seven percent (7%) to meet this overall patient demand. Unfortunately, increased donor rejections due to stricter donor eligibility regulations, donated units failing strict infectious disease transmission testing criteria, and tight donor recruiting budget restraints will make it difficult to provide an adequate supply of blood products (Erickson et al., 2008; Zou, Musavi, Notari, & Fang, 2008; McCarthy, 2007; Pitocco & Sexton, 2005).

The three major blood product suppliers in the United States include a large network of interconnected, community-based blood centers known as America’s Blood Centers (ABC), the American Red Cross (ARC), and various hospitals that have their own blood banks. The ABC and ARC each contribute about 45 percent to the nation’s blood supply. The US hospitals, as well as other independent blood centers and the Department of Defense, contribute approximately 10 percent to the national supply. Ideally, suppliers prefer to maintain a three-day inventory supply at any given time (Erickson et al., 2008; Ramsey, 2008; United States General Accounting Office [USGAO], 2002).
Current mathematical models state that approximately 120 million people in the United States, or 40 percent of the population, are eligible to donate one pint of blood every two months. However, of this eligible population, only five percent (5%) donate blood at least once each year and only three percent (3%) donate more than once yearly. Fortunately, 80 percent of blood donors are repeat donors (James et al., 2012; Seifried et al., 2011; Erickson et al., 2008; Zou et al., 2008; Pitocco & Sexton, 2005; Hess, 2004; USGAO, 2002).

Often, the public mistakenly views the blood supply as a depository of liquid RBC units, indefinitely stocked and consistently available to withdraw any amount to meet any demand. However, developing a blood supply is a complex, multi-factorial process that involves extensive donor screening, various collection strategies, complicated blood component separation processes, numerous strict testing procedures, massive distribution routes, and storage challenges (Erickson et al., 2008; Zou et al., 2008). Whole blood cannot be stored or stockpiled into a reserve. Within 24 hours after donation, the whole blood must be separated into its components to include RBC’s, platelets, and plasma, with storage shelf-lives of five to forty-two days. Therefore, blood collection centers depend heavily upon living donors who regularly donate blood to build and maintain an adequate supply of blood products and consistently meet the customer demands, striving to maintain an average three to five-day supply of red blood cells, the most commonly used product (Erickson et al., 2008; Zou et al., 2008; McCarthy, 2007). Despite the efforts of these blood donor agencies, 95 percent of the population fails to donate in any given year and 60 percent of the population has never donated (Solomon, 2012).

Interestingly, however, major disasters have provoked a strong sense of altruism within the people of communities to donate blood and results in a massive influx of donors and collection of blood largely in excess of the actual needs of the disaster victims. Given the short
shelf-life of RBC products, this type of a response is logistically taxing and wasteful. In these situations, qualified phlebotomy personnel are in short supply at the blood donation centers and there may be hasty recruitment of poorly trained temporary blood center staff. The lack of properly trained staff and oversight leads to a higher risk of collection, processing, testing, and storage errors. Because the supply often exceeds the demand, most of the donated blood becomes outdated and is discarded. This can damage public relations as the donors become disheartened that their “gift of life” was not used to save lives (Stanger, Yates, Wilding, & Cotton, 2012; Kuruppu, 2010; Erickson et al., 2008).

The terrorist attack in America on September 11, 2001 serves as an example of this scenario. During the immediate aftermath of the attacks in New York City, there was an extraordinary influx of local blood donors, with major backups and long waiting lines. This prompted the Federal Drug Administration (FDA) to allow partially trained technicians to collect, process, and test the blood. Partially tested units of blood labeled “For Emergency Use Only” expended valuable storage space and resources, comprising a substandard supply that was eventually wasted. Overall, almost 600,000 extra units of blood were collected and approximately 250,000 units were discarded with financial losses topping $5 million (Stanger et al., 2012; Kuruppu, 2010; Erickson et al., 2008; Hess & Thomas, 2003). Increasing donor motivation during times of normal operations and decreasing the emotional altruistic response during times of a crisis are the keys in balancing the supply and demand sides of the transfusion process.

However, blood is traditionally a scarce commodity and future challenges to ensure a sufficient blood supply will likely present themselves in most communities for a number of reasons. The percentage of Americans aged 65 years and older is expected to rise from 12.6
percent in 2000 to 20 percent by 2030, an increase of more than 30 million people. By 2050, this population is anticipated to double in size (Sayers & Centilli, 2012; Seifried et al., 2011; Zou et al., 2008). This population will more likely receive rather than donate blood as their risk for developing chronic diseases (cardiovascular disease, diabetes, malignancy) and need for complex surgical procedures requiring blood transfusions increases (Sayers & Centilli, 2012; Seifried et al., 2011; Zou et al., 2008). Therefore, the need to maintain a consistent national blood supply will become more urgent.

More than 16 million blood donations occur annually, providing blood products to more than 4 million recipients (Solomon, 2012; McCarthy, 2007). However, despite these donations, episodes of periodic and predictable acute shortages have recurred, creating unmet demands for blood products and affecting overall patient care (Solomon, 2012; Erickson et al., 2008; McCarthy, 2007). Predictable shortages of all blood types occur during the summer months and winter holidays, particularly because the donor numbers are down due to vacations and changes in routines (DCBC Transfusion Services Senior Staff, 12 February 2013; Solomon, 2012; Erickson et al., 2008; McCarthy, 2007). In addition to these routine and predictable periods of shortages, a number of unpredictable factors now challenge blood collection services and create potentially serious blood shortage problems. These factors are related to the characteristics of the blood products themselves, the donors, and the environment.

First, the storage capacity and shelf-life of donated liquid blood is limited, and therefore, predisposes itself to wastage. As demonstrated in the aftermath of the 9/11 attacks, if donations remarkably increase over a short period of time, some of this donated blood may not get used before its shelf-life expires within the five to forty-two day window and some will be wasted. Blood wastage is costly in terms of money, resources, and potentially negative donor relations
and, therefore, limits the amount of liquid blood inventory maintained by the blood collection centers (Solomon, 2012; Erickson et al., 2008; McCarthy, 2007).

Second, the number of potential donors in the United States is decreasing for various reasons. Donors are rejected due to increased strict screening criteria such as travel to certain countries, positive exposure status to certain infections or diseases, and donor participation in various risky personal behaviors. Also, the willingness of people under age 50 to donate blood is significantly lower than those aged 50 and older. Despite their altruism, people aged 50 and older are predicted to receive rather than donate blood due to increased incidence of chronic diseases and more complex surgical procedures requiring blood transfusions. With fewer people donating and more people receiving blood products, the potential for extended near-future critical blood shortages exists (Solomon, 2012; Erickson et al., 2008; Zou et al., 2008).

Lastly, the unpredictable nature of the physical environment creates additional stresses on blood product supply and demand. Natural and manmade disasters create injury victims in need of blood and remove individuals from the donor population (Hess & Thomas, 2003). Unpredictable weather patterns, emerging infectious disease threats, and potential terrorist attacks face blood collection centers worldwide. For example, an influenza pandemic can have major impacts on the supply of blood products by increasing donor deferrals, decreasing donor attendance and blood center staff availability, thereby disrupting blood collection services and compromising the overall safety of the donated blood due to blood collection and processing by inexperienced, temporary staff (Kuruppu, 2010; Erickson et al., 2008). Based on the unpredictable nature of these factors affecting the blood supply, blood collection centers must have blood management contingency plans in place to monitor and manage inventory levels during all times of normal operations, temporary shortages, and critical long-term shortages.
DCBC Blood Shortage/Disaster Plan

The Impact Status Table (Figure 1) monitors and grades daily inventory levels based on a description of the impact levels, their causes, and recommended actions.

<table>
<thead>
<tr>
<th>Status</th>
<th>Blood Inventory Level</th>
<th>Hospital Impact/Recommended Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>No Shortages</td>
<td>CBC and Hospital:</td>
</tr>
<tr>
<td></td>
<td>CBC Inventory ≥ 3 days</td>
<td>Follow standard operating procedures for ordering, shipping, receiving and returning blood products.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NOTE: CBC notifies hospital transfusion services when inventory levels of red blood cells or platelets fall below a defined optimal inventory level. This notification process is not included in the Blood Product Shortage Contingency Plan.</td>
</tr>
<tr>
<td>Yellow</td>
<td>Temporary Shortages</td>
<td>CBC:</td>
</tr>
<tr>
<td></td>
<td>CBC Inventory &lt; 2 days</td>
<td>Send hospital correspondence memo: Notification of Blood Shortage-Status: Yellow to hospital transfusion service managers, medical directors and hospital emergency management directors.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discontinue stocking platelets at hospitals</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manage hospital blood order requests per CBC medical director instructions.</td>
</tr>
<tr>
<td></td>
<td>May apply to one or more blood products and/or one or more blood groups.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>May result from an unexpected decrease in donations (e.g. pandemic flu).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>May result from a large or unexpected need for products due to a local/regional disaster with injuries (e.g. tornado, large explosion).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>May be used as an alert for an anticipated shortage due to local/regional/national disaster.</td>
<td></td>
</tr>
<tr>
<td>Red</td>
<td>Critical Shortages</td>
<td>CBC:</td>
</tr>
<tr>
<td></td>
<td>CBC Inventory ≤ 1 day</td>
<td>Send hospital correspondence memo: Notification of Blood Shortage-Status Red to hospital transfusion service managers, medical directors and hospital emergency management directors.</td>
</tr>
<tr>
<td></td>
<td>Generally applies to all products and all blood types.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Used during severe and prolonged shortages.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Used when a severe threat to the inventory has been identified and is imminent (e.g. pandemic flu).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospital:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Activate emergency blood management plan for status: yellow.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Notify key clinical services and physicians of blood status.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monitor blood ordering and transfusion practice according to defined guidelines.</td>
<td></td>
</tr>
<tr>
<td>Recovery</td>
<td>Inventory levels returning to normal</td>
<td>NOTE: CBC medical director approval required for distribution of blood products to hospitals.</td>
</tr>
<tr>
<td></td>
<td>Threat to inventory levels has been removed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Critical inventory levels expected to gradually increase until normal.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Distribution of blood supply to be strictly managed by CBC until risk of destabilizing recovery is removed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospital:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maintain emergency blood management plan for temporary shortages.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monitor blood ordering and transfusion practice according to defined guidelines.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ALL:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Participate in CBC/hospital evaluation of blood shortage process as requested.</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1. Dayton CBC Blood Shortage/Disaster Plan: Hospital Impact
Note: Taken verbatim from (DCBC, 2000c)
This plan is designed to operate at all times and communicate to the hospitals the center’s current inventory status during shortages with recommended actions for effective mobilization of blood products. The DCBC strives to maintain a three-day inventory supply of all blood products (DCBC, 2000a; DCBC Inventory Senior Staff, 1 March 2013).

The DCBC Impact Status Table schematically differentiates inventory levels into Green, Yellow, Red, and Recovery Alert situations. The Green (Go) Level indicates no inventory shortage exists, therefore, blood center and hospital transfusion services are to follow normal operating procedures for ordering, shipping, receiving, and returning blood products (DCBC, 2000c).

The Yellow (Caution) Level indicates a short-term, temporary, localized inventory of less than or equal to two days of one or more blood products or blood groups. This may result from a sudden large unexpected need for products by a local trauma center treating a mass casualty situation (DCBC, 2000c). The blood products will be consumed immediately in the beginning, causing a temporary shortage in the inventory. But, the inventory is anticipated to recover in approximately two days because the donor population is not expected to be affected by the local incident causing the mass casualty (DCBC Transfusion Services Senior Staff, 12 February 2013; DCBC, 2000c).

The Red (Stop) Level indicates a critical, long-term inventory of less than or equal to one day of all products and blood types. This is used when a severe threat to the inventory has been identified and is imminent, such as during a severe winter blizzard, a tornado, or an outbreak of the pandemic flu. In these cases, the blood center will be shut down with only essential personnel remaining for extremely limited operations. The donors will not have access to the center and the mobile units will be inoperable. In fact, the donors may likely be affected by the
disaster themselves, either ill or stranded in their homes. The blood shortage will be long-term, recovery of the inventory is anticipated to be prolonged, and supplies will need to be purchased and distributed from outside resources. Blood shortage notifications are issued to the local hospitals served by the DCBC when the impact level is Yellow or Red (Dayton CBC Transfusion Services Senior Staff, 12 February 2013; DCBC, 2000c).

The Recovery (Restock) Level indicates the threat to the inventory level has been removed and inventory levels are expected to gradually return to normal status. The DCBC will continue to strictly manage the blood supply until the risk of destabilizing the recovery is eliminated. Hospitals are notified of the Recovery Level once the overall threat is removed. Daily notifications to the hospitals cease when the impact level returns to the Green level (DCBC, 2000c). Figure 2 demonstrates a decision flow-chart used by the DCBC to assist hospitals with implementing this plan (DCBC, 2000b).
After the 9/11 attacks, the US blood center community established the American Association of Blood Banks (AABB) Interorganizational Task Force on Domestic Disasters and Acts of Terrorism. This task force is composed of ABC, the ARC, the Armed Services Blood Program Office, and local community blood centers from around the nation. It seeks to improve community blood center disaster preparedness efforts by sustaining sufficient inventory levels, effectively managing donation rates, and developing efficient communication and transportation routes for emergency blood inventory management (Kuruppu, 2010; AABB, 2008; Erickson et al., 2008).

During any short-term acute increase in demand or a long-term critical supply shortage, the affected blood collection center will assess the local need for blood products and communicate this need to the AABB task force. The task force reviews the situation, convenes with other blood collection centers in the region of the affected center, recalls needed blood product supplies from unaffected centers, and coordinates the quickest form of transportation to deliver the products to the affected blood collection center. The task force continues to interface with the affected center and all unaffected centers in the region and manage the supply shortage as described above, until the crisis has resolved (Kuruppu, 2010; AABB, 2008; Erickson et al., 2008).

Although this system efficiently provides blood components to affected centers, it can potentially leave unaffected regional centers secondarily undersupplied. Local disasters can create a trickle-down effect, where a local supply shortage can deplete the supplies of an entire region and its surrounding areas, and produce further shortages (DCBC Transfusion Services Senior Staff, 12 February 2013; Erickson et al., 2008). Therefore, the focus has now shifted toward maintaining an adequate inventory of blood products at all times through the
development of a strategic reserve blood supply. This reserve would allow blood collection centers to improve inventory management, maintain normal operations, and extend limited supplies and resources during a short-term or long-term blood supply deficit, ultimately improving their emergency preparedness efforts. The key component to this strategy is the development of a reserve of cryo-preserved red blood cells (DCBC Transfusion Services Senior Staff, 12 February 2013; Erickson et al., 2008; Ramsey, 2008; USGAO, 2002).

**Blood Cryopreservation**

Cryopreservation of blood product is defined as the process of freezing a blood product to a very low temperature and storing it at that same temperature to protect the product’s normal biological structure and function, allowing for long-term product storage (Scott, Lecak, & Acker, 2005). Damage during freezing and thawing must be minimized to maintain these desirable qualities. Injuries to RBCs from freezing are reduced with the addition of a chemical cryo-protectant agent, glycerol, during the RBC freezing process. However, post-thaw washing of the RBC’s to reduce the glycerol concentration to one percent is necessary to prevent post-transfusion intravascular hemolysis (Johnson & Swiatkowski, 2007; Valeri & Ragno, 2006; Scott et al., 2005). In 1950, Dr. Audrey Smith of the National Institute for Medical Research demonstrated that human RBC’s could be cryo-preserved with glycerol, thawed, rinsed free of the glycerol, and transfused into recipients with normal survival of the recovered RBCs within the recipient. Since then, more than a hundred facilities in the United States have frozen RBC units, stored these units for several years, and, subsequently shipped these units all over the world to various urban centers and remote rural locations for successful re-infusion into recipients to meet the ever-increasing demand for transfusions. However, this freezing capability
has been primarily restricted to the United States military and large hospitals due to time, labor, and cost concerns (Chaudhari, 2009; Valeri & Ragno, 2006; Hess, 2004).

The development of strategic frozen RBC community reserves has several advantages. Foremost, fresh frozen RBC units can be stored for 10 years (Ramsey, 2008) and, therefore serves as a valuable resource during severe blood shortages. It would eliminate the need for blood rationing and provide a continuous source of blood to support hospital needs without relying on replenishment of blood products from outside regional blood collection centers (Erickson et al., 2008; Bandarenko et al., 2007). Fresh frozen RBC units have an efficient oxygen carrying capacity, are screened for infectious markers in advance of the urgent need for transfusion, and is important during an infectious disease pandemic or bioterrorist attack, when donor suitability and availability are low (Chaudhari, 2009). The strategic frozen RBC reserve would support routine surgical, medical, and emergency procedures in the hospitals and, therefore allow blood collection centers to meet blood product demands, sustain a balanced budget, and maintain a favorable public image due to less wastage of donated blood (Erickson et al., 2008).

However, despite these advantages, there are some disadvantages associated with the freezing of RBCs using a traditional system. Previous cryopreservation systems are open systems. An open system uses a non-sterile technique during the freezing and thawing processes that lowers the threshold for potential bacterial contamination of the final RBC product, thereby limiting the post-thaw shelf-life of this product to only 24 hours (DCBC Transfusion Technician, 7 March 2013; Haemonetics Sales Representative, 25 February 2013). In addition to this short post-thaw shelf-life, the high costs and the labor-intensive, technically demanding nature of the glycerolization and deglycerolization processes deterred many blood centers from developing a
frozen RBC reserve. Cryopreservation had been available for more than 50 years, but the freezing technology was stunted by slow, manual, and open systems (Chaudhari, 2009; Bandarenko et al., 2007; Valeri & Ragno, 2006; Scott et al., 2005).

In 1998, a major scientific advance occurred when Haemonetics Corporation (Braintree, Massachusetts) developed the Haemonetics Automated Cell Processor 215 (the ACP-215). This cost-effective, efficient, closed system processor reduces the risks of bacterial contamination during the glycerolization and deglycerolization processes. So, unlike the 24-hour expiration from thaw to transfusion mandated by the open systems, RBCs processed with the ACP-215 can be stored for up to 14 days post-thaw when resuspended in the appropriate nutrient solution, resulting in an acceptable 24-hour post-transfusion RBC survival in the recipient and no post-transfusion adverse events (Chaudhari, 2009; Bandarenko et al., 2007; Johnson & Swiatkowski, 2007; Valeri & Ragno, 2006; Scott et al., 2005). The FDA granted Haemonetics Corporation clearance in 2001 for the ACP-215 to be used in the transfusion services industry (Ramsey, 2008). Since then, this instrument has been widely used by the United States Department of Defense and several large hospitals within the United States. Its use by the DCBC is now being encouraged through a grant offered by the Greater Dayton Area Hospital Association Emergency Preparedness Committee.

**Methodology**

The primary investigator performed a cost-benefit analysis of implementing the ACP-215 at the not-for-profit DCBC in Ohio to improve its emergency preparedness efforts. A literature search and review was accomplished to gain an understanding of the operability, efficacy, safety, and clinical uses of the ACP-215. The operational advantages and disadvantages of the ACP-215 were studied and documented. The primary investigator conducted interviews with
Haemonetics Corporation personnel, transfusion medicine personnel who use the device, and the DCBC inventory, donor relations, and transfusion safety personnel to gain factual data on the ACP-215 and personal experiences and opinions regarding the processor. All the data from the interviews were collected anonymously with no personally identifiable information documented.

Then, data on all the costs related to the ACP-215, including the costs of purchase, supplies, training, maintenance, and repairs, were collected. The Haemonetics sales staff provided this data upon request by the primary investigator. The DCBC desired to purchase two ACP-215 processors and submitted a proposal to the Greater Dayton Area Hospital Association (GDAHA), requesting grant money to fund the purchase these two processors.

The DCBC anticipated processing 350 RBC units per year by predicting, at most, two shortages annually (summer and winter holiday shortages) in which 150 frozen RBC units are needed per crisis (DCBC Hospital and Laboratory Services Staff Interview, 12 February 2012). Therefore, the annual cost of supplies was calculated to process 350 RBC units per year. The purchase of one operator manual and one service manual was added to the costs of supplies.

Staff training would be conducted by the Haemonetics sales representative and is included with the purchase of the processor. The DCBC currently has one trained medical transfusion technician, who would train the other eight technicians (Haemonetics Sales Representative, 28 February 2013; DCBC Transfusion Technician, 7 March 2013).

For a center having two processors, the “pay as you go” service contract was the most cost-effective plan. The cost of this service contract includes one preventive maintenance service per machine, a service engineer travel cost, and any necessary repairs or emergency issues. In the US, the ACP-215 is currently 98% reliable and the need for emergency repairs is
“rare”, therefore the cost of repairs was not included in this cost analysis (Haemonetics Sales Representative, 28 February 2013).

The cost of purchasing two processors, maintaining supplies to process 350 units of RBCs per year, training nine transfusion technicians, and administering one annual preventive service per machine was summed to determine the total cost for ACP-215 implementation. The cost of the two processors was then subtracted from this total as grant money would be used in this acquisition. The result was the initial start-up cost to the DCBC to implement the ACP-215. Then, the one-time purchase of the two ACP-215 manuals was subtracted from the initial start-up cost as the two manuals were not considered recurring annual costs. The result was the recurring annual cost to the DCBC to implement the ACP-215.

Then, the DCBC’s annual import budget and expense reports from 2007 to 2012 were collected. The DCBC’s Inventory Senior Staff provided this data upon request by the primary investigator. An import is defined as the purchase of a blood product from an outside source when the blood center’s inventory of that particular product is unable to meet the demand from the community (DCBC Inventory Senior Staff, 1 March 2013). The annual import budget was compared to the annual import expenses for each year from 2007 to 2012.

The estimated cost of annual import expenses expected with the addition of a strategic frozen RBC reserve at the DCBC was calculated for 2007 to 2012. This estimated cost was compared to the actual annual import expenses without the strategic frozen RBC reserve for 2007 to 2012. Then, the difference between the actual annual import expenses and the estimated annual import expenses was calculated. The result was the cost-savings afforded to the DCBC if they had implemented the ACP-215 to establish a strategic frozen RBC reserve.
The primary investigator determined that implementation of the ACP-215 would benefit the DCBC from an advantage-disadvantage and cost-savings perspective if the advantages double the disadvantages and the comparison of annual import costs with and without ACP-215 implementation results in an annual cost-savings. This methodology was approved by the IRB as exempt (Appendix A).

Results

Logistics, Benefits and Limitations

The Haemonetics Corporation (Braintree, MA) developed the ACP-215 device in 1998. This automated, functionally closed medical device performs the entire freeze-thaw-wash process in 3 steps: glycerolization, deglycerolization, and resuspension in additive solution. Via the ACP-215 instrument, one liquid RBC unit is steriley attached to a disposable glycerolization kit to add glycerol to the liquid RBC unit. The glycerolized RBC concentrate and its container are wrapped up in a plastic bag, placed within a rigid cardboard box, and stored in a mechanical freezer set at -80 degrees Celsius to freeze the glycerolized RBC unit. Glycerol is a cryo-protectant agent that minimizes ice crystal formation and, consequently prevents RBC membrane damage during freezing (DCBC Transfusion Technician, 7 March 2013). The blood center then stores these frozen glycerolized RBC units for a 10-year storage limit (Peyrard, Pham, Le Pennec, & Rouger, 2009).

When a frozen RBC unit is needed, the rigid cardboard box containing the frozen glycerolized RBC unit is removed from the storage freezer. The glycerolized RBC and its container are removed from the cardboard box, unwrapped from the plastic bag, and placed into a thawing bath maintained at 36 degrees Celsius for 40 minutes, to achieve a surface temperature of 34 degrees Celsius, monitored by an infra-red scanner. The thawed glycerolized RBC
concentrate is then steriley attached to a disposable deglycerolization kit via the ACP-215 instrument to remove the previously added glycerol from the RBC concentrate (DCBC Transfusion Technician, 7 March 2013).

After washing, the RBCs are resuspended in an additive solution (AS), referred to as AS-3. The AS-3 solution contains glucose, adenine, and phosphate to provide nourishment for the RBCs during storage. Deglycerolized RBCs processed in the Haemonetics ACP-215 can be stored in the AS-3 for up to 14 days at four degrees Celsius and maintain less than one percent hemolysis during storage (DCBC Transfusion Technician, 7 March 2013). Current regulations require that thawed deglycerolized RBCs have a post-thaw recovery of at least 80% and a hemolysis rate below one percent (Henkelman et al., 2010).

The ACP-215 provides numerous advantages in the development of a strategic frozen RBC supply. It extends post-thaw liquid RBC unit storage from 24 hours to 14 days. The ACP-215 is an automated, standardized, and closed system that performs the glycerolization and deglycerolization processes in a sterile environment. Subsequently, this system minimizes the risk of bacterial contamination of the RBC units and lengthens their post-thaw shelf-life to 14 days (Haemonetics Sales Representative, 25 February 2013; Henkelman, Lagerberg, Graaff, Rakhorst, & Van Oeveren, 2010; Bandarenko et al., 2007; Grabmer et al., 2006)

The ACP-215 maintains acceptable RBC quality after processing and storage of the RBC units in the AS-3 nutrient solution for up to 14 days. Studies demonstrate satisfactory viability and function of the thawed deglycerolized RBC units processed with the ACP-215. Post-thawed RBCs had normal morphology and normal oxygen transport functions with an acceptable freeze-thaw-wash recovery of approximately of greater than 80%, maintenance of aggregability and deformity allowing for the easy passage of RBCs through the vascular system, and a mean
hemolysis rate of less than one percent after storage in the AS-3 for 14 days (Haemonetics Sales Representative, 25 February 2013; Henkelman et al., 2010; Chaudhari, 2009; Peyrard et al., 2009; Bandarenko et al., 2007).

The ACP-215 cell processor has been continuously licensed by the FDA since 2001. The washing of thawed RBCs eliminates most cell debris, white blood cells, platelets, residual plasma, and other potential allergens, thereby reducing the occurrence of potential post-transfusion reactions. Furthermore, the extended 14-day post-thaw storage period allows more time for pre-transfusion safety testing (Haemonetics Sales Representative, 25 February 2013; Peyrard et al., 2009; Erickson et al., 2008; Scott et al., 2005).

This device is 50% more efficient compared to other non-automated, manually operated processors. The total freeze-thaw-wash process using the ACP-215 technology requires 2 hours. It glycerolizes 3 liquid RBC units in 1 hour and deglycerolizes 1 thawed RBC unit in 1 hour. However, deglycerolization requires only 15 minutes of the operator’s time, allowing the operator to accomplish other tasks during the remaining 45 minutes. Therefore, the total time to process 3 RBC units for freezing and 1 RBC unit for transfusion, using the ACP-215, is 75 minutes per operator, down 50% from the 150 minutes total time using the typical manually operated machines to process the same amount of product (Haemonetics Sales Representative, 25 February 2013).

The ACP-215 cell processor permits a blood product supplier to have a well-managed inventory of blood products. With the reduction in the donor population due to various reasons previously described and the extended 14-day post-thaw shelf-life of the RBC products, the strategic frozen RBC supply can be used to supplement the liquid RBC reserve, maximize inventory flexibility, and reduce expensive wastage. Suppliers will ultimately have an increased
control of the supply to meet the demand of RBC products under most circumstances (Haemonetics Sales Representative, 25 February 2013; Erickson et al., 2008; Valeri & Ragno, 2006). The ACP-215 offers many benefits in the development of the strategic blood supply. However, there are disadvantages to consider.

Staffing by trained technicians during an emergency is essential for successful implementation of the ACP-215. Unfortunately, many emergency or disaster situations that affect the blood supply can also affect staffing levels, such as inclement weather, transportation problems, or an infectious disease pandemic. Trained staffing must be adequate to deploy the strategic frozen blood supply, in addition to maintaining normal operations (Erickson et al., 2008). This will increase the workload on certain departments within the blood center, particularly the donor relations, blood components, and inventory departments. Donor relations will need to recruit more donors to replenish both the strategic frozen and liquid RBC supplies. The components department will need to work longer shifts to thaw the needed RBC units from the frozen reserve and then freeze more RBC units to replenish those used from this reserve. And, the increased inventory oversight and periodic refreshing of frozen units to prevent wastage of outdated products (at 10 years) increases the inventory department’s responsibilities (DCBC Donor Relations Senior Staff, 12 February 2013; DCBC Inventory Senior Staff, 1 March 2013).

Each ACP-215 operator must have initial and annual training on how to freeze liquid RBC’s for storage and select, thaw, and process frozen RBC units for transfusion. Supervisors must continuously monitor and periodically evaluate the operators for competency in these skills. Insufficient training in these areas weakens the effectiveness of the strategic frozen RBC reserve (Haemonetics Sales Representative, 25 February 2013; Erickson et al., 2008).
Adequate storage of equipment, supplies, and products is a crucial component of the frozen RBC reserve. An isolated, easily accessible countertop space is required on which to place the ACP-215 device. Several large shelves and cupboards, nearby the device, are needed for the storage of multiple supplies. The maintenance of a large number of frozen RBC units requires an operable and spacious -65 degrees Celsius or colder freezer unit. And, optimal deployment of the strategic frozen RBC reserve necessitates reliable electricity with appropriate back-up generator support if needed (DCBC Transfusion Technician, 7 March 2013; Erickson et al., 2008).

Development of a strategic, frozen community blood supply and its appropriate implementation requires close communication between the blood center senior staff and its employees, state and federal agencies, local law enforcement, public utilities, hospital clinicians, and donors. During critical blood product shortages, the senior staff must decide when to begin thawing procedures and assign employees to that task. It must assess the ongoing situation and communicate it to the state and federal emergency offices that provide additional assistance, local law enforcement agencies that assist with transport of blood supplies, public utilities that resume various essential services if they are non-functional, hospital clinicians who rely upon the blood supply to provide services to their patients, and the donors who provide needed blood donations. Many unforeseeable events to include loss of electricity, loss of communication channels, simultaneous mass casualties requiring immediate access to liquid blood, or destruction of the blood collection center itself can complicate this communication issue even further (DCBC Transfusion Services Senior Staff, 12 February 2013; Erickson et al., 2008). In addition to these operational advantages and disadvantages, the DCBC must also consider the
total costs involved with utilization the ACP-215 in the development of the strategic frozen RBC reserve.

Cost Comparison

Table 1 demonstrates the total annual costs incurred by the DCBC to implement the ACP-215 cell processor in development of a strategic frozen RBC reserve.

<table>
<thead>
<tr>
<th>Item</th>
<th>Price per Unit</th>
<th>Number of Units</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACP-215</td>
<td>$57,432.00</td>
<td>2</td>
<td>$114,864.00</td>
</tr>
<tr>
<td>Glycerolization Kit</td>
<td>$842.50</td>
<td>7</td>
<td>$5,897.50</td>
</tr>
<tr>
<td>De-Glycerolization Kit</td>
<td>$1,428.80</td>
<td>18</td>
<td>$25,718.40</td>
</tr>
<tr>
<td>AS3</td>
<td>$186.50</td>
<td>14</td>
<td>$2,611.00</td>
</tr>
<tr>
<td>ACP-215 Operator Manual</td>
<td>$600.00</td>
<td>1</td>
<td>$600.00</td>
</tr>
<tr>
<td>ACP-215 Service Manual</td>
<td>$600.00</td>
<td>1</td>
<td>$600.00</td>
</tr>
<tr>
<td>Staff Training</td>
<td>-</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>Service Contract</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preventive Maintenance</td>
<td>$500.00</td>
<td>2</td>
<td>$1,000.00</td>
</tr>
<tr>
<td>Service Engineer Travel Cost</td>
<td>$2,160.00</td>
<td>1</td>
<td>$2,160.00</td>
</tr>
<tr>
<td>TOTAL</td>
<td>$61,089.80</td>
<td></td>
<td>$153,450.90</td>
</tr>
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</table>

Subtract cost of ACP-215 (given as grant money) $114,864.00

Initial start-up cost for blood center $38,586.90

Subtract cost of (2) ACP-215 manuals $1,200.00

Recurring annual cost for blood center $37,386.90

The first item on this table shows the total cost of two ACP-215 devices. This purchase would be covered with the grant money given to the DCBC by the GDAHA, and therefore poses no direct cost to the center itself (DCBC Transfusion Services Senior Staff, 12 February 2013; DCBC Hospital and Laboratory Services Senior Staff, 13 March 2013).

The total supply cost was calculated based on an estimation of processing 350 RBC units per year. The supplies include the glycerolization kit, the deglycerolization kit, the AS3 resuspension nutrient solution, one ACP-215 Operator manual, and one ACP-215 Service
The two manuals represent a one-time purchase only and were not considered annual recurring costs (Haemonetics Sales Representative, 28 February 2013).

Staff training would be free with the purchase of the ACP-215. One lead technician, trained by the Haemonetics sales representative, would continue to train the other eight DCBC transfusion technicians. Thus, training poses no cost to the DCBC (DCBC Hospital and Laboratory Services Senior Staff, 13 March 2013, Haemonetics Sales Representative, 28 February 2013).

The ACP-215 requires one preventive maintenance visit per year. Routine maintenance would be done by the DCBC staff on a daily or monthly basis at no additional cost to the center. The one annual preventive maintenance visit would be the only service requiring a Haemonetics service engineer to travel to the center. The final cost analysis concluded that the initial start-up cost to the DCBC for ACP-215 implementation was calculated to be $38,586.90 and the subsequent annual recurring cost would be $37,386.90.

Figure 3 demonstrates the DCBC’s annual import budget and expenditures from 2007 through 2012. The DCBC’s import budget is designated for the purchase of imports only. It has a separate budget designated for the purchase of supplies and another for the purchase and maintenance of equipment. The import expenditures involve the purchase of RBC, platelet, and plasma products only. These expenditures exceeded the import budget every year from 2007 to 2012 (DCBC Inventory Senior Staff, 1 March 2013).
Figure 4 compares the annual costs between import expenditures with and without implementation of the ACP-215 from 2007 through 2012. The import expenditures without the ACP-215 include RBC, platelet, and plasma product purchases. The import expenditures with the ACP-215 would include platelet and plasma product purchases only. It would exclude the purchase of RBC product imports because, theoretically, the DBCB would have used it frozen RBC reserve to cover the shortage in its liquid RBC inventory. The cost of imports without the ACP-215 each year between 2007 and 2012 either exceeded or equaled the estimated cost of imports expected with the addition of the ACP-215 implementation. In 2010 and 2011, the DCBC purchased only platelet and plasma product imports. No RBC product imports were purchased during those 2 years (DCBC Inventory Senior Staff, 1 March 2013).
Figure 5 demonstrates the final cost-savings to the DCBC if it had implemented the ACP-215 from 2007 through 2012.

The cost-savings is either a significantly positive number or zero from 2007 to 2012, with an average cost-savings of $249,000 over those 5 years. The cost-savings would be zero in 2010.
and 2011 because the blood center purchased only platelet and plasma product imports. No RBC product imports were purchased during those 2 years (DCBC Inventory Senior Staff, 1 March 2013).

**Discussion**

The ACP-215 device would be a valuable resource for the DCBC in its efforts to develop a strategic frozen RBC reserve to be used during a crisis when critical long-term blood product shortages are in effect. As Figure 3 summarizes, the ACP-215 is a safe, efficient, and effective device that allows for long-term storage of frozen RBC units of up to 10-years, extends the post-thaw shelf-life up to 14 days, and meets required post-storage RBC standards for quality and function (Henkelman et al., 2010; Peyrard et al., 2009; Bandarenko et al., 2007). In terms of emergency preparedness efforts, these advantages offered by the ACP-215 are “huge for the Dayton Community Blood Center” (DCBC Transfusion Services Senior Staff, 12 February 2013).

The ACP-215 does present unique challenges or disadvantages, most notably with staffing, training, storage capacity, and communications. The DCBC has developed several written disaster plans and a freezing schedule to address these issues. During a trauma case, types O positive and O negative blood get hit the hardest because they are the universal donors and the DCBC’s scarcest products. Therefore, the CBC plans to build the frozen reserve with O positive and O negative RBC units first. After this reserve is established, the CBC could freeze some type A and B units, but the type O products are the most important to have in the reserve stockpile. The DCBC would build up its strategic supply during times of heavy donations, freezing 10-20 units a week, depending upon availability of the blood, until the reserve was complete. The selected freezer would hold up to 350 RBC units (DCBC Donor Relations Senior
Ideally, a strategic supply is reserved for use only during an emergency, when the donors are also affected by the particular crisis. But, the reserve units could be used during the lean months if necessary (DCBC Transfusion Services Senior Staff, 12 February 2013). For example, in December 2012, there were five to six days of almost no blood collections due to a blizzard that hit the Dayton area, as well as an increase in flu incidence among the elderly. The DCBC was unable to sustain its supply to meet the demands from the community and, therefore had to rely on imports. This cost the center $28,250 in RBC and platelet product imports. The center could have saved at least $23,500 if a frozen RBC reserve was stockpiled using the ACP-215 device (DCBC Donor Relations Senior Staff, 12 February 2013; DCBC Inventory Senior Staff, 1 March 2013).

Figure 5 demonstrates that the DCBC would gain significant savings with implementation of the ACP-215 to establish a strategic frozen RBC reserve, theoretically recovering an average of $249,000 over 2007 to 2012. A strategic frozen blood supply results in better inventory management during longer periods of critical shortages by freeing up more resources. For example, if there is a shortage of platelets, the center can use the frozen RBC reserve to supplement the liquid RBC reserve and redirect its focus on donor platelet collections, as platelets have only a 5-day post-collection shelf-life and cannot be frozen (DCBC Transfusion Services Senior Staff, 12 February 2013). In 2010 and 2011, the CBC imported only platelet and plasma products. No RBC product imports were purchased, resulting in no theoretical cost-savings per Figure 5. However, if a frozen RBC stockpile was in place, the center could have
used this reserve to supplement the liquid RBC inventory and could have redirected its resources to increasing platelet and plasma collections, avoiding import purchases.

This case study presents some limitations. It is difficult to estimate when a crisis or critical shortage will occur and how many frozen RBC units will need to be thawed in response to a particular crisis. This cost-analysis used the figure of processing 350 RBC units per year by predicting, at most, 2 shortages per year (summer and winter holiday shortages) in which 150 frozen RBC units are needed per crisis (this is the amount that was needed during the blizzard of December 2012). And, only one RBC unit can be thawed in one hour using the ACP-215. With two ACP-215 devices and one eight hour shift per technician, approximately 16 units per technician can be thawed in one hour. Sixteen RBC units per hour may not be sufficient to deal with a particular emergency or critical RBC shortage. Once the DCBC has developed its frozen reserve and begins to utilize it in times of shortages, more specific figures can be used to reflect more accurate calculations.

It is also difficult to estimate the cost of emergency calls to repair the ACP-215. The repair could be a minor problem or a major problem. The average cost per emergency service call from the last 12 months in North America is $657 per call. This is the cost of parts only and does not include the engineer travel cost if an engineer should be needed by the center. However, the ACP-215 does not fail often. Over the last 12 months globally, the failure rate has been one failure per 700 procedures done. With a 98% reliable rating, the need for repairs to the instrument is extremely rare (Haemonetics Sales Representative, 28 February 2013). Further research into all of these areas is needed.
Conclusion

Blood is a costly and scarce resource, not to be used irresponsibly or wasted. As the number of blood donations decline and transfusion needs rise, critical shortages of blood products will continue, especially during the summer and winter holidays and potential emergencies. Effective strategies are needed to maintain a blood product supply that will meet the demands under any circumstances. The establishment of a strategic frozen RBC reserve is one strategy that effectively manages blood usage and minimizes waste (McCarthy, 2007; Shander et al, 2007). Overall, the benefits of the Dayton CBC implementing the ACP-215 device to establish its strategic frozen RBC reserve and improve its emergency preparedness efforts outweigh the disadvantages and costs, particularly where seasonal shortages, weather conditions, and a decreasing donor population chronically threaten the community’s blood supply.
References


Dayton Community Blood Center [DCBD] Donor Relations Senior Staff Interview (12 February 2013).

Dayton Community Blood Center [DCBD] Hospital and Laboratory Services Senior Staff Interview (13 March 2013).
Dayton Community Blood Center [DCBD] Inventory Senior Staff Interview (1 March 2013).
Dayton Community Blood Center [DCBD] Transfusion Services Senior Staff Interview (12 February 2013).
Dayton Community Blood Center [DCBD] Transfusion Technician Interview (7 March 2013).
Haemonetics Sales Representative Interview (25 February 2013).
Haemonetics Sales Representative Interview (28 February 2013).


DATE:   April 11, 2013

TO:     Angela M. Albrecht, Grad. Student
        Public Health
        Mark E. Gebhart, MD, Fac. Adv.
        Community Health

FROM:   B. Laurel Elder, Chair
        WSU Institutional Review Board

SUBJECT: SC# 5146
         'A Case Study: The Feasibility of Implementing the ACP-215 at the Dayton Community'

At the recommendation of the IRB Chair, your study referenced above has been recommended for exemption. Please note that any change in the protocol must be approved by the IRB; otherwise approval is terminated.

This action will be referred to the Full Institutional Review Board for ratification at their next scheduled meeting.

NOTE: This approval will automatically terminate two (2) years after the above date unless you submit a “continuing review” request (see http://www.wright.edu/rsp/IRB/CR_se.doc) to RSP. You will not receive a notice from the IRB Office.

If you have any questions or require additional information, please call Robyn Wilks, IRB Coordinator at 775-4462.

Thank you!

Enclosure
RESEARCH INVOLVING HUMAN SUBJECTS

ACTION OF THE WRIGHT STATE UNIVERSITY
EXPEDITED REVIEW
Assurance Number: FWA0002427

Title: 'A Case Study: The Feasibility of Implementing the ACP-215 at the Dayton Community'

Principal Investigator: Angela M. Albrecht, Grad. Student
Public Health
Mark E. Gebhart, MD, Fac. Adv.
Community Health

The Institutional Review Board Chair has approved an exemption with regard to the use of human subjects on this proposed project.

REMINDER: Federal regulations require prompt reporting to the IRB of any changes in research activity [changes in approved research during the approval period may not be initiated without IRB review (submission of an amendment), except where necessary to eliminate apparent immediate hazards to subjects] and prompt reporting of any serious or on-going problems, including unanticipated adverse reactions to biologicals, drugs, radioisotope labeled drugs or medical devices.

Signed Chair, WSU-IRB
Approval Date: April 11, 2013
IRB Mtg. Date: May 20, 2013
## Domain #1: Analytic/Assessment
- Identify the health status of populations and their related determinants of health and illness (e.g., factors contributing to health promotion and disease prevention, the quality, availability and use of health services)
- Describe the characteristics of a population-based health problem (e.g., equity, social determinants, environment)
- Use variables that measure public health conditions
- Use methods and instruments for collecting valid and reliable quantitative and qualitative data
- Identify sources of public health data and information
- Recognize the integrity and comparability of data
- Identify gaps in data sources
- Adhere to ethical principles in the collection, maintenance, use, and dissemination of data and information
- Describe the public health applications of quantitative and qualitative data
- Collect quantitative and qualitative community data (e.g., risks and benefits to the community, health and resource needs)
- Use information technology to collect, store, and retrieve data
- Describe how data are used to address scientific, political, ethical, and social public health issues

## Domain #2: Policy Development and Program Planning
- Gather information relevant to specific public health policy issues
- Describe how policy options can influence public health programs
- Explain the expected outcomes of policy options (e.g., health, fiscal, administrative, legal, ethical, social, political)
- Gather information that will inform policy decisions (e.g., health, fiscal, administrative, legal, ethical, social, political)
- Participate in program planning processes
- Incorporate policies and procedures into program plans and structures
- Apply strategies for continuous quality improvement

## Domain #3: Communication
- Communicate in writing and orally, in person, and through electronic means, with linguistic and cultural proficiency
- Solicit community-based input from individuals and organizations
- Participate in the development of demographic, statistical, programmatic and scientific presentations
- Apply communication and group dynamic strategies (e.g., principled negotiation, conflict resolution, active listening, risk communication) in interactions with individuals and groups

## Domain #4: Cultural Competency
- Incorporate strategies for interacting with persons from diverse backgrounds (e.g., cultural, socioeconomic, educational, racial, gender, age, ethnic, sexual orientation, professional, religious affiliation, mental and physical capabilities)
- Recognize the role of cultural, social, and behavioral factors in the accessibility, availability, acceptability and delivery of public health services
- Respond to diverse needs that are the result of cultural differences

## Domain #5: Community Dimensions of Practice
- Recognize community linkages and relationships among multiple factors (or determinants) affecting health (e.g., The Socio-Ecological Model)
- Demonstrate the capacity to work in community-based participatory research efforts
- Identify stakeholders
- Collaborate with community partners to promote the health of the population
- Maintain partnerships with key stakeholders
- Use group processes to advance community involvement
- Describe the role of governmental and non-governmental organizations in the delivery of community health services
<table>
<thead>
<tr>
<th>Domain #5: Community Dimensions of Practice (Cont’d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify community assets and resources</td>
</tr>
<tr>
<td>Gather input from the community to inform the development of public health policy and programs</td>
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<tr>
<td>Inform the public about policies, programs, and resources</td>
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<thead>
<tr>
<th>Domain #6: Public Health Sciences</th>
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<tbody>
<tr>
<td>Describe the scientific foundation of the field of public health</td>
</tr>
<tr>
<td>Identify prominent events in the history of the public health profession</td>
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<tr>
<td>Relate public health science skills to the Core Public Health Functions and Ten Essential Services of Public Health</td>
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<tr>
<td>Identify the basic public health sciences (including, but not limited to biostatistics, epidemiology, environmental health sciences, health services administration, and social and behavioral health sciences)</td>
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<tr>
<td>Describe the scientific evidence related to a public health issue, concern, or, intervention</td>
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<tr>
<td>Retrieve scientific evidence from a variety of text and electronic sources</td>
</tr>
<tr>
<td>Discuss the limitations of research findings (e.g., limitations of data sources, importance of observations and interrelationships)</td>
</tr>
<tr>
<td>Describe the laws, regulations, policies and procedures for the ethical conduct of research (e.g., patient confidentiality, human subject processes)</td>
</tr>
<tr>
<td>Partner with other public health professionals in building the scientific base of public health</td>
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</tbody>
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<tr>
<th>Domain #7: Financial Planning and Management</th>
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<tbody>
<tr>
<td>Describe the local, state, and federal public health and health care systems</td>
</tr>
<tr>
<td>Describe the organizational structures, functions, and authorities of local, state, and federal public health agencies</td>
</tr>
<tr>
<td>Adhere to the organization’s policies and procedures</td>
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<tr>
<td>Participate in the development of a programmatic budget</td>
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<tr>
<td>Operate programs within current and forecasted budget constraints</td>
</tr>
<tr>
<td>Identify strategies for determining budget priorities based on federal, state, and local financial contributions</td>
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<tr>
<td>Report program performance</td>
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<tr>
<td>Translate evaluation report information into program performance improvement action steps</td>
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<tr>
<td>Contribute to the preparation of proposals for funding from external sources</td>
</tr>
<tr>
<td>Apply basic human relations skills to internal collaborations, motivation of colleagues, and resolution of conflicts</td>
</tr>
<tr>
<td>Demonstrate public health informatics skills to improve program and business operations (e.g., performance management and improvement)</td>
</tr>
<tr>
<td>Participate in the development of contracts and other agreements for the provision of services</td>
</tr>
<tr>
<td>Describe how cost-effectiveness, cost-benefit, and cost-utility analyses affect programmatic prioritization and decision making</td>
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</tbody>
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<tr>
<th>Domain #8: Leadership and Systems Thinking</th>
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<tbody>
<tr>
<td>Incorporate ethical standards of practice as the basis of all interactions with organizations, communities, and individuals</td>
</tr>
<tr>
<td>Describe how public health operates within a larger system</td>
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<tr>
<td>Participate with stakeholders in identifying key public health values and a shared public health vision as guiding principles for community action</td>
</tr>
<tr>
<td>Identify internal and external problems that may affect the delivery of Essential Public Health Services</td>
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<tr>
<td>Use individual, team and organizational learning opportunities for personal and professional development</td>
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<tr>
<td>Participate in mentoring and peer review or coaching opportunities</td>
</tr>
<tr>
<td>Participate in the measuring, reporting and continuous improvement of organizational performance</td>
</tr>
<tr>
<td>Describe the impact of changes in the public health system, and larger social, political, economic environment on organizational practices</td>
</tr>
</tbody>
</table>