

Nursing & Interdisciplinary Research Committee

Research Manual



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Introduction

Welcome from Co-Chairs

Welcome to the world of research! The Nursing and Interdisciplinary Research Committee (NIDRC) is excited to have you join us on our journey into systematic inquiry.

Although, as healthcare professionals, we acknowledge the importance of research and evidence-based-practice in providing excellent patient care, the process of research and research utilization may seem overwhelming. In hopes of dispelling some of those beliefs, the NIDRC has developed a research “how to” manual. The purpose of this manual is to encourage and support providers of healthcare at all levels to be able to conduct and apply research in clinical practice in order to provide optimal patient care. A goal we all share.

We hope you find the manual helpful. Please feel free to contact the co-chairs or any NIDRC member if you require further assistance with your project.

Reetta Stikes, RN, MSN
Chair Nursing and Interdisciplinary Research Committee

Nursing and Interdisciplinary Research Committee Mission and Goals

The mission of the Nursing and Interdisciplinary Research Committee is to educate, engage, and empower the U of L Healthcare team to integrate research into practice.

As a leading academic center with learning and continuous improvement as one of its core values, this committee will facilitate research into structures and processes that enhance the quality and safety of patient care.

Goals of the Nursing and Interdisciplinary Research Committee include:

- Creation of a central repository for education in regards to defining research, what it can do, and the value of research consistent with the organization’s mission.
- Developing plans that engage team members and actively involves them in research.
- Providing the tools and support needed to empower those who take on the role of researcher.

Acknowledgements

This manual was prepared by the education committee of Nursing and Interdisciplinary Research Committee (NIDRC). Our goal is to give you printed examples to supplement the classes you will be attending to help you become U of L Research Champions. If you have any questions or additions that you feel could benefit you or others who will follow in your footsteps, contact someone who was instrumental in planning this book. The names of those who compiled the following information are located below. We look forward to all of you joining us for NIDRC meetings which are held on the fourth Thursday of each month.

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Introduction to Research

Definition of Research

Research: “Studious inquiry or examination aimed at the discovery and interpretation of new knowledge, or the collecting of information about a particular subject” (Webster, Webster's New American Dictionary, 1995). Research is an orderly inquiry process that involves purposeful and systematic collection, analysis, and interpretation of data in order to gain new knowledge or verify knowledge that is already in existence (Dempsey, 2000).

Every field of study and/or profession has potential to contribute to the areas of research; science, mathematics, and literature. Healthcare professions are no different. Nursing and other healthcare professionals have multiple opportunities to contribute the body of healthcare knowledge through research. The healthcare professional's major role is typically considered to be care of patients at the bedside although there are many more aspects of this role, including research. For example, many of the nurses that provide direct patient care are also nurse researchers. Nurses do not have to choose between one role and the other. Nurses may integrate the two roles to contribute to the body of nursing knowledge. Nursing research is done by nurses in order to gain new knowledge about many things and is not limited to the practice of nursing or patient care issues. Nursing research may involve: patient care practices, nursing practices, staff education, patient education, or leadership. The healthcare profession as a whole is rapidly changing due to the generation of new knowledge and research which, as contributions to the medical sciences, will ultimately lead to improved patient outcomes.

Depsey, P. A. (2000). *Using Nursing Research* (5ed.). New York: Lippincott.

Webster, M. (1995). *Webster's New American Dictionary*. New York: Amithmark Publishers.

Expectations for Research by Educational Level of Nurse

In the practice of nursing there are various ways that one can become a nurse. There are two and four year programs, master's degree nurses, and doctoral degree nurses; but they are all nurses. Because each type of nurse has a different educational background, each will have different expectation when it comes to research. While these expectations are different, all are essential to the development and performance of research.

Associate Degree Nurse: Associate degree nurses demonstrate an awareness of the value and need for research within the nursing profession. They can assist in the identification of problem areas in nursing practice and may also assist in the collection of data within an established structured format.

Baccalaureate Degree Nurse: The Baccalaureate degree nurse reads, interprets and evaluates research for applicability to nursing practice. They identify nursing problems that need to be investigated and participate in the implementation of scientific studies. Besides using nursing practice to gather data that will lead to refining and extending nursing practice, the Baccalaureate nurse applies

established findings of nursing and other health-related research to nursing practice and disseminates these findings with colleagues.

Master's Degree Nurse: The Master's degree nurse has more experience than the previous two and so has a wider variety of responsibility when it comes to research. They analyze and reformulate nursing practice problems so the scientific knowledge and methods can be used to find solutions. They enhance quality and clinical relevance of nursing research by providing expertise in clinical problems and knowledge about the way in which clinical services are delivered. The Master's degree nurse also facilitates investigation of problems in clinical setting for the purpose of monitoring the quality of the practice of nursing. Teamwork is a very important aspect in nursing science and this nurse can also assist others in applying scientific knowledge in nursing practice.

Doctorate Degree Nurse: This nurse is the one with the highest degree and the most experience. They provide the leadership for the integration of scientific knowledge with other types of knowledge for the advancement of practice. The Doctorate degree nurse conducts the investigations and research activities. Developing methods to monitor the quality of the practice of nursing in a clinical setting and evaluating contributions of nursing activities to the well-being of the clients, are all a part of the expectations of the doctorate nurse (Houser, 2008).

Houser, J. (2008). Nursing Research. Sudbury, MA: Jones and Bartlett.

Common Roles of Healthcare Professionals in Research Studies

Preparing, conducting, and presenting research may be a lengthy process, and should be a effort. Each person within the research team plays a vital role. Each piece of the team is essential to the success of the final product.

Primary investigator/ Co-investigator: The person/persons, who is primarily responsible for the research study. This person takes responsibility for all elements of the study and is the first author listed on publications and presentations.

Key personnel: These are the people who oversee the research study, collect data from participants, enter data into the databases, ensure that all ethical procedures are followed, and analyze the data.

Research project director: This person oversees the process, ensures the process/procedures are ethical and is being followed by all involved parties.

Research assistant: Research assistants are the people in the field collecting data, passing out surveys, or interviewing participants.

Clinical coordinator: This person works under the supervision of the principle investigator and is responsible for conducting clinical trials and ensuring good clinical practice. The responsibilities of the coordinator also include ethical responsibilities such as maintaining confidentiality of subjects and that trials are sound and clearly described.

Polit, D., Beck, C. (2003). *Nursing Research: Principles and Methods* (7 ed.). New York: Lippincott.

Steps in the Research Process

Regardless of the type of research being conducted, the process is generally the same. The research process upon first glance, looks like a series of steps, however, it is really a fluid process, basically a continuous piece of work until the final piece has been completed. Pieces come together at various rates, some pieces may take longer than others, but it is a work in progress. The process research process is as follows:

1. **Define a research problem.** This step allows the researcher the opportunity to find an area of interest, identification of a problem, question, or gap in knowledge that may be addressed by scientific research methods. This is the first step in the process, because upon completion it provides direction for the researcher. Once the problem has been identified, the research team can then decide if a qualitative or quantitative approach will best answer the research question.
2. **Scan the literature.** Completing a scan, or review of various types of literature related to the problem allows the researcher to provide themselves with basic knowledge. Not only does the researcher want to gain basic knowledge for themselves, but also find out the general knowledge within their field of study, such as nursing. Finally, scanning the literature provides the researcher with possible relevant research problems that have been identified in the past. At the end of this process the research team will identify what is *not* known about the topic.
3. **Select a theoretical framework.** The theoretical framework is a discussion of a theory, or various related theories which support the need for the study. Selecting the framework allows the researcher to determine a theoretical basis for the thoughts he/she has regarding study of the problem.
4. **Determine an appropriate design.** Research design is the general outline of the study being conducted. This outline will detail all the major components of the research. It is important to select a design that is appropriate for the question being asked, the intentions of the researcher, and the timeframe in which the study will be conducted. Examples include: experimental, quasi-experimental, descriptive, and exploratory designs.
5. **Define a sampling strategy.** A sampling strategy is a plan that provides details as to how subjects will be recruited, assigned to groups if applicable, as well as the number of subjects needed to adequately fulfill the goals of the researcher in gaining the desired information.
6. **Collect the data.** During this phase, the researcher gathers data, using appropriate and reliable data collection protocols/tools according to a pre-established data collection plan.
7. **Analyze the collected data.** Researchers apply analytical techniques that are appropriate for the type of data that has been collected and will also answer the questions being asked.

8. **Communicate/Disseminate the findings.** Circulate the findings to the appropriate audiences using various methods such as conferences and publications.
9. **Use the findings to support practice.** Endorse the utilization of the research by connecting it to specific guidelines for practice (Houser, 2008).

Houser, J. (2008). *Nursing Research*. Sudbury, MA: Jones and Bartlett.

Training Requirements for Research Personnel

Research compliance training is required to do research at University of Louisville Hospital. This training consists of 3 requirements: HIPAA training for Privacy, Security and Research Fundamentals, CITI Basic Course for human subject's research and Conflict of Interest disclosure of significant financial interest. All three of these requirements must be met prior to submitting a research proposal to the Research Council.

If you are new to this process, then you will need to set up a Sponsored account through the Research Integrity office. The form for requesting this information can be found in the following link:

<http://louisville.edu/research/researchintegrity/Sponsored%20Account%20Request%20Form.pdf/view>

Once this request has been made, it will take 5-7 day to have the account set up. You will only need this account for the HIPAA training and Conflict of Interest.

Once you have a user name and password for Blackboard (this is where the HIPAA training will be found), then you can begin the research training.

In the subsequent pages, you will find a detailed description of the 3 required elements of research compliance.

HIPAA Training

HIPAA training is needed when an individual is working with Protected Health Information. HIPAA Privacy, Security and Research Fundamentals training consists of two courses. These courses are located in the University of Louisville Blackboard system. The username and password given to you with the Sponsored account will grant you access to this system.

<https://blackboard.louisville.edu/webapps/login/?action=relogin>

Blackboard @ U of L

[Blackboard Help](#)
[Blackboard Faculty Training](#)
[IT HelpDesk](#)

[Guest Access](#)
[Course Catalog](#)

*Blackboard@UofL Maintenance:
Each Friday, 10 PM - 2 AM EST
Each Sunday, 2 AM - 5:30 AM EST
System unavailable during this time.*

If you already have an account, enter your login information here and click the "Login" button below. If you do not have an account, please click on one of the buttons to the left.

▶ USERNAME:

▶ PASSWORD:

▶

Once you have logged into Blackboard, the course link should be on the right side of the screen under the heading "My Organizations Plus". Both HIPAA Security Fundamentals and HIPAA Research Fundamentals are required to be completed in order to have completed the HIPAA training. There are 4 modules in both courses, and you must obtain and 80% on each module to complete the course. The HIPAA training expires after 2 years. If you have had the training, but it is expired then the Refresher course is needed to participate in research. This course can be found by logging into Blackboard and seeing "HIPAA Privacy Training-Refresher" under "My Organizations Plus". This re-certification is good for 2 years.

CITI Training

Human Subjects training is required for anyone participating in research. The University of Louisville requires the CITI Basic Course as baseline training for anyone involved with Human Subjects research. The CITI Basic Course can be accessed at the website listed below. This site does not require the U of L Sponsored account username and password.

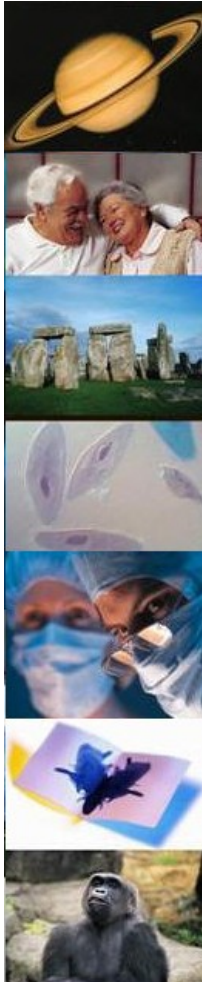
<https://www.citiprogram.org/Default.asp?>

Welcome

CITI Login and Registration Page

- i** The CITI Program is a subscription service providing research ethics education to all members of the research community. To participate fully, learners must be affiliated with a CITI participating organization.

The CITI course is a protected site. If you are a new learner at a participating organization you must register to create your own username and password and gain access to the site.



i New Users [Register Here](#)

i Already Registered? [Login Below](#)

Username

Password

**Select Curriculum -
University of Louisville**

Select the group appropriate to your research activities to be enrolled in the **basic group** .

[Forgot login information](#)

[Contact the CITI Helpdesk](#)

Select the group appropriate to your research activities to be enrolled in the **basic group** .

Choose one answer

- Group 1.:** Biomedical Research Investigators and Key Personnel. Investigators with VA appointments conducting research at the Louisville VAMC should contact the Louisville VAMC regarding any additional training requirements.
- Group 2.:** Social, behavioral or educational researchers - Researchers must read all 11 Social Behavioral modules and complete the quizzes.
- Group 3: Undergraduate Students only**
- I have already completed the basic course.**

Next

Start Over

Once registered for the CITI Basic Course, you must select a Curriculum.

Choose Group 1: if you will be participating with Quantitative Research

Choose Group 2: if you will be participating with Qualitative Research

DO NOT Choose Group 3.

CITI Basic Course certification is good for 2 years and must remain current as long as you are participating in Human Subjects research. If you need a refresher course, it can be taken by going to the CITI website and using your username and password to complete the refresher.

Conflict of Interest Form (COI)

The Conflict of Interest form must be completed one time per year. This form is used to disclose any significant financial interest. This form can be located at

https://webapp.louisville.edu/coldfusion2/webs/vpr_sfi_2010/default.htm

Login to this website with your Sponsored account username and password and complete electronic form.

Password Information

Passwords given from the University of Louisville Service Sponsored account must be changed every 180 days. There will not be a reminder of this need to change the password, therefore you must keep track. You may want to set a calendar reminder to change this password.

If you have had your password reset with a temporary password, you must log in using the temporary password and you will be prompted to set a new password. You must change the temporary password at the time you gain access as there is limited access to the system with a temporary password.

If you are a current or former student at the University of Louisville, you will need to contact the Research Integrity Office at the following link to set up your Service Sponsored Account:

<http://louisville.edu/research/researchintegrity/Sponsored%20Account%20Request%20Form.pdf/view>

Frequently Asked Required Training Questions

I am a former or current student of the University of Louisville, how to I get the HIPAA training assigned to blackboard?

Current and former students of U of L must contact the Research Integrity office to have HIPAA assigned in Blackboard. Also, former students may have username and password issues that this office can help to resolve.

U of L Research Integrity office ori@louisville.edu or (502)852-2454

Who on my research team needs to have the training?

Everyone on your research team needs to have all the requirements of the research compliance training. This includes Principle Investigator, Research Assistant, Data Collector, etc. Anyone accessing information or taking part in the study must have up to date certifications in HIPAA and CITI as well as COI on record.

When does the training expire?

HIPAA training is a 2 year certification. A refresher course will be available on Blackboard 3 months before the expiration of the certification.

CITI training is a 2 year certification. A refresher course will be available on the CITI website 6 months prior to the expiration of the certification.

Conflict of Interest must be digitally signed one time per year.

What do I do with the completion information once the training is complete?

Take a copy of the completion form for HIPAA and CITI to the Nursing Education and Research Dept.

Keep a copy for your records.

If you do not have copies, please contact the Research Integrity office for records

U of L Research Integrity office ori@louisville.edu or (502)852-2454

My sponsored account will not let me into Blackboard, what do I need to do?

There is a chance that the password for the account has expired, as this password needs to be changed every 180 days. If your username and password are not allowing you access to Blackboard, please contact the Research Integrity office.

U of L Research Integrity office ori@louisville.edu or (502)852-2454

If you are assigned a temporary password, then you must change the temporary password to your own private password when you access the account. Follow the prompts to change the password.

What training do I need if I am going to do both Qualitative and Quantitative Research?

HIPAA, CITI and COI must all be done for either Qualitative or Quantitative Research. If you are going to be participating in both, then you must complete Group 1 AND Group 2 of CITI training, as these two courses do differ. There are no additional requirements for HIPAA or COI.

What do I do when I have my compliance training complete?

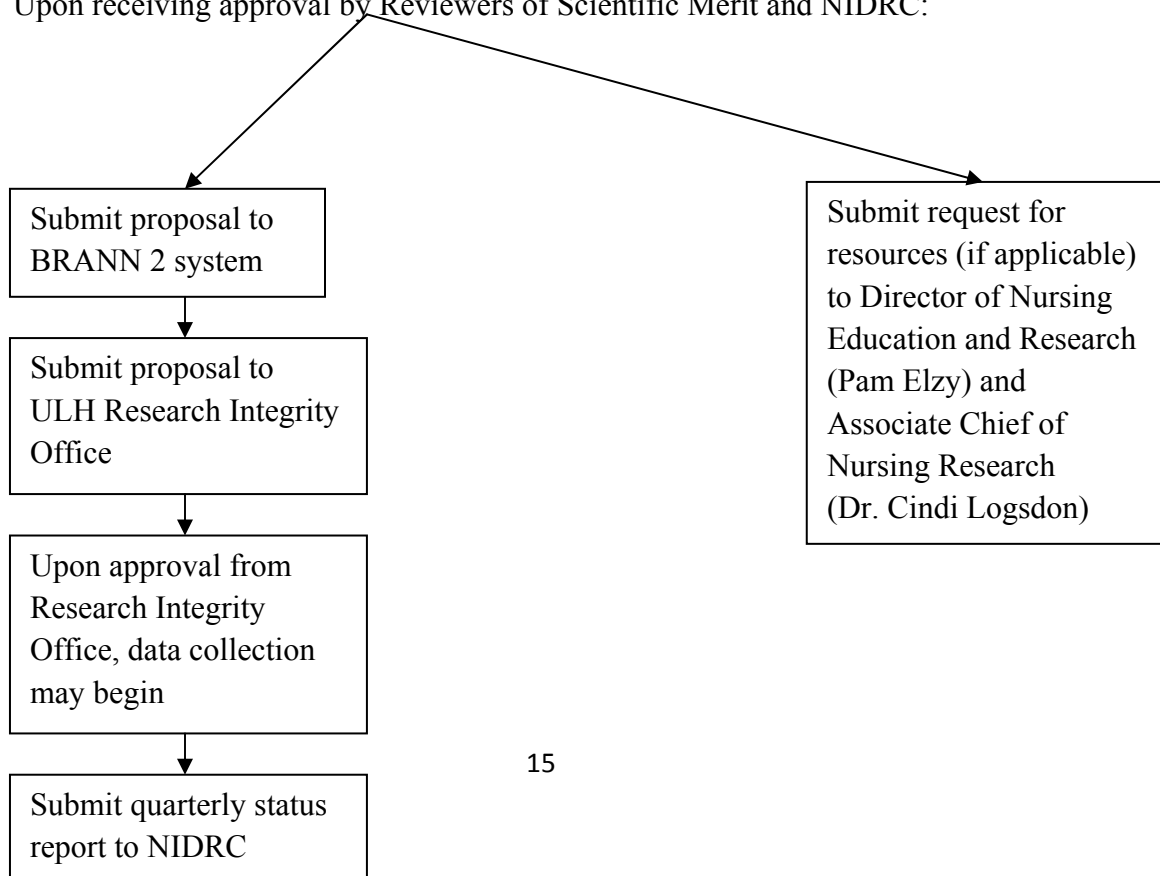
Turn in a copy of your completion documentation. You will not always get a completion certificate, but contact Amy Lawson in Nursing Education to let her know that you are complete. She will also ask for your Username at that time, for tracking purposes only.

Steps in Approval Process and Timeline before a Study can be Conducted

1. Proposals for new research studies must be submitted to the Nursing and Interdisciplinary Research Committee (NIRC) for review of scientific merit (see below). If the study is research for review before the monthly business meeting, then the study could be reviewed that same month. If the study is ready for review after the monthly business meeting, then the study will be reviewed by the next business meeting.
2. Once the proposed study has met approval with the NIRC, the next step is to place the proposed study in the BRAAN2 system. This process is lengthy and may take upwards of a week for all the information to be correctly entered into the BRAAN2 system, approval can take upwards of 2 weeks to a month. The BRAAN2 system is online at the following web address:
<http://louisville.edu/research/braan2>
3. After receiving approval from the BRAAN2 system the study will go for final approval through the Compliance office. This can take 2-4 weeks.

Prior to Conducting a Research Study:

1. Complete CITI, HIPPA training and complete COI form.
2. Create research proposal.
3. Submit proposal to chair of NIDRC who will submit to Reviewers of Scientific Merit and NIDRC for approval.
4. Upon receiving approval by Reviewers of Scientific Merit and NIDRC:



Expectations and Resources

Principal Investigator/Project Director

The Principle Investigator (PI) or Project Director (PD) is ultimately responsible for the effective and compliant management of all scientific, fiscal and programmatic aspects of the sponsored research project. These responsibilities include, but are not limited to the following:

- Preparing proposals and ensuring that all information provided is accurate and correct;
- Ensuring that reviews by compliance committees are completed as appropriate during the proposal clearance/pre-award process.
- IRB reports
- Maintenance of confidential files: please refer to U of L research handbook fopr more information:
- (<http://louisville.edu/research/research-handbook/chapter-one-general-information.html>)

Resources

It is possible that limited funds may be available to support pilot research studies, including, but not limited to:

- Supplies
- Equipment
- Lab costs
- Stipends for research subjects
 - Staff time
- Copying instruments

Requests for financial assistance, including a detailed budget, should be submitted electronically to Pam Elzy & M. Cynthia Logsdon after acceptable scientific merit review by the NIRC.

Research Critique Forms

Research Critique Form for Quantitative Research Study

Criteria	Is it there?	Is it good enough?
Documentation of clear need for study including what is not known? Comments:	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no
Clear study aims or purpose. Comments:	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no
Description of study design, IV, DV, Intervention, intervention dose and fidelity, instruments to measure study variables, reliability and validity of instruments, sampling plan including justification for sample size. Comments:	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no
Ethical considerations addressed. Comments:	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no
Clear results and description of statistical analysis. Comments:	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no
Threats to internal or external validity of study addressed. Comments:	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no
Discussion of Research and Clinical implications of findings. Comments:	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no

Research Critique Form for Qualitative Research Study

Elements influencing believability of the research	
Elements	Questions
Writing style	Is the report well written – concise, grammatically correct, avoids the use of jargon? Is it well laid out and organized?
Author	Do the researcher’s qualifications/position indicate a degree of knowledge in this field?
Report title	Is the title clear, accurate and unambiguous?
Abstract	Does the abstract offer a clear overview of the study, including the research problem, sample, methodology, findings and recommendations?
Elements influencing robustness of the research	
Elements	Questions
Statement of the phenomenon of interest	Is the phenomenon to be studied clearly identified? Are the phenomenon of interest and the research question consistent?
Purpose/significance of the study	Is the purpose of the study/research question clearly identified?
Literature review	Has a literature review been undertaken? Does it meet the philosophical underpinnings of the study? Does the review of the literature fulfill its objectives?
Theoretical framework	Has a conceptual or theoretical framework been identified? Is the framework adequately described? Is the framework appropriate?
Method and philosophical underpinnings	Has the philosophical approach been identified? Why was this approach chosen? Have the philosophical underpinnings of the approach been explained?
Sample	Is the sampling method and sample size identified? Is the sampling method appropriate? Were the participants suitable for informing research?
Ethical considerations	Were the participants fully informed about the nature of the research?
Data collection/data analysis	Are the data collection strategies described? Are the strategies used to analyze the data described? Did the researcher follow the steps of the data analysis method identified? Was data saturation achieved?
Rigour	Does the researcher discuss how rigor was assured? Were credibility, dependability, transferability and goodness discussed?
Findings/discussion	Are the findings presented appropriately? Has the report been placed in the context of what was already known of the phenomenon? Has the original purpose of the study been adequately addressed?
Conclusions/implications and recommendations	Are the importance and implications of the findings identified? Are recommendations made to suggest how the research findings can be developed?
References	Were all the books, journals and other media alluded to in the study accurately referenced?

Ryan, F., Coughlan, M. & Cronin, P. (2007)

Research Critique Form for Quantitative Research Study

Elements influencing believability of the research	
Elements	Questions
Writing style	Is the report well written – concise, grammatically correct, avoids the use of jargon? Is it well laid out and organized?
Author	Do the researcher’s qualifications/position indicate a degree of knowledge in this field?
Report title	Is the title clear, accurate and unambiguous?
Abstract	Does the abstract offer a clear overview of the study, including the research problem, sample, methodology, findings and recommendations?
Elements influencing robustness of the research	
Elements	Questions
Statement of the phenomenon of interest	Is the phenomenon to be studied clearly identified? Are the phenomenon of interest and the research question consistent?
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Rigour	Does the researcher discuss how rigor was assured? Were credibility, dependability, transferability and goodness discussed?
Findings/discussion	Are the findings presented appropriately? Has the report been placed in the context of what was already known of the phenomenon? Has the original purpose of the study been adequately addressed?
Conclusions/implications and recommendations	Are the importance and implications of the findings identified? Are recommendations made to suggest how the research findings can be developed?
References	Were all the books, journals and other media alluded to in the study accurately referenced?

Coughlan, M., Cronin, P., & Ryan, F. (2007).

MNRS: Guidelines for Scientific Integrity

The Midwest Nursing Research Society (MNRS) Publishes guidelines for conducting research, including information on: conflicts of interest, protection of human subjects, managing data, appropriate roles in collaborative relationships, and publishing findings. The guidelines are included in this packet or may be downloaded as a pdf from the following link:

<http://www.mnrs.org/files/public/MNRSGuidelinesforScientificIntegrity.pdf>

For more information on MNRS, go to:

<http://www.mnrs.org/i4a/pages/index.cfm?pageid=1>

Sample Research Abstracts and Proposals

Use of Social Media by Adolescent Mothers to Obtain Health Information

Principle Investigator: M. Cynthia Logsdon DNS, ARNP, FAAN

Co-investigators: Diane Eckert RN, BSN and Roselyn Tomasulo RN, MSN

Abstract

Objective(s) of the study and related hypothesis: Overall Aim: To determine how teen mothers use social media to obtain health information, and determine acceptability of a social media intervention to increase rates of treatment for postpartum depression.

Significance of the proposed study: Although treatment is very effective, less than ¼ of teen mothers who experience depression receive treatment, resulting in adverse consequences on the adaption and development of the teen and her infant. At the same time, there is a growing trend for teens of all income levels to use social media to communicate and as a source of information. Thus, a social media intervention is a promising vehicle to encourage depression treatment in teen mothers. However, it has not been determined if the unique life challenges experienced by teen mothers impacts their use of social media (e.g., most teen mothers are low income and have many time commitments as they balance work and school responsibilities with child care). With funding from this project, our **new**, multidisciplinary team plans to conduct Step 1 of a 5 step study and obtain baseline information on how teen mothers use social media, as well as the acceptability of a social media intervention to increase rates of treatment for postpartum depression. The remaining steps will be included in an application for extramural funding. In order to provide the entire context of the problem and our solution, we have described all 5 steps in the attached proposal. Results of our research will lead to a better understanding of the needs, access issues, and quality of care in this population. Study results can be leveraged for use with other low income teen mothers with similar demographics. **Basic Study Design and**

Methodology: Quantitative research methods will be used to survey teen mothers (n=100) to understand how they use social media and the acceptability of a social media intervention to increase rates of treatment for postpartum depression. **Future Directions:** Results of the study will allow Kentucky to take a national leadership role in improving health care use for teen mothers with depression.

Proposal

A. Specific Aims

A. 1. Aims of this preliminary study

Social media is a promising vehicle for marketing public health messages to teens who heavily utilize social networks. Although it is not clear which social media are used and preferred by primarily low income, teen mothers in Kentucky, USA, teen mothers in the United Kingdom commonly use Facebook sites such as Bubblicious to give and receive peer support and receive expert advice. When social media is used as an aspect of marketing public health messages, experts are needed in marketing, health communication, the content area and population, and biostatistics in order to create the best profile, use applications to build a brand around the health message, and measure outcomes. Our **new multidisciplinary research team** has this expertise. **Our initial work together that is described in this research proposal** will focus on helping us to define the **market** (understand how teen mothers use

social media; where they receive health information; who they prefer to receive health information from). In addition, we want to know if teen mothers would find it acceptable to receive an intervention about postpartum depression using social media.

A. 2. Aims of the study for NIH proposal after this study is completed

Once this work is completed, our next study will have 4 parts: **message development** (obtain the opinions of teen mothers concerning what the message should be and the image of the message); development of the message by ad agency; and in **concept and message testing** (pilot testing of the message with teen mothers). Then outcomes related to the public health, social marketing intervention will be measured. **Aim of NIH study:** Determine the efficacy of a public health, social marketing intervention to improve health care use of teen mothers with symptoms of depression.

B. Background and Significance

B.1. Symptoms of Depression and Lack of Treatment Are Common in Teen Mothers

About 1000 teens become mothers in Jefferson County each year, and most are low income (Logsdon, 2008). Our research team has demonstrated high rates of depressive symptoms in teen mothers, ranging from 33 to 47% (Logsdon et al, 2005, 2008). However, the rate of adherence to referrals and treatment ranged from 0 to 25% (Logsdon et al, 2008, 2009).

B.2. Depression Has Adverse Impact on Mothers and Infants

A plethora of international research studies have demonstrated that mothering is adversely impacted in women with postpartum depression (Logsdon et al, 2006), including impaired maternal infant interaction (Beck, 1995), diminished gratification in the maternal role (Killien, 1998), and lower feelings of self efficacy (Froman & Owen, 1990). Infants of depressed mothers have difficulties in regulating affective states and concentrating. Field determined that depressed mothers and their three month old infants shared negative behavior states more often and positive behavior states less often than non-depressed mothers and their infants (Field et al, 1990). Thus, treatment of depression is critical to improve public health and mental health outcomes, particularly in vulnerable teen mothers and their infants.

B.3. Social Marketing and Public Health

Social marketing is a social or behavior change strategy that applies marketing principles to improve public health or influence society. Marketing strategies to improve public health have included ads in print, television and radio, outdoor advertising, and more recently, social media such as Facebook, text messages, YouTube and twitter. Supported by Theories of Planned Behavior, Self Efficacy, and Planned Change, individuals adopt new attitudes and change behaviors if the new behavior is compatible with social norms, has an advantage over existing behavior, can be tried out, is not too complex, and they can see someone else doing it. Social marketing can make the new attitude or behavior easy, fun, popular, and more likely to occur. Examples of successful public health, social marketing campaigns include VERB (promote exercise in youth), BuckleupAmerica (encourage seat belt use), 5ADay (eat more vegetables and fruit), and Mediacampaign (antidrug for youth).

B.4. Social Marketing Programs Improve Health Outcomes in Teens

Social marketing programs have been successful in changing health behaviors in teens. Targets for successful behavior change have included smoking, nutrition and exercise, and HIV/AIDS prevention. The VERB campaign also utilized social media such as mobile phones and text messaging to promote their health message and encourage behavior change. However, no studies have tested the effectiveness of public health, social marketing interventions in low income, teen mothers who may have unique characteristics impacting use of social media.

C. Preliminary Studies

C.1. Barriers to depression treatment in low-income teen mothers

This study explored barriers to depression treatment in low-income, unmarried, teen mothers in a southern, urban area of the United States. Logsdon, Hines Martin, & Rakestraw (2009) utilized a phenomenological approach and focus group methodology. Participants were enrolled in a teen parent program, an option of the public school system. The metaphor of a merry-go-round emerged from the data and represented the ups and downs that the teen mothers experience as they struggle to adjust to the role of mother. The teen mothers did not realize their feelings could be labeled depression, and they did not know how to seek assistance from professionals for these feelings. Childbirth education for low income teen mothers should include information on depression and the process of depression treatment.

C.2. Intention to seek mental health treatment in teen mothers

The aims of the study were: (a) to determine the efficacy of the Theory of Reasoned Action in predicting intention to seek depression treatment in teen mothers ($n=64$). Logsdon, Usui, Pinto Foltz, & Rakestraw (2009) found that subjective norms, but not attitude, was a significant predictor of intention to seek depression treatment in teen mothers ($F=4.82$; $p=.00$; $R^2=.14$). Thus, the peers and family culture and values of the teen mother determined her intention to seek mental health treatment. Findings from this study, as well as support from the literature, established the need for a culturally sensitive educational intervention related to depression and use of health services for treatment that includes messages that family and peers find mental health treatment to be acceptable.

C.3 Telephone based depression care management intervention for teen mothers

This Phase 1 clinical trial combined qualitative and quantitative methods to modify a collaborative care, telephone based, depression care management intervention for teen mothers, and to determine the acceptability, feasibility, and initial efficacy of the intervention in a sample of teen mothers ($n=97$) who were recruited from a teen parent program. Findings by Logsdon, Pinto Foltz, Stein, Usui, & Josephson (In press) indicated that 25% of adolescent mothers received mental health treatment. Feasibility and acceptability of the intervention were limited by the use of an adult to deliver the message, subjective norms, and challenges related to when the teens were free to receive telephone calls. Many of the teens were employed, as well as attended school full time and cared for their infants. A different approach to overcoming barriers to depression treatment rather than telephone based depression care management is needed for low income teen mothers.

C.4. Depression Treatment Improves Maternal Role Functioning

The ability to mother her infant is reduced in a woman with postpartum depression. Dr. Logsdon and colleagues investigated whether mothering improved with antidepressant treatment in women with postpartum depression. A subset of women ($n=27$) from a randomized clinical trial (double-blind eight week trial of nortriptyline compared with sertraline) completed three outcome measures of mothering. The two antidepressants were equally efficacious in improving maternal gratification and self efficacy. Results of the study can help women and their health care providers to understand the benefits of antidepressant treatment in the postpartum period.

In summary, our preliminary work has strengthened our commitment to investigate how we can assist teen mothers with symptoms of depression to use health services and to improve their health and lessen the impact of depression on their infant. This study will provide baseline information that will help us to understand how teen mothers use social media; where they receive health information; who they prefer to receive health information from. In addition, we will determine if teen mothers would find it acceptable to receive an intervention about postpartum depression using social media.

D. RESEARCH DESIGN AND METHODS

D.1. Overview of Study Design

The research project will incorporate quantitative methods.

D. 2. Patient Population and Data Collection Procedures

Participants will be recruited from the University of Louisville Hospital. In Jefferson County, approximately 50% of all teen mothers ($n=500$) deliver their children at ULH each year. The ULH nursing and social work staff will approach each teen mother with a flier to ask their interest in study participation. If any teen mother is interested, the staff will contact the research assistant. The RA will obtain informed consent and HIPPA waivers from teen mothers and their parent/ guardians, administer questionnaires, and distribute stipends.

D. 3. Sampling Plan; Power Analysis

The first 100 teen mothers who deliver at ULH and are interested will be invited to participate in the proposed study. Based upon previous studies, we anticipate 10% of teens may be unwilling or unable to participate, thus we anticipate an adequate sample size.

D.5. Study Measures

Questions for the study related to use of social media were adapted from national survey conducted by Pew Corporation and available to public www.pewinternet.org. For example, one question states, "People get information about health issues from different sources. Please tell me how much information about health you have gotten from the following." The options listed include individuals, print media, health professionals, social media, etc. Questions related to acceptability of intervention on postpartum depression delivered by social media were developed by the investigators.

D.6. Table 1: TIMELINE OF STUDY

Month of Study →	1	2	3	4	5	6	7	8	9	10	11	12
Activity:												
Orient staff/IRB	*											
Participant Recruitment		*	*	*	*	*	*	*	*			
Step 1: Survey		10	10	10	10	10	10	10	10			
Data Analysis						*			*	*	*	
Reports, manuscripts											*	*

E. FUTURE DIRECTIONS

Study findings will provide pilot data for NIH proposal in which a public health, social marketing intervention delivered by social media will be tested in a randomized clinical trial. **Kentucky has received failing grades from national organizations on mental health services provided to our citizens (NAMI, 2006). Data collected in this study will provide a foundation for improving that status and allow Kentucky to take a national leadership role in providing treatment for teen mothers with depression.**

D. 7. Evaluation Plan

Step 1: Descriptive statistics will be used to portray the characteristics of the population and results of scales and questionnaires. We will utilize market segmentation strategies to determine if messages should be adapted for African American teen mothers in order to address **health disparities** with health care use.

Table 2. Data Analysis Plan

Question	Variables	Instrument	Analysis Strategy
Question 1: A public health, social marketing intervention will be acceptable to teen mothers (acceptability).	<ul style="list-style-type: none">• Satisfaction	<ul style="list-style-type: none">• Individual question about satisfaction• Narrative comments	<ul style="list-style-type: none">• Descriptive statistics and themes of narrative comments

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The Impact of Routine Nursing Care on Cerebral and Renal Hemdynamic Activity Utilizing Near-Infrared Spectroscopy in the Premature Infant

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Abstract

Problem: Routine nursing care can affect the physiologic stability of the preterm infant. There are few studies that address the frequency of physical assessments and/or endotracheal suctioning as it relates to oxygenation at the tissue level in the kidney and the brain.

Purpose: To assess the impact of routine nursing assessments and endotracheal suctioning on cerebral and renal regional tissue saturation levels (rSO₂) in preterm infants.

Method: Utilizing near-infrared spectroscopy, an observational study of renal and cerebral rSO₂ values was undertaken in preterm infants 24 to 32 weeks gestation. Sensors were placed on the forehead and flank. Recordings were obtained during the first 24 hours after placement of an umbilical artery catheter (UAC). Event markers noted each physical assessment and suctioning episode.

Analysis: A dramatic drop in tissue oxygenation levels in renal and cerebral organ systems was noted in a majority of instances during which physical assessments and/or endotracheal suctioning was performed. The manufacturer proposes that a greater than 20% drop from baseline is significant. On average, the drop in baseline for cerebral oxygenation was 29% and renal oxygenation was 47% with an 11 minute recovery time.

Conclusion: Data revealed that routine assessments and suctioning decreased cerebral and renal perfusion. Findings from this study support the need to decrease the frequency of routine assessments and suctioning and to determine the critical level for change from baseline. Further research is needed to enable development of protocols that minimize the iatrogenics of neonatal intensive care.

M45. Relationship of Clinical Symptoms and Detectability of Influenza Virus in an Adult Population

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Background: Influenza virus epidemics can cause significant morbidity and mortality. In the U.S. an estimated 20,000 deaths and 100,000 hospitalizations occur annually. Fever (101-104° F) is usually regarded as an important symptom for influenza infection along with other symptoms including chills, sweating, myalgia, headaches, runny nose, nasal congestion, cough, sore throat, and fatigue. Accurate detection of influenza virus by laboratory testing combined with clinical presentation is vital for proper patient management. **Objective:** The purpose of this study was to investigate the relationship of clinical symptoms in adult patients with suspected Influenza virus infection and the presence of the virus using two laboratory diagnostic methods for isolation and detection of this virus. **Methods:** Nasopharyngeal (NP) swabs were collected from emergency room patients during the 2008 influenza season. Demographic and observational symptom information was obtained from each patient. Each specimen was tested for the presence of Influenza virus with cell culture (R-Mix™, Diagnostics Hybrids, Athens, OH) and molecular amplification of viral DNA (NucliSENS® EasyQ Influenza A/B assay, bioMérieux, Inc., Durham, NC). **Results:** The study population of 143 adults was comprised of 67 males and 76 females with an age range of 18-62 years (mean=35.35 yrs). Symptoms typical of Influenza virus infection were observed for each patient, with cough (89.5%), myalgia (73%), and chills (57%) being the most prominently observed. The presence of fever was observed in 35% (54/143) of the total patients. Influenza virus was detected in 97 patients (68%), with 71 positive results obtained with both test methods, 25 by molecular testing only, and 1 by cell culture only; Influenza Type A was observed more frequently than Influenza Type B (91 vs. 6, respectively). In the 97 cases in which Influenza virus was detected, fever was observed in 43%; fever was detected in 26% of the patients without detectable virus. **Conclusions:** (1) For patients with positive Influenza test results, the most commonly observed symptoms were cough, myalgia, and fever; for patient with negative test results, the most commonly observed symptoms were cough, myalgia, sore throat, and chills; (2) Molecular testing yielded 28.8% additional positives versus culture; (3) Fever is an important symptom for influenza infection, but the absence of fever appears to occur frequently in adults infected with this virus. This observation may be related to the time of patient presentation for evaluation or self-medication for fever relief.

D-1560 Positive ESBL Screens in *E. coli* (EC), *Klebsiella pneumoniae* (KP), *Klebsiella oxytoca* (KO) and *Proteus mirabilis* (PM) Due to AmpC Production

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Amended Abstract

Background: Isolates of EC, KP, KO, and PM may yield positive CLSI ESBL screens but be ESBL confirmatory test negative due to production of an AmpC β -lactamase. Previous studies have shown that AmpC production may interfere with detection of ESBLs placing infected patients at risk of inappropriate cephalosporin therapy. We investigated the occurrence of ESBL screen-positive, confirmatory test-negative isolates of EC, KP, KO, and PM at a Louisville teaching hospital using a Tris/EDTA-based test for AmpC detection. **Methods:** ESBL screens were performed by microdilution methodology using the 5 CLSI-recommended ESBL screening drugs. 952 isolates (682 EC, 152 KP, 44 KO, and 70 PM) were screened. A Tris/EDTA-based disk test for AmpC detection was performed on all isolates with positive ESBL screens and negative confirmatory tests. **Results:** 29 isolates of EC (4.3% of all EC), 16 KP (10.5%), 3 KO (6.3%), and 0 PM (0%) were ESBL screen-positive but confirmatory test-negative. Of these, 28 EC (97%) and 12 KP (75%) yielded positive AmpC tests. No KO or PM isolates were AmpC-positive. The AmpC-positive KP isolates were assumed to produce plasmid-mediated AmpC β -lactamases because KP does not have a chromosomally-mediated AmpC β -lactamase. The AmpC-positive EC isolates were assumed to produce either chromosomally-mediated or plasmid-mediated AmpC β -lactamases. **Conclusions:** Positive ESBL screens due to AmpC production were detected in EC and KP, but not KO or PM. Because AmpC-producing isolates may also harbor ESBLs that are not detected with the CLSI confirmatory tests, clinical laboratories should 1) be able to test for AmpC production to recognize such isolates, and 2) have the capability to detect ESBLs in AmpC-producing isolates.

Introduction

Detection of AmpC β -lactamases is important because production of these enzymes may interfere with detection of ESBLs placing infected patients at risk of inappropriate therapy [1]. It is currently unknown how often isolates are encountered that require an ESBL detection test that is accurate in the presence of high-level AmpC production. Therefore a study was designed to determine how many isolates of *E. coli*, *Klebsiella pneumoniae*, *K. oxytoca*, and *Proteus mirabilis* in the patient population of a Louisville teaching hospital were ESBL screen positive but confirmatory test negative and produced an AmpC β -lactamase. The aim was to determine how many isolates had the potential for producing a “hidden” ESBL.

Methods

Isolates: During the period 1 May 2006 to 28 February 2007, 952 isolates from patients at the University of Louisville Hospital, Louisville, KY, were analyzed. They comprised 682 isolates of *E. coli*, 152 *K. pneumoniae*, 44 *K. oxytoca*, and 70 *P. mirabilis*

ESBL tests: Isolates were screened for ESBL production by microdilution methodology using the CLSI-recommended screening drugs, cefotaxime, ceftriaxone, ceftazidime, cefpodoxime, and aztreonam. Screen positive isolates were tested by the CLSI ESBL disk confirmatory method [2].

AmpC Tests: All isolates with positive ESBL screens and negative ESBL confirmatory tests were investigated for AmpC production using a Tris/EDTA-based disk test (Figure) [3]. Isolates that were confirmed as ESBL producers were not tested further.

Multiplex PCR: Gene identification was investigated by polymerase chain reaction (PCR) using primers specific for *bla*_{DHA}, *bla*_{FOX}, *bla*_{CMY}, *bla*_{ENT}, *bla*_{ACT}, and *bla*_{ACC} [4].

Results and Discussion

As shown in the Table, the majority of ESBL screen positive isolates were ESBL negative and, on the basis of phenotypic testing, most were AmpC producers. That is, the types of isolates for which CLSI ESBL confirmatory tests are known to be unreliable.

In detail, 37 isolates of *E. coli*, 20 *K. pneumoniae*, 3 *K. oxytoca*, and 1 *P. mirabilis* were ESBL screen-positive. Of these, 8 *E. coli* (22% of the screen-positive *E. coli*), 4 *K. pneumoniae* (25% of the screen-positive *K. pneumoniae*), and 1 *P. mirabilis* were confirmed as ESBL producers by CLSI methodology. Negative ESBL confirmatory tests were obtained for the remaining 29 *E. coli*, 16 *K. pneumoniae*, 3 *K. oxytoca*, and 0 *P. mirabilis*. Of these 28 *E. coli* (97% of screen-positive, confirmatory test negative isolates, or 76% of all screen-positive isolates) and 12 *K. pneumoniae* (100% of screen-positive, confirmatory test negative isolates, or

75% of all screen-positive isolates) yielded positive AmpC tests. No *K. oxytoca* or *P. mirabilis* isolates were AmpC-positive.

The AmpC-positive *K. pneumoniae* isolates were assumed to produce plasmid-mediated or imported AmpC β -lactamases because *K. pneumoniae* does not have a chromosomally-mediated AmpC β -lactamase. PCR testing of 6 representative *K. pneumoniae* isolates identified a FOX-like β -lactamase gene in all 6 isolates.

The remaining AmpC-positive *E. coli* isolates that were not tested by PCR were assumed to produce either chromosomally-mediated or plasmid-mediated AmpC β -lactamases.

Conclusions

1. Positive ESBL screens were more often associated with AmpC production than ESBL production.
2. This is a concern because AmpC-producing isolates may harbor ESBLs that are not detected with the CLSI confirmatory tests.
3. Clinical laboratories need to be able to test for:
 - a. AmpC production to recognize isolates in which ESBL detection is problematic, and
 - b. ESBLs in AmpC-producing isolates (e.g. by detecting enhanced cefepime activity in the presence of clavulanate).
4. These findings are specific for a particular time period and patient population. Their applicability to other patient populations is unknown.

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Table. ESBL Screen-positive Isolates that Produced Extended Spectrum or AmpC β -lactamases

Species	ESBL Screen Positive	ESBL Positive ¹	AmpC Positive
<i>E. coli</i>	37	8 (22%)	28 (76%)
<i>K. pneumoniae</i>	16	4 (25%)	12 (75%)
<i>K. oxytoca</i>	3	0	0
<i>P. mirabilis</i>	1	1	0

¹ AmpC status not investigated if ESBL confirmed

Figure. Positive AmpC Disk Test



Tris/EDTA disk test with distortion of zone surrounding a cefoxitin disk indicating positive test. The test isolate was inoculated onto the upper disk (Tris/EDTA) and *E. coli* ATCC 25922 was the lawn culture used as an assay organism to visualize the inactivation of cefoxitin by β -lactamase derived from the test isolate.

Sample Poster Presentations of Findings

Acceptability, Feasibility, and Efficacy of New Mother Program: Telephone Based Depression Care Management with Adolescent Mothers

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Background & Significance

- Up to 50% of adolescent mothers have symptoms of depression throughout the first postpartum year (Reid & Meadows, 2007) with potential long term adverse consequences on development of mother and baby (Jolley et al., 2009).
- However, few adolescent mothers receive mental health evaluation or treatment. Logsdon et al. determined that there were no differences between rates of depression in adolescent mothers at 12 months postpartum (Logsdon et al., 2005; Logsdon, 2008), and that no adolescent mothers pursued referrals for mental health treatment.
- Barriers to treatment include lack of knowledge, life stressors, and limited access to mental health services barriers (Logsdon et al., 2009 a, b).

Collaborative Care

Collaborative care that includes a DCM and psychiatric consultation is an effective mechanism to increase patient adherence to treatment, and the results are long lasting (Gibody et al., 2005).

The role of DCM includes education, monitoring depression symptoms, and facilitating treatment.

Telephone Interventions

Telephone is a powerful tool in enhancing rates of psychiatric treatment (Dietrich, 2000).

Dr. Katherine Wisner has successfully utilized telephone based DCM with adult postpartum women at UPAC, but use in adolescent mothers has not been tested (Wisner, Scholle, & Stein, 2008).

Purpose

The aim of the study was to determine the acceptability, feasibility, and efficacy of telephone based depression care management in reducing depressive symptoms in adolescent mothers.

Theoretical Frameworks

- Theory of Planned Change (Prochaska & Velicer, 1977)
- Adolescent Development Theory (Erikson, 1959)
- Principles of Family Intervention (Josephson, 2008)

METHODS

Adolescent mothers (n=97) were recruited from public school. An experienced child/adolescent psychiatric clinical nurse specialist (DCM) delivered the intervention. Fidelity of intervention was established. Independent evaluators who were blind to study aims conducted baseline, three month, and six month evaluations of all participants, i.e., those who are enrolled in the intervention and the control group (low depressive symptoms at baseline).

Results: Acceptability & Feasibility



Figure 1 - Phase 1 Clinical Trial

RESULTS: Initial Efficacy

Use of Mental Health Services Across Time

Variable	0	1	6	6	6	6	6	6
Average visits to hospital or other treatment facility for mental health problems	3.24	3.18	0.97	1.21	1.36	0.98		
Average visits to hospital or other treatment facility for any personal or family problems	0.00	0.19	0.00	0.40	0.00	0.00		
Average visits to hospital emergency room	1.00	2.79	0.10	0.71	0.52	0.00		
Average visits to hospital emergency room	10.91	10.41	1.19	1.07	1.00	1.00		
Average visits to hospital emergency room	0.00	2.00	0.10	0.40	0.00	0.00		
Average visits to hospital emergency room	1.00	0.48	0.23	0.40	0.25	0.07		

Measures of Depression Symptoms and Functioning: Intervention and Non-Intervention Groups

Intervention Measure	Time 1	Time 2	Time 3
CES-D (Depression)	M = 24.08	M = 14.14	M = 15.00
CES-D (Functioning)	M = 10.38	M = 6.40	M = 4.70
GHAT (Depression)	F(4, 8) p = 0.00	F(2, 16) p = 0.00	F(1, 8) p = 0.00
GHAT (Functioning)	M = 10.28	M = 10.07	M = 10.07
GHAT (Functioning)	M = 10.03	M = 10.70	M = 10.04
GHAT (Functioning)	F(1, 16) p = 0.11	F(1, 8) p = 0.36	F(1, 8) p = 0.15
GHAT (Functioning)	M = 7.18	M = 7.18	M = 7.18
GHAT (Functioning)	M = 10.38	M = 10.38	M = 10.38
GHAT (Functioning)	F(1, 8) p = 0.00	F(1, 8) p = 0.00	F(1, 8) p = 0.00

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Depression Care Management

- Intervention delivered by Depression Care Manager (Psychiatric Clinical Nurse Specialist) to assist in the adolescent mother with decision making and decrease barriers to depression treatment.
- DCM encourages and manages and engages family in supportive services that are culturally appropriate and age appropriate.
- DCM monitors depressive symptoms, discusses barriers to depression treatment, and provides referrals for mental health services and other appointments. The DCM helps the adolescent to plan her next steps.
- DCM encourages use of community resources.
- DCM provides information regarding depression by notifying provider that adolescent is enrolled in New Mother Program.
- DCM assists adolescent and family with obtaining emergency treatment.
- DCM confirms compliance with appointments, and treatments with the adolescent and family. The DCM provides a final report to the provider at the completion of the New Mother Program.

Discussion

Contrary to findings in our previous study in which symptoms of depression were elevated in adolescent mothers who were present at 12 months postpartum, in this study symptoms of depression improved with the DCM intervention. However, the study has several limitations and threats to validity. One child/adolescent CNS delivered the telephone based depression care management intervention. Her skills, as opposed to the New Mother Program itself, could be responsible for improved depression scores. In addition, depressive symptoms of the adolescent mothers could have improved over time without the intervention. A larger, longitudinal RCT would address limitations and allow a comparison of the intervention with Usual Care in adolescent mothers with symptoms of depression over a longer time period.

Research Implications

Women's Health Nurse Practitioners are well positioned to screen adolescent mothers for symptoms of depression during the perinatal period, and to make referrals for those in need of treatment. A prudent mental health referral would include services that help adolescent mothers to overcome individual barriers to treatment, such as that provided by a DCM.

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D-1560

Positive ESBL Screens in *E. coli* (EC), *Klebsiella pneumoniae* (KP), *Klebsiella oxytoca* (KO) and *Proteus mirabilis* (PM) Due to AmpC Production

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Amended Abstract

Background: Isolates of EC, KP, KO, and PM may yield positive CLSI ESBL screens but be ESBL confirmatory test negative due to production of an AmpC β -lactamase. Previous studies have shown that AmpC production may interfere with detection of ESBLs placing infected patients at risk of inappropriate cephalosporin therapy. We investigated the occurrence of ESBL screen-positive, confirmatory test-negative isolates of EC, KP, KO, and PM at a Louisville teaching hospital using a Tris/EDTA-based test for AmpC detection. **Methods:** ESBL screens were performed by microdilution methodology using the 5 CLSI-recommended ESBL screening drugs. 952 isolates (682 EC, 152 KP, 44 KO, and 70 PM) were screened. A Tris/EDTA-based disk test for AmpC detection was performed on all isolates with positive ESBL screens and negative confirmatory tests. **Results:** 29 isolates of EC (4.3% of all EC), 16 KP (10.5%), 3 KO (6.3%), and 0 PM (0%) were ESBL screen-positive but confirmatory test-negative. Of these, 28 EC (97%) and 12 KP (75%) yielded positive AmpC tests. No KO or PM isolates were AmpC-positive. The AmpC-positive KP isolates were assumed to produce plasmid-mediated AmpC β -lactamases because KP does not have a chromosomally-mediated AmpC β -lactamase. The AmpC-positive EC isolates were assumed to produce either chromosomally-mediated or plasmid-mediated AmpC β -lactamases. **Conclusions:** Positive ESBL screens due to AmpC production were detected in EC and KP, but not KO or PM. Because AmpC-producing isolates may also harbor ESBLs that are not detected with the CLSI confirmatory tests, clinical laboratories should 1) be able to test for AmpC production to recognize such isolates, and 2) have the capability to detect ESBLs in AmpC-producing isolates.

Introduction

Detection of AmpC β -lactamases is important because production of these enzymes may interfere with detection of ESBLs placing infected patients at risk of inappropriate therapy [1]. It is currently unknown how often isolates are encountered that require an ESBL detection test that is accurate in the presence of high-level AmpC production. Therefore a study was designed to determine how many isolates of *E. coli*, *Klebsiella pneumoniae*, *K. oxytoca*, and *Proteus mirabilis* in the patient population of a Louisville teaching hospital were ESBL screen positive but confirmatory test negative and produced an AmpC β -lactamase. The aim was to determine how many isolates had the potential for producing a "hidden" ESBL.

Methods

Isolates: During the period 1 May 2006 to 28 February 2007, 952 isolates from patients at the University of Louisville Hospital, Louisville, KY, were analyzed. They comprised 682 isolates of *E. coli*, 152 *K. pneumoniae*, 44 *K. oxytoca*, and 70 *P. mirabilis*.

ESBL tests: Isolates were screened for ESBL production by microdilution methodology using the CLSI-recommended screening drugs, ceftaxime, ceftazidime, ceftiofime, and aztreonam. Screen positive isolates were tested by the CLSI ESBL disk confirmatory method [2].

AmpC Tests: All isolates with positive ESBL screens and negative ESBL confirmatory tests were investigated for AmpC production using a Tris/EDTA-based disk test (Figure) [3]. (Isolates that were confirmed as ESBL producers were not tested further.)

Multiplex PCR: Gene identification was investigated by polymerase chain reaction (PCR) using primers specific for bla_{HDH}, bla_{FOX}, bla_{CIMY}, bla_{ENT}, bla_{ACT}, and bla_{CC} [4].

Results and Discussion

As shown in the Table, the majority of ESBL screen positive isolates were ESBL negative and, on the basis of phenotypic testing, most were AmpC producers. That is, the types of isolates for which CLSI ESBL confirmatory tests are known to be unreliable.

In detail, 37 isolates of *E. coli*, 20 *K. pneumoniae*, 3 *K. oxytoca*, and 1 *P. mirabilis* were ESBL screen-positive. Of these, 9 *E. coli* (22% of the screen-positive *E. coli*), 4 *K. pneumoniae* (25% of the screen-positive *K. pneumoniae*), and 1 *P. mirabilis* were confirmed as ESBL producers by CLSI methodology. Negative ESBL confirmatory tests were obtained for the remaining 29 *E. coli*, 16 *K. pneumoniae*, 3 *K. oxytoca*, and 0 *P. mirabilis*. Of these 29 *E. coli* (97% of screen-positive, confirmatory test negative isolates, or 76% of all screen-positive isolates) and 12 *K. pneumoniae* (100% of screen-positive, confirmatory test negative isolates, or 75% of all screen-positive isolates) yielded positive AmpC tests. No *K. oxytoca* or *P. mirabilis* isolates were AmpC-positive.

The AmpC-positive *K. pneumoniae* isolates were assumed to produce plasmid-mediated or imported AmpC β -lactamases because *K. pneumoniae* does not have a chromosomally-mediated AmpC β -lactamase. PCR testing of 6 representative *K. pneumoniae* isolates identified a FOX-like β -lactamase gene in all 6 isolates.

The remaining AmpC-positive *E. coli* isolates not tested by PCR were assumed to produce either chromosomally-mediated or plasmid-mediated AmpC β -lactamases.

Table. ESBL Screen-positive Isolates that Produced Extended Spectrum or AmpC β -lactamases

Species	ESBL Screen Positive	ESBL Positive ¹	AmpC Positive
<i>E. coli</i>	37	8 (22%)	28 (76%)
<i>K. pneumoniae</i>	16	4 (25%)	12 (75%)
<i>K. oxytoca</i>	3	0	0
<i>P. mirabilis</i>	1	1	0

¹ AmpC status not investigated if ESBL confirmed

Figure. Positive AmpC Disk Test



Tris/EDTA disk test with distortion of zone surrounding a cefoxitin disk indicating positive test. The test isolate was inoculated onto the upper disk (Tris/EDTA) and *E. coli* ATCC 25922 was the lawn culture used as an assay organism to visualize the inactivation of cefoxitin by β -lactamase derived from the test isolate.

Conclusions

Positive ESBL screens were more often associated with AmpC production than ESBL production. This is a concern because AmpC-producing isolates may harbor ESBLs that are not detected with the CLSI confirmatory tests.

Clinical laboratories need to be able to test for AmpC production to recognize isolates in which ESBL detection is problematic, and ESBLs in AmpC-producing isolates (e.g. by detecting enhanced cefepime activity in the presence of clavulanate). These findings are specific for a particular time period and patient population. Their applicability to other patient populations is unknown.

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The Impact of Routine Nursing Care on Cerebral and Renal Hemodynamic Activity Utilizing Near-Infrared Spectroscopy in the Premature Infant

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Introduction

- Routine nursing assessments including physical exams, vital signs, and suctioning in this level III Neonatal Intensive Care Unit are required every four hours.
- Routine nursing care can affect the physiologic stability of the preterm infant.
- There are few studies that address the impact of physical assessments and/or endotracheal suctioning as it relates to oxygenation at the tissue level in the kidney and the brain. In addition, there is little evidence to support the frequency of these practices.
- Care of the preterm infant should include a focus on survival without neurological impairment.
- The purpose of this study is to assess the impact of routine nursing assessments and endotracheal suctioning on cerebral and renal venous weighted regional hemoglobin oxygen saturation levels (rSO₂) in preterm infants.



Methods

- Utilizing the Somanetics INVOS System, Cerebral/Somatic Oximetry® near-infrared spectroscopy, an observational study of renal and cerebral rSO₂ values were undertaken in 14 preterm infants at 24 to 32 weeks gestation. A single case study is presented here.
- Sensors were placed on the forehead and flank. Recordings were obtained during the first 24 hours after placement of an umbilical artery catheter (UAC).
- Event markers noted each nursing assessment and suctioning episode.

Results



- Twenty-four week gestational infant at rest (graph 1).
- Cerebral and peri-renal saturations of 68 and 85 respectively were noted during routine nursing assessment. There were markedly decreasing values in regional oxygen saturation occurring for over 9 minutes (graph 2).
- Routine endotracheal tube suctioning revealed a cross-over between the cerebral and peri-renal oxygen trends and was noted at the lowest saturation (graph 3).
- Percent of decrease from baseline of cerebral saturations (18%) was not as severe as the peri-renal saturation (33%) suggesting the shunting of blood from the periphery to more critical areas such as the brain. Recovery to baseline occurred after 37 minutes (graph 4).

Analysis

- A dramatic drop in regional hemoglobin oxygen saturation levels in renal and cerebral organ systems was noted in a majority of instances during which nursing assessments and/or endotracheal suctioning was performed.
- On average, the drop in baseline for cerebral rSO₂ was 29% and renal rSO₂ was 47% with a 19.4 minute recovery time.
- The manufacturer proposes that a greater than 20% drop from baseline is a significant event.

Conclusions

- By using the noninvasive INVOS System, healthcare providers could utilize cerebral and peri-renal saturations to guide clinical practice of routine nursing care in the NICU.
- Findings from this study suggest that there is a need to decrease the frequency of routine assessments and suctioning and to determine the critical level for change from baseline.
- Further research is needed to enable development of protocols that minimize the iatrogenics of neonatal intensive care and to determine the critical level of change in rSO₂ from baseline.



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