Optimization of Adult Learner Experiences by Clinical Research Preceptors via Application of Andragogical Principles

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ABSTRACT

Utilization of andragogical (adult learning) principles by preceptors employed in various clinical research settings in a post baccalaureate Clinical Research Associate Training Program (CRATP) for minority registered nurses enhanced the overall learning process. Clinical assignments — hands-on tasks and experiential learning — served as the clinical learning platform that enabled students to achieve high-quality learning outcomes and contributed to the overall success of the CRATP. Understanding and applying adult learning principles to enhance the preceptor/student relationship is imperative to achieve optimal student learning outcomes. Students, preceptors, and the training agencies cumulatively proved that the application of andragogical principles to the development and implementation of clinical assignments optimized the clinical experience of adult learners.
INTRODUCTION

The lack of diversity of subjects enrolled in clinical trials is at an all-time high. It is evident that there is a need to train a more diverse group of clinical research professionals to improve the diversity of subjects volunteering for clinical trials [1]. To help meet the increasing demand for clinical research nursing professionals with minority ethnicity in the job marketplace, the Dillard University Minority Health and Health Disparities Research Center offered a 1-year Clinical Research Associate Training Program (CRATP) in New Orleans, Louisiana. The CRATP (Figure 1) provides students with 96 hours of hands-on practical experience through the completion of a series of clinical assignments at approved regional clinical research facilities after they successfully complete 45 hours of didactics in a classroom setting [2].

Each adult student enrolled in the CRATP must self-identify as a minority candidate, have a baccalaureate degree in nursing, possess an active unencumbered registered nurse license, and have the motivation to learn the components of the role of the clinical research coordinator/associate in clinical trials (Table 1). The long-term strategic objective of the CRATP is to increase the number of clinical research professionals with minority backgrounds in Louisiana who can ultimately increase the accrual of minority subjects in clinical trials.

The CRATP was developed in accordance with adult learning principles. Students engaged in 11 didactic learning modules and 9 clinical assignments to enhance clinical experiences. Oversight for clinical assignments was provided by well-qualified preceptors.

Andragogical Approach

Unlike pedagogy, andragogy is the science and art of helping adult students learn [3]. Whereas child learners are motivated by external pressures such as competition for grades and
consequences for failure, adult learners are internally motivated for self-esteem, recognition, richer quality of life, self-confidence, and self-actualization [4]. Because of these motivations, adult learners cultivate knowledge differently than children. Therefore, an innovative approach had to be employed for adult learners enrolled in the CRATP. The CRATP practicum requires students to successfully complete 9 clinical assignments designed to develop foundational knowledge. These clinical assignments, initially developed by the CRATP coordinator and further enhanced by the CRATP preceptors, incorporate both andragogical principles and the nursing process to assist students’ matriculation through the clinical experience. Knowles proposed that learning is continuous and occurs across the life span. He further suggests that when an individual achieves a self-concept of self-direction, he psychologically begins to think as an adult [3].

**Characteristics of an Adult Learner**

Knowles et al [5] identified 6 characteristics associated with the adult learner. They are:

1) **Basic desire**: Learner’s need to know the why, what, and who

2) **Self-concept**: Self-directing that allows adults to enhance their ability to transfer experience to the task at hand

3) **Prior knowledge**: Bringing prior experience to the learning environment

4) **Readiness to learn**: Life experiences and developmental tasks

5) **Orientation to learn**: Problem centered

6) **Motivation to learn**: Internal motivation and drive

This internal motivation allows the adult to become involved in the task (task orientation) and thus complete the task at hand (self-reflection). Together, these concepts allow the CRATP student to develop the required skill set for performing the duties of the clinical research associate in a clinical setting.
Role of Clinical Preceptors

Preceptors are used extensively in the healthcare arena to assist in bridging theory to practice through hands-on clinical experience. Preceptors are professionals who provide students the opportunity to participate in reality-based experiences while under their watch. In 2010, the Patient Protection and Affordable Care Act [6] and the Institute of Medicine 2011 report *The Future of Nursing* [7] identified the need for additional advanced practitioners. Additional advanced preceptors are also needed for clinical research practicums.

The CRATP clinical preceptors have a complex intertwined role (Table 2). After orienting students to the clinical facility, the preceptors assume the roles of teacher, mentor, and role model [8-11].

Based on their expertise, diverse experience, and proven success in the clinical trials/research industry, the preceptors were regionally appointed to facilitate clinical assignments at their workplace. Clinical sites included hospitals, hospital-based Clinical Research Units, primary care facilities, and institutional review boards to ensure that students received diverse clinical experiences. Because the clinical assignments were conducted at the clinical preceptors’ workplaces, students had access to real-world experience and necessary resources. The preceptor received a copy of the clinical assignment in advance from the CRATP Program Coordinator with the name of the student and the date and time the student would arrive at the clinical facility.

CONCEPTUAL FRAMEWORK

As previously stated, the nursing process and andragogical principles of adult learning guided the development of the clinical assignments that created a cyclic continuum designed to close the gap between didactic learning and applied skill. The nursing process (Figure 2) consists of five sequential and interrelated constructs: assessment, diagnosis, planning, intervention, and
evaluation. The process continues until the goal is successfully achieved [12]. The learner must be able to use assessment skills to develop the correct plan for the person or situation. The application of the nursing process to the clinical assignments of the CRATP is intended to develop the learner’s skill in outlining subjective and objective data and following specific guidelines to manage a situation within set parameters.

The post baccalaureate nurse is an active participant in the learning process. Each nurse brings critical thinking skills, communication, and assessment techniques along with a number of management skills to the practicum of the clinical assignments. The structured combination of clinical assignments with the oversight of a designated clinical preceptor moves the adult student from a prescribed and simple learning environment to a more challenging and complex learning environment. The preceptor assists students individually after assessing their existing skill set and the expectations for accomplishing the activity for the day as they become more proficient in their roles [3].

The clinical assignments were thoughtfully constructed and logically optimized by juxtaposing the sequential 3-step andragogical learning process with the sequential 5-step nursing process as shown in CRATP Clinical Assignment #2 (Table 3).

Self-evaluation, hands-on practicum, and self-reflection are the three andragogical principles of adult learning that were applied to the development of clinical assignments (Figure 3). The first stage of learning (student activities 1, 2, 3) guided students to initiate their learning through self-evaluation of their current knowledge and by performing independent research on the assigned subject matter so they were prepared for the clinical assignment at the preceptor’s research facility. During the second stage of learning (student activities 4, 5, 6), students participated in practical hands-on learning for knowledge advancement at an assigned research
facility under the direction of a practicing preceptor. In the final stage (student activities 7 and 8),
the students were given the opportunity to self-reflect and compile the knowledge gained during
the process through formative and summative evaluations.

RESULTS

The Clinical Preceptor Survey (Table 4) is a 10-item Likert-type survey developed and
reviewed by the 3 authors and reviewed for content by 2 clinical preceptors. The survey
measured the need for clinical research associates, integration of the nursing process, satisfaction
of the students, and the role of the clinical preceptor. Nine of 11 respondents (81.8%) were
registered nurses and all agreed that the nursing process was evident in the clinical assignments.
About 89% concurred that the clinical assignments provided satisfactory hands-on clinical
practicum experiences for the student. Again, 9 of the 11 (81.8%) respondents for questions 9
and 10 rated the role and expectations of the clinical preceptor as “clear”.

Since the development of clinical assignments in fall 2010, 40 students have enrolled in 6
cohorts. A total of 32 students have successfully completed the goals and objectives of the
program. Via semi-structured student exit surveys (Table 5), 96% of students made positive
comments about the importance of the clinical assignments. Themes from their responses include
1) acceptable program rigor, 2) exceeding the expectations of the course, 3) feeling of
accomplishment, and 4) degree of usability of content.

Additionally, 6.25% of the matriculated students have received national certification
through The Society of Clinical Research Associates (SOCRA) and elsewhere, while 10% are
preparing to take the examination in fall 2015. Currently, 15.63% are employed as clinical
research coordinators, while others work in a variety of settings where knowledge regarding
clinical trials/research is required and utilized.
DISCUSSION

The integration of adult learning principles and the nursing process proved to be beneficial in the development of clinical assignments by providing strategies that assisted students and preceptors in the successful completion of the clinical assignments. Collaboration among preceptors, faculty, and students is an essential component of the success of hands-on clinical experiences that incorporate current evidence-based literature in adult education, adult learning principles, roles of the preceptor, and the fundamental nursing process. The findings of this study indicated that the support provided for the students by the CRATP was adequate for the student to meet their academic needs.

Weisman described 4 essential components of the clinical preceptor [11]. These 4 crucial factors are identified below with an explanation of how they were applied in the CRATP.

1) Workplace support of the preceptor. The CRATP Program Coordinator was responsible for achieving this balance. During the course of the program, a meeting was conducted every 2 years with preceptors and their supervisors to discuss pros and cons, as well as to gather suggestions for ensuring a learning environment where one-on-one instruction could be conducted and strategies were in place to support a positive learning experience even when the worksite demand was perceived as too busy. Evaluations of the clinical site by the student and clinical preceptor, as well as the clinical preceptor’s evaluations of the student and the CRATP, were also valuable in assessing the need for change and facilitating change.

2) Acknowledgements through rewards and incentives. Preceptors were acknowledged and rewarded through letters to their supervisors, inclusion of the
preceptors and/or their organizations on poster presentations or manuscripts, and award presentations at each cohort’s closing ceremony in the “Preceptor of the Year” and “Best Clinical Site” categories.

3) **Positive relationships with the institutional faculty.** To maintain positive relationships with preceptors, Dillard University conducted the following activities: a) meetings every other year, b) clinical preceptor surveys, c) clinical preceptor evaluations, d) acceptance of input for enhancing the clinical assignments, and e) a minimum of 2 visits to the clinical sites or weekly telephone calls in lieu of the visits.

4) **Preceptor competence.** Annual preceptor meetings provided a necessary venue to discuss preceptor competence. A number of competent and efficient clinical professionals were asked to serve as preceptors. However, faculty development workshops became crucial for keeping preceptors informed of program needs and student learning outcomes.

As the CRATP prepares to welcome the second wave of preceptors for the new clinical research associate program, a variety of novel teaching and learning strategies, such as role playing and discussions, will be incorporated. Role playing, used prior to the beginning of the hands-on clinical assignments, helps to reduce students’ anxiety and to increase their success rate [8, 13, 14].

**CONCLUSION**

Clinical assignments—hands-on tasks and experiential learning—served as the clinical learning platform that enabled students to achieve high-quality learning outcomes and contributed to the overall success of the CRATP. Although rigorous, the CRATP clinical assignments 1) made the learning experiences rich and long-lasting through hands-on training; 2)
provided a guide to the expectations of the clinical experience, 3) transferred class activities to
the worksite, and 4) gave students a feeling of accomplishment when they applied classroom
theory to the clinical experience and mastered the skill. The application of andragogical
principles in the development of clinical assignments optimized the adult learner clinical
experience as shown from the responses on the student exit surveys.

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REFERENCES


Figure 1: Clinical Research Associate Training Program process

NURSING PROFESSIONAL (experienced) → DIDACTICS (45 HOURS) → CLINICAL ASSIGNMENTS (96 HOURS) → CLINICAL RESEARCH PROFESSIONAL (entry level) → CRATP

Figure 2: Nursing process

NURSING PROCESS

- EVALUATION
- INTERVENTION
- ASSESSMENT
- PLANNING
- DIAGNOSIS
Figure 3: Andragogical (adult learning) principles used in the Clinical Research Associate Training Program

- **SELF-EVALUATION**
  - Need to know
  - Task evaluation

- **HANDS-ON PRACTICUM**
  - Task orientation
  - Didactic application to clinical setting

- **SELF-REFLECTION**
  - Solving the problem
  - Summation of the lessons learned
Table 1: Clinical Research Associate Training Program enrollment eligibility criteria

- Baccalaureate degree in nursing
- Unencumbered registered nurse (RN) licensure
- Self-identified as minority candidate
- Self-motivated to learn about clinical research profession

Table 2: Clinical Research Associate Training Program preceptor roles

<table>
<thead>
<tr>
<th>Teacher</th>
<th>Mentor</th>
<th>Role Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide appropriate learning experiences to enable utilization of knowledge and skills learned in the classroom setting</td>
<td>Display interest and commitment to student learner</td>
<td>Model professional practice and behaviors</td>
</tr>
<tr>
<td>Provide clinical experiences that prepare students for future practice as a beginning CRA and CRC</td>
<td>Be accessible to students for their learning and academic development needs</td>
<td>Facilitate role socialization</td>
</tr>
<tr>
<td>Provide sufficient number of learning experiences and resources appropriate for student to achieve learning outcomes</td>
<td>Facilitate a professional, working relationship while protecting privacy, maintaining confidentiality, and establishing appropriate boundaries</td>
<td>Demonstrate a warm and caring demeanor</td>
</tr>
<tr>
<td>Create conditions that are conducive to self-learning and self-evaluation</td>
<td>Allocate sufficient time to listen to student needs</td>
<td>Be attentive to safety and to the physical, mental, and emotional needs of patients</td>
</tr>
<tr>
<td>Review progress toward the achievement of the course objectives</td>
<td>Share information on “unwritten rules of success” with students</td>
<td>Understand and model the tools of reflection and self-evaluation</td>
</tr>
<tr>
<td>Provide constructive criticism</td>
<td>Expand mentee’s network of contacts for future professional development</td>
<td>Display the utmost ethical behaviors</td>
</tr>
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Table 3: Operation model of clinical assignments in the Clinical Research Associate Training Program

<table>
<thead>
<tr>
<th>NURSING PROCESS</th>
<th>CRATP Clinical Assignment # 2 (8 Hours) Evaluation of Pre-Study Site for Study Approval</th>
<th>ANDRAGOGICAL PRINCIPLES (Knowles)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Study Site Personnel: Clinical Research Nurse/Coordinator, Site Manager, and/or Physician Investigator</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical Sites: Primary Care Clinic and CTRC</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I) ASSESSMENT (A-1, 2, 3, 4)</th>
<th>A. Clinical behaviors for CRATP students:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-work</td>
<td>1) Evaluate the site for potential utilization as a clinical trial study site</td>
</tr>
<tr>
<td>Review Subjective and Objective Data</td>
<td>2) Follow ICH/GCP procedures for inspecting potential clinical site for clinical trial study, i.e. inspection of study site for sufficient patient safeguards during patient treatment</td>
</tr>
<tr>
<td></td>
<td>3) Evaluate the ability of the site to meet protocol requirements of the proposed study and the ability of the site to meet criteria of the study:</td>
</tr>
<tr>
<td></td>
<td>a. Investigator recruitment and validation of Study Site as evident by ICH/GCP guidelines (Form 1572)</td>
</tr>
<tr>
<td></td>
<td>b. Complete Site Evaluation Report</td>
</tr>
<tr>
<td></td>
<td>c. Complete Teaching Plan for noted deficit areas, i.e. personnel training</td>
</tr>
<tr>
<td></td>
<td>4) Display competency in ensuring the integrity of the clinical data</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>II) DIAGNOSIS (A-1,2,3,4)</th>
<th>II) SELF-EVALUATION: Need-to-know and task evaluation (A-1, 2, 3, 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify, interpret and analyze data</td>
<td>Pre-work</td>
</tr>
<tr>
<td>-Utilization of guides to analyze data (federal, state and site policies)</td>
<td>Previous experiences</td>
</tr>
</tbody>
</table>

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<tr>
<th>III) PLANNING (GOALS) (B-1,2)</th>
<th>B. Student Activities:</th>
</tr>
</thead>
<tbody>
<tr>
<td>-Mutual, measurable and executed within established protocol(s)</td>
<td>1) Obtain appropriate documents for pre-study site visit (PSSV)</td>
</tr>
<tr>
<td>IV) INTERVENTION (B-3,4,5,6)</td>
<td>2) Review protocol for components and clarity</td>
</tr>
<tr>
<td>-Hands-on practicum</td>
<td>3) Prepare for site visit</td>
</tr>
<tr>
<td>-Execute activities based on ICH/GCP and other policies that govern practice</td>
<td>4) Conduct a pre-study site visit</td>
</tr>
<tr>
<td>V) EVALUATION (B-7,8)</td>
<td>5) Demonstrate understanding of the role of the CRA/CRC with evaluation of study site as approved by the IRB</td>
</tr>
<tr>
<td>-Evaluate goals (Met or Unmet)</td>
<td>6) Demonstrate universal understanding of all persons involved regarding responsibilities and certifications related to protocol</td>
</tr>
<tr>
<td>-Complete data sets</td>
<td>7) Complete site evaluation report</td>
</tr>
<tr>
<td>-Complete internal and external audits</td>
<td>8) Using the components of the Nursing Process -Develop a teaching plan</td>
</tr>
</tbody>
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<tr>
<th>II) HANDS-ON PRACTICUM: Task orientation and didactic application to clinical setting (B-1,2,3,4,5,6,7)</th>
<th>II) SELF-REFLECTION: Solving the problem and summation of lessons learned (B-7, 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>-Hands-on practicum</td>
<td>-Post-work</td>
</tr>
<tr>
<td>-Execute activities based on ICH/GCP and other policies that govern practice</td>
<td>-Knowledge completion</td>
</tr>
<tr>
<td>-Enhanced Knowledge</td>
<td></td>
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Table 4: Clinical preceptor survey

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<tr>
<th>Dillard University</th>
<th>Minority Health and Health Disparities Research Center</th>
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<tbody>
<tr>
<td>Clinical Research Associate Training Center</td>
<td>Clinical Preceptor Survey</td>
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**Directions:** Rate the following questions on a scale of 5–1 with 5 meaning strongly agree with the statement and 1 meaning strongly disagree with the statement.

**Question Rating Scale:** 5 = Strongly Agree  4 = Agree  3 = I am not sure  2 = Disagree  1 = Strongly Disagree

1. There is a need for more Clinical Research Associates (CRAs) and Clinical Research Coordinators (CRCs) to manage clinical trials locally.
   - 5  4  3  2  1

2. I am familiar with the nursing process.
   (Circle -0- if you are not familiar with the nursing process)
   - 5  4  3  2  1  0

3. The nursing process is visible throughout the clinical assignments required by learners enrolled in the CRA training program.
   (Circle -0- if you are not familiar with the nursing process)
   - 5  4  3  2  1  0

4. I believe each clinical research assignment scaffolds to include the components of the nursing process.
   (Circle -0- if you are not familiar with the nursing process)
   - 5  4  3  2  1  0

5. The clinical assignments exhibit a hands-on practicum experience for learners.
   - 5  4  3  2  1

6. I am able to assess the cognitive abilities and skills of the learners when conducting select components of the clinical assignments.
   - 5  4  3  2  1

7. When learners arrive on site they are cognizant of regulatory laws and guidelines to assist them with the learning activity for the day.
   - 5  4  3  2  1

8. During the specific clinical assignment CRC/CRA learners’ exhibit critical thinking and problem solving techniques to achieve learning objectives.
   - 5  4  3  2  1

9. The role of the Preceptor is clear.
   - 5  4  3  2  1

10. Preceptor expectations are clear.
    - 5  4  3  2  1

**Reflective notes:**

Ch/lbj/preceptor survey
2013-2014
Table 5: Student exit survey

DILLARD UNIVERSITY
MINORITY HEALTH AND HEALTH DISPARITIES RESEARCH CENTER
CLINICAL RESEARCH ASSOCIATE TRAINING CENTER
STUDENT EXIT INTERVIEW FORM

Directions: Please complete the following form prior to your scheduled interview.

NAME: ______________________________________________ DATE: ____________

1. What component of the CRA Training Program helped you the most?

2. What part of the CRA Training Program helped you the least?

3. If you could improve 2 aspects of the CRA Training program, would you they be? How would you improve it?

4. Rate your overall score of the CRA training program. 1 = lowest score and 5 = highest score.
   
   5 – Excellent
   4 – Good
   3 – Okay
   2 - Poor
   1 – Unsatisfactory

5. Comments