A MEDICATION RECONCILIATION EDUCATIONAL INTERVENTION TO IMPROVE MEDICATION ADHERENCE IN A MEDICALLY UNDERSERVED POPULATION: A PILOT STUDY

An Evidence-Based Practice Research Grant Proposal

Presented to the faculty of the School of Nursing

California State University, San Marcos

Submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

in

Nursing

(Nursing Education)

by

Virgie Stella Delgado, RN, BSN

SPRING SEMESTER

2013
CALIFORNIA STATE UNIVERSITY SAN MARCOS

PROJECT SIGNATURE PAGE

PROJECT SUBMITTED IN PARTIAL FULLFILLMENT
OF THE REQUIREMENTS FOR THE DEGREE

MASTER OF SCIENCE

IN

NURSING

PROJECT TITLE: A Medication Reconciliation Educational Intervention to Improve Medication Adherence in a Medically Underserved Population: A Pilot Study

AUTHOR: Virgie Stella Delgado, RN, BSN

DATE OF SUCCESSFUL DEFENSE: 04/23/2013

THE PROJECT HAS BEEN ACCEPTED BY THE PROJECT COMMITTEE IN PARTIAL FULLFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING.

Dr. Karen McGurk
PROJECT COMMITTEE CHAIR

Dr. Denise Boren
PROJECT COMMITTEE MEMBER

SIGNATURE
DATE

04/23/2013
Student: Virgie Stella Delgado, RN, BSN

I certify that this student has met the School of Nursing format requirements, and that this project is suitable for shelving in the Library and credit is to be awarded for the project.

[Signature]
Dr. Denise Boren
Director

Date: 5/12/13

School of Nursing
College of Education, Health, and Human Services
California State University San Marcos
Abstract

of

A Medication Reconciliation Educational Intervention To Improve Medication Adherence

In A Medically Underserved Population: A Pilot Study

by

Virgie Stella Delgado, RN, BSN

Statement of Problem
Medication non-adherence is a significant problem in health care because medications are critical to care. Medication non-adherence causes about 10% of hospitalizations (Mann, 2009); and since 2001 has caused 1.1 million deaths in the U.S. (New England Health Institute, 2009). Significant to public health is the impact this problem has in medically underserved adults who lack finances, health insurance, and have inadequate access to health care (Jackson, 2011). According to the literature, individual barriers exist (Bohlman, 2004). A patient’s ability to adhere is dependent on their personal struggles, perceptions, personal choice to adhere, and patterned behaviors. Data links patient medication reconciliation, adhering aiding tools, and education with decreased outpatient visits and hospitalizations at a cost to savings ratio ~1:10 with long-term results (National Council on Patient Information and Education, 2007). Educational interventions addressing disease/medication knowledge, medication safety, and self-management are effective in improving adherence (Bohlman, 2004). Limited evidence exists on the benefits of such interventions in the medically underserved. Additional research needs to test the utility and efficiency of this intervention in the medically underserved.

Sources of data
A convenience sample of medically underserved adults seeking healthcare at a free clinic project, in a small coastal community in southern California, will provide data. A questionnaire adapted from the 2010 U.S. Census will serve to collect descriptive and representative data of the sample. A medication record review will help compare the prescribed medications to actual medications taken; a Medication Discrepancy Tool will serve to document then report discrepancies found (Smith, Coleman, Min, 2004). A manual pill count will provide a ratio measure of adherence, both pre and post intervention. Finally, a Medicine Knowledge Assessment form will help to identify gaps in knowledge.

Conclusion
Findings of this quasi-experimental one group pretest post-test pilot study is expected to show that improving the patient’s medication and disease education, tailoring medication routines, and improving self-management skills will increase adherence.

Key words: medication reconciliation, medication discrepancies, adherence/non-adherence, medication communication, health literacy, self-management, medically underserved

Karen McGurk, Committee Chair or Director 4/23/13

Date
DEDICATION

I would like to dedicate this proposal first to GOD: Thank you for being with me always providing guidance and direction. For blessing my life with opportunities to help the sick and the needy here on earth. I acknowledge that without you such opportunities and accomplishments are meaningless. Thank you for making a way for me to accomplish this goal. I trust that you will continue to lead, guide and direct me.

To my deceased mother who taught me invaluable lessons in life; especially “never surrender”. Mother, this accomplishment is more yours than it is mine. I achieve this goal because as I watched you live your life, it taught me to work hard, endure and persevere. You inspired me to never give up on this dream, no matter the obstacles or challenges. To believe that I have the ability to help those in need. Here is to you; the outcome of your love, commitment, dedication and devotion. Losing you has by far been the greatest challenge of my life… In Loving Memory of an Awesome Mother and best friend:

Olivia Maria Diaz

Rest in Peace

11/12/42 ~ 6/27/09

Always in my heart, never forgotten
ACKNOWLEDGEMENTS

This project is the end of a joint effort; it could not have been completed in solitude. I wish to thank individuals who contributed to this proposal. I am deeply grateful to California State University San Marcos, School of Nursing’s Graduate Program—its faculty and staff, for encouraging and guiding me in this path. I thank my committee chair, Dr. Karen McGurk, as well as my committee member Dr. Denise Boren, who read my revisions and assisted in making sense of this arduous process. A heart-felt thank you to Professor Claire Mouw and Professor Stacy Campo for inspiring, motivating and encouraging me to press forward with my goal of becoming a nurse educator. Their professionalism, understanding of the adult learner, ability to engage and stimulate students, have served as a beacon for me; showing by example what a life of commitment and hard work can ultimately achieve. On days when I felt like an exacerbated runner, desperately trying to get to a finish line I doubt existed; it was their encouraging words that gave me strength to propel forward. As I reminisce on this journey, I know it was worth the time and effort because these Professors were running by my side, every step of the way.

To my first and most formative mentor, Ms. Erma Moore, MSN, thank you for being an outstanding role model; for creating in me a love for the field of geriatrics and supporting my career endeavors since my first day at Visiting Nurse Service of New York. For stimulating and sharing ideas on the topic of Medication Adherence. Your wisdom, care and guidance have served as inspirational gifts.

To my loving husband and pillar of support, David thank you for the humor, understanding, and encouragement serving to propelled me to achieve success. You make me realize the importance and value of my inner strength, motivation and faith in God.
To my Daughters Tiffany Marie and Cassie Nicole, thank you for your support, words of encouragement, unconditional love, and for understanding my severe time constraints. Cassie, thank you for walking along my side, every step of this journey. Your constant stimulation enabled me to aim high. You have inspired me to never give in or give up, no matter the obstacles. You are my “NO-NONSENSE HERO”!

To my beautiful granddaughters, Natalya Elise, Naylise Olivia-Marie, Ava Kamalani and Amaris Taina, you are all true heavenly blessings. You make me want to continue being a positive role model; passing along this love for learning. Natalya and Naylise thank you for making me laugh, especially on days when school work was taxing and overwhelming. You were both a momentary relieve from the academic chaos.

To my appointed extended family members, thank you for existing and being you; it helped to form and shape the person I am today, enabling me to understand the purpose and role your existence played in this journey.

A heart-felt appreciation to my spiritual family members “the TDC crew” blood could not have brought us any closer. Linda and Elliot Vazquez, Jael and Dora Suarez, Lourdes Lopez, Dulce Cruz, the Cepeda family, Primabera, Ariel, Mikey and Nancy Vazquez; thank you for the ongoing years of true kinship, prayers, encouraging phone calls, unwavering support, belief in my abilities and unconditional love. As the years have passed, I understand Gods purpose for keeping you at my side. It has allowed me to endure the most challenging moments in my life, including this arduous process. Finally, to my beloved late mother Olivia Maria Diaz, who passed down her love for the “TDC crew” and left me an amazing support system. Mom your words of encouragement are still deeply embedded in me, thank you. I can still hear your favorite phrase “I just knew you could do it!” Forever missed, always present in my heart.
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Department of Health and Human Services Public Health Services

Grant Application
Do not exceed character length restrictions indicated.

1. TITLE OF PROJECT (Do not exceed 81 characters, including spaces and punctuation.)
   A Medication Reconciliation Educational Intervention To Improve Adherence In... A Pilot Study

   Number: PA-12-023  Title: Primary Interventions To Improve Adherence in Primary Care

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION
   (If “Yes,” state number and title)
   NO  □ YES

3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR
   3a. NAME (Last, first, middle)
       Delgado, Virgie S.

       3c. POSITION TITLE (Graduate Student)

6. DATES OF PROPOSED PERIOD OF SUPPORT (month, day, year—MM/DD/YY)
   From 09/01/13 Through 06/01/14

7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD
   7a. Direct Costs ($)  7b. Total Costs ($)  8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT
   $ 53,461.70  $53,461.70  8a. Direct Costs ($)  8b. Total Costs ($)  $68,430.98

9. APPLICANT ORGANIZATION
   Name
   CSUSM School of Nursing

10. TYPE OF ORGANIZATION
    Public:  □ Federal  □ State
           Local Private:  □ Private
           Nonprofit
           For-profit:  □ General  □ Small Business

11. ENTITY IDENTIFICATION NUMBER
    DUNS NO.  XXXXXXXX  Cong. District  XXXXXXXX

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE
    Name XXXXXXXXXXXXXXXX
    Title Sponsor Project Administrator
    Address
    CSUSM UARSC
    333 S. Twin Oaks Valley Rd.
    San Marcos, CA 92096
    Tel: 760-750-4000
    FAX: 760-750-4710

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
    Name XX XXXX XXXX Title XX XXXX XXXX
    Address
    CSUSM
    333 S. Twin Oaks Valley Rd.
    San Marcos, CA 92096
    Tel: XXX-XXX-XXXX FAX: XXX-XXX-XXXX
    E-Mail: XXXX@csusm.edu

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, administrative penalties

   SIGNATURE OF OFFICIAL NAMED IN 13.  (In ink. “Per” signature not acceptable.)  DATE
   XX/XX/XX

OMB No. 0925-0001

LEAVE BLANK—FOR PHS USE ONLY.

Type  Activity  Number
Review Group  Formerly
Council/Board (Month, Year)  Date Received
PROJECT SUMMARY (See instructions):
Medication adherence is defined by the World Health Organization as the “extent to which a person’s behavior in taking medication... corresponds with agreed recommendations from a health care provider” (p. 3, 2003). Medication non-adherence, not taking medication as indicated, is a global, dangerous and costly medical problem, concerning among older adults and the medically underserved. Older adults are at a risk due to age-related changes and multiple chronic conditions that often require multiple medications prescribed by multiple providers who often do not communicate; while the medically underserved are also at risk due to a limited or lack of insurance and financial resources making it difficult to obtain care.

Not following the medication regimen increases health care spending, and can potentially lead to disability and early death. The primary aim of the proposed quasi-experimental one group pre-test, post-test Evidence-Based Practice (EBP) pilot study is to test the effects of a medication reconciliation educational intervention to improve medication adherence, in medically underserved adults seeking healthcare at a free clinic project, in a small coastal community in southern California. The secondary aim is to intercept medications discrepancies that can potentially cause harm and lead to medication non-adherence. The aims will be accomplished by meeting the following objectives:

**Objective 1.** Institute an EBP medication reconciliation educational intervention that will involve: medication reconciliation-correcting discrepancies; a pill count to measure adherence; disease and medication education; while addressing the behavior component of medication taking. Adhering-aiding tools will assist patients in establishing their patterned behavior for medication taking at home.

**Objective 2.** Evaluate the effectiveness of the intervention to measure the outcomes of interest-Adherence:
- a) Medication Ratio: find statistical differences in medication adherence using manual pill counts;
- b) Medication Discrepancy Tool (MDT): find statistical differences in medication discrepancies;
- c) Medication Knowledge Assessment Form: assess improvements in medication knowledge pre and post intervention.

**Research Question#1:** Does a medication reconciliation educational intervention improve medication adherence in medically underserved?

**Question #2** Does a Medication reconciliation educational intervention intercept medication discrepancies?

RELEVANCE (See instructions):
Data links patient self-management and adherence programs with decreased hospitalizations, days in a hospital and outpatient visits; a cost to savings ratio ~1:10 in some cases, with long-term results. (National Council on Patient Information and Education, 2007). In addition to the potential cost savings impact, the proposed pilot study will expand future nursing research, care, and medication management in the medically underserved.

PROJECT/PERFORMANCE SITE(S) (if additional space is needed, use Project/Performance Site Format Pages)

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<td>Street1: 4790 Santa Monica Avenue Street2:</td>
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<td>City: Ocean Beach County: San Diego State: California</td>
</tr>
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<td>Province: Country: USA Zip/PostalCode: 91120</td>
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<td>Project/PerformanceSiteCongressionalDistricts: 53rd Congressional District</td>
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Program Director/Principal Investigator: Delgado, Virgie S.

SCIENTIFIC/KEY PERSONNEL. See instructions. Use continuation pages as needed to provide the required information in the format shown below. Start with Program Director(s)/Principal Investigator(s). List all other key personnel in alphabetical order, last name first.

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<td></td>
<td>CSUSM, SON</td>
<td>PI</td>
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OTHER SIGNIFICANT CONTRIBUTORS

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<td>Methodologist: Consultant</td>
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Human Embryonic Stem Cells  ☒ No  Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp. Use continuation pages as needed.

If a specific line cannot be referenced at this time, include a statement that one from the Registry will be used.

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<td>17. Appendix A-1: Literature Review Chart Summary</td>
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<tr>
<td>18. Appendix B: Participant Consent/Authorization form</td>
<td>B1-B4</td>
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<td>19. Appendix C: Basic Demographic Questionnaire</td>
<td>C1-C4</td>
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<tr>
<td>20. Appendix D: Medication Discrepancy Tool, Just ask MDT Tool, MDT Psychometric Properties,</td>
<td>D1-D3</td>
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<td>21. Appendix E: Medication Knowledge Assessment Instructions and Form</td>
<td>E1-E2</td>
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<tr>
<td>Medication List for Wallet</td>
<td>F3-F5</td>
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<td>Pillbox and Medication Bag</td>
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*Follow the page limits for these sections indicated in the application instructions, unless the Funding Opportunity Announcement specifies otherwise.
## Detailed Budget for Initial Budget Period

**Direct Costs Only**

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**Subtotals**

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**Consultant Costs**

1) TBD: Statistician Consultant (AI), 20 hours total in 6 months (10 hours for pre-test consult, 10 hours for post-test consult) $150.00/hour for a total of $3,000 for the Statistician Consultant; 2) TBD: Methodologist Consultant (AI), 40 hours total in 6 months, $75.00/hour for a total of $3,000 for the Methodologist Consultant.

**Equipment**

N/A

**Supplies**

- Lap top, printer, diskettes, external hard drives, CDs, paper, printer cartridges, general office supplies: pens, pencils, paper clips, post notes, copier expenses, staples, stapler, dissemination supplies;
- Software: qualitative data management software, SPSS 20.0 Statistical software

**Travel**

Airfare, lodging, meals, car rental, taxi, gas, conference registration fees

**Inpatient Care Costs**

N/A

**Outpatient Care Costs**

N/A

**Alterations and Renovations**

N/A

**Other Expenses**

Dissemination supply expense, poster for presentation, postage stamps, copier expense; medication adherence tools: insulated medication bags, jumbo pill box, printed medication cards, printed medication lists, educational booklets, program brochures/poster's to advertise the study, business cards, pill counter.

**Consortium/Contractual Costs**

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## BUDGET FOR ENTIRE PROPOSED PROJECT
**PERIOD DIRECT COSTS ONLY**

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### TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD

**$53,461.70**

**JUSTIFICATION.** Follow the budget justification instructions exactly. Use continuation pages as needed.
Budget Justification

Personnel Cost: **$26,838.00**

*Virgie S. Delgado, RN, BSN will serve as Principle Investigator (PI)* for this quantitative pilot study project. Mrs. Delgado is a graduate student prepared in Advance Practice-Community Health. She will be responsible for the overall direction of the project including (1) presenting the protocol before the Institutional Review Board and the Graduate Student Committee, (2) coordinating the efforts of the project team, (3) leading project team meetings before, during, and after the study, (4) overseeing the study budget, (5) preparing the reports for transcription, and (6) presenting the outcome of the study, (7) complying with the California State University San Marcos and CSUSM School of Nursing policies and procedures related to project management and personnel policies, and (8) complying with all sponsor rules, regulations and or terms and conditions of the award. Her salary will be paid through the grant award.

PI’s yearly salary is: $60,000/12 = $5,000 X 6 months = $30,000 X .30 (devoted time) = $9,000 + X .26 (fringe) = $2,340 = Total project salary for the PI = **$11,340.00**

**TBA. Mentor and Associate Investigator (AI).** The ideal candidate for this mentor and Associate Investigator (AI) position will be a doctorally prepared faculty member who has performed multiple qualitative and quantitative research studies and received prior funding for grant proposals. For the proposed project, this candidate will devote 20% of his/her time. This individual will be responsible for providing guidance to the PI on the overall direction of the project including (1) presenting the protocol before the Institutional Review Board initially and annually, (2) coordinating the efforts of the project team and (3) attending at least five (5) project team meetings in person or telephonically. As a faculty member at CSUSM SON, the candidate’s salary should be paid by CSUSM and he/she will request 10% “buy-out” time from the grant.

The AI salary is: $73,000. The total of the payment will be calculated for the AI as follows: $73,000/12 = $6,083.33 X 6 months = $36,499.99 X .20 (devoted time) = $7,300 + X .26 (fringe) = $1,898 = Total project salary for the AI = **$9,198.00**

**TBA. Research assistant (RA).** The ideal candidate for this project’s position of Research Assistant will be a Masters prepared individual with at least two years’ experience as a Research Assistant. This individual will be the primary liaison between the data collection site and will be responsible for explaining the project to participants and staff members, and securing meeting space for the project teams. The RA will devote 100% of his/her time to this project, 1) Responsibilities will include:
transporting material to and from the project site, 2) assisting with the data collection from participants over the course of the [6 months] project, including checking returned forms and surveys for completeness and initial coding of the structured questionnaires, 3) inputting data into SPSS 20.0 analysis software and 4) assisting with transcription and analysis of qualitative data including loading transcribed data into a variety of computer assisted qualitative data analysis software. The RA will be an employee on this project, devoting 20% of his/her time to this project.

The RA’s yearly salary is: $50,000.00. The total payment will be calculated as follows: $50,000/12 = $4166.66 X 6 months = $25000 X .20 (devoted time) = $5,000 + X .26 (fringe) = $1,300 = Total project salary for the RA = $6,300.00

**Mentors: $6,000**

**TBA. Quantitative Statistical Mentor.** The ideal candidate for this position will provide guidance and mentoring in statistical methodology and data analysis including but not limited to multiple correlational analyses. The person will provide 20 hours of statistical consultation at a price of $150.00 per hour for a total of 20 hours mentoring time in 6 months.

*Total estimated cost for this expense: $3,000.*

**TBA. Methodologist Mentor.** The ideal candidate for this mentoring position will provide methodology guidance and direction for the intervention portion of the study, to assist the PI. The person will provide 40 hours of Methodology services in years 01 at a price of $75.00 an hour for a total of 40 hours mentoring time in 6 months.

*Total estimated cost for this expense: $3,000*

**Major Equipment:** N/A

**Materials/computer supplies: $5,955.00**

**Computer CDs and Diskettes.**

*Laptop computer and dedicated printer:* needed to generate reports, correspondence, flyers, and to store and analyze data in study ($1,500 for the computer and $200 for the printer).

*Total cost estimated for this expense: $1,700*

**External hard drive, CDs and diskettes:** will be used to back up data on hard-drive and diskettes, total cost estimated for this expense: **$350.00.**

Printer ink cartridges: **$550.00.**
Software:

**TBA: Qualitative Data Management Software:** facilitates the activities involved in analysis and interpretation of qualitative data: selecting, coding, annotating, and comparing segments; provides a comprehensive overview of work as well as rapid search, retrieval and browsing of all data segments and notes relevant to an idea; enables building of unique networks which allows the connection of SPSS 20.0 Statistical software product for data management and analysis includes Base 13 for Windows and ($1,400) and Advanced Models module ($775).

*Total cost estimated for this expense: $2175.*

**General Office Supplies:**

General office supplies (pens, pencils, staplers, paper clips, post notes) needed for this study.

Total cost estimated for general office supplies: **$1,000.00**

**Copy paper:** needed for questionnaires, forms, correspondence, and transcribed data to include consent forms, disease and medication patient educational materials, and interim/final reports; $30/case x 6 cases x 6 months. *Total cost estimated for this expense: $180.*

**Travel Costs:** $8,550

*PI out of area Travel to facility site for pre-test, post test data collection (10 days total):*

**Car rental:** $76.25 per day x10 days total (5 during pretest, 5 during posttest) =

*Total cost estimated for PI car rental: **$762.50***

**Lodging:** $133.00 x 8 nights (4 nights at pre-test, 4 nights at post-test)

*Total cost estimated for PI lodging: **$1064.00***

**Per Diem Meals:**

*Per diem meals first and last day of travel $53.25 + per diem meals during pre & post-test intervention days $71.00. Total cost estimated for PI per diem meals: **$674.50**

Research team travel. Evidence-based project leaders (or primary consultants) will meet once in six months at the major project site. *Total estimated cost for research team travel: **$3,074**

Travel for dissemination of evidence-based findings. Project leaders (or primary research consultants) will present evidence-based findings at one national nursing conference at the end of the study $4,200  (4,200 x 1 projects) is requested for this expense, which will cover conference registration fees, airfare, lodging, per diem, and car rental and meals.

*Total cost estimated for this expense: **$2975**

Research-related Patient Costs: **NA**
**Total Other Expenses:** $6118.70

A. Total Additional Expenses: $980.00

*Dissemination additional supply costs, One Poster:* One presentation is requested for dissemination of findings. Media graphics services. A poster will be used to assist in presenting & disseminating findings of the project. Media graphics professionally produces tabletop or wall-mounted posters for presentation, $450 is requested for this expense.

*Total cost estimated for poster is:* $450

*Postage:* Postage stamps will be needed for submission of reports and correspondence with mentors and granting agency, $300 is requested for this expense.

*Total cost estimated for postage is:* $300

*Copier Expenses:* Consent forms will be copied for each participant and copies of progress reports will be made, $150 is requested for this expense.

*Total cost estimated for copier service is:* $150

*Table top Manual Pill Counting Trays:* Tabletop pill counting trays are needed to facilitate the manual pill count to be done as part of the medication reconciliation intervention. Various are needed to efficiently count multiple medications, per participants: cost per table top manual pill counting tray is $8.00 x 10: *Total cost estimated for manual pill counting tray is:* $80.00

B. Total Medication Adherence-Aiding Tools: $2333.70

*Medication insulated bags:* Medication bags will be disseminated to participants to serve as a transporter for medication bottles and reminder for patient to take medications to provider and hospital when seeking care. This tool promotes medication communication and safety. Wholesale price per medication bag is $6.00 x 125: *Total cost estimated cost for medication bag is:* $750.

*Jumbo 24/7 Medication Tray Organizer (Pill box):* A pill box will be disseminated to participants to facilitate medication reminders. Wholesale price per pill box is $6.00 x125:

*Total cost estimated for pillboxes is:* $750.

*Printed medication cards for purse/wallet:* A professionally printed medication card will be disseminated to participants as a way of facilitating medication communication throughout the health care continuum: $2.50 per card x 125: *Total cost estimated for medication cards:* $312.50.

*Medication Printed forms:* A professionally printed medication form on special cardstock will be disseminated to participants for the refrigerator door, to serve as an additional medication adhering-aiding tool: $1.49 x 125: *Total cost estimated for medication forms:* $186.25.
**Program educational booklets.** Program educational booklets will be professionally printed to serve to reinforce patient education on importance of medication self-management and adherence: $2.68/per booklet x 125. Total estimated cost: **$334.95**

C. Total Participant incentive: $2,450

  Participant incentive. Participant incentive is needed to ensure return for post-test. The population of interest is highly mobile (some are homeless) and is more likely to return if there is a much needed monetary gain. A total of $50.00 will be provided to each participant, half ($25.00) once pre-test is completed and half ($25.00) when post-test is completed. The proposed sample size is n=49 x $50.00, total cost estimated for this expense is: **$2,450**

D. Program Promotional Items: **$355.00**

  Brochures/Poster Ads to promote the program, Total estimated cost **$320.**
  Business cards, to disseminate among participants, Total estimated cost **$35.**
A. Personal Statement

The goal of the proposed pilot study is to investigate the effects of a medication reconciliation intervention on adherence. Specifically, the intent is to measure medication adherence before and after an intervention is completed over a six-month period, in a medically underserved population. I have the ability, leadership and interest necessary to successfully carry out the proposed work. I have an extensive background in nursing with specific training and abilities in key areas pertinent to this pilot study. As a Clinical Coordinator, I conducted formal site audits and medical record reviews to ensure guidelines were followed and quality care maintained for a grant program under the California Department of Health Services. I collected data, educated patients, assisted with coordinating and presenting at provider educational training sessions for the Breast Cancer Early Detection Program, then the California Breast Cancer Treatment Fund. The later program was funded by a grant made possible for the uninsured women in California by the California Endowment. I organized community outreach, health fairs, and provided patient education, recruited participants into the program and disseminated promotional materials when promoting monthly self-breast exams and annual breast screens. Additionally, I successfully translated all program materials into the Spanish language to reach the medically underserved, encouraging participation in the program. I assisted the primary site investigator with monthly, quarterly, and annual grant reports, as well as
reporting data for quality benchmarks.

For the past eleven years I have worked as an Independent Nurse Consultant for Long Term Care Insurance Companies. My patient base is predominantly made up of community dwelling older adults ≥65 years, who take between 9-18 medications for multiple medical conditions, and are treated by multiple providers. One of my responsibilities is medication reconciliation, noting discrepancies in prescribing, and working together with multiple disciplines to correct errors. As a result, I have experience networking, collaborating, and communicating with various disciplines ensuring medication safety. Additionally, I have a basic understanding in constructing realistic research plans, timelines, and monetary budgets. The current application builds logically on my previous experience. During 8/98-12/00 I had a career disruption due to family obligations. However, upon returning to the field I immediately resumed my research collaborations and successfully competed for the California Endowment support. In summary, I have a demonstrated record of accomplished and productive collaborations in research projects, in an area of high relevance to our aging population. My prior experience has prepared me to lead the proposed project.

B. Positions and Honors

*Intensive Care Staff Nurse/ ICU, Telemetry*
1985-1987
Pelham Bay General Hospital, Bronx, NY

*Emergency Room Staff Nurse*
1987-1989
Pelham Bay General Hospital, Bronx, NY

*Medical Surgical Staff Nurse*
1990-1992
Pelham Bay General Hospital, Bronx, NY

*Geriatric Staff Nurse*
1992-1994
Pelham Bay General Hospital, Bronx, NY

*Home Health Nurse*
1994-1996
Visiting Nurse Service of New York, NY

*Home Health/Public Health Nurse*
1996-1997
Valverde Home Health Agency, Del Rio, TX
Case Manager/Health Care Finder/Utilization Review Nurse  
1996-1998  
Laughlin Air Force Base, Del Rio, TX

Clinical Care Coordinator  
2000-2001  
Desert Sierra Breast Cancer Partnership, Riverside, CA

Patient Care Coordinator/Case Manager  
2001-2003  
California Breast Cancer Treatment Fund, Riverside, CA

Case Manager/Utilization Review Nurse  
2003-2008  
Concentra Integrated Services, Orange, CA

Substitute Teacher/School Nurse  
2000-Present  
Temecula Unified School District, Temecula, CA

Independent Nurse Consultant  
2001-Present  
Univita (NCL), St. Paul, MN

Professional Licenses and Certifications
California Basic Education Skills Test (CBEST) certified, State of CA, 1999
California Professionally Licensed Registered Nurse, 2000

C. Other Experience and Professional Memberships
Sigma Theta Tau International Alpha Phi Chapter  
1993
Sigma Theta Tau International Phi Theta chapter  
2012

D. Selected Peer-reviewed Publications
Non applicable

E. Research Support
Non applicable
The facility for the proposed pilot study is: CSUSM SON student health care project in Ocean Beach, California and has its own designated:

1) administrative office: used in this pilot study for receiving participants monthly calls for five months after the pretest, in a private/confidential setting;
2) examination room: for administering the medication reconciliation intervention, in a confidential setting;
3) washing lavatory: for hand washing before and after the manual pills counts, and between participants;
4) management team: will help the research team in coordinating the days for the pre-test and post-test (based on the facilities availability);
5) electronic patient database system: to help the research team get the current prescribed medication lists, as per the medical record.

CSUSM SON student health care project is affiliated with two major Universities: California State University San Marcos and University of California San Diego serving as a clinical teaching site for various graduate and undergraduate health care programs (e.g. Nursing, Medicine and Physician Assistant students). The Doctorally prepared Nurse Practitioners who give free, convenient, and high-quality primary care services to the medically underserved members of the community of Ocean Beach, CA are also educators, mentors, and offer collegial support. The Nurse Practitioners at the facility impart their skills and knowledge to new investigators while providing guidance and supervision. This scientifically and academically enriched environment will foster an excellent intellectual opportunity for this new investigator to learn from experts in the field while obtaining invaluable direction, support and guidance as the proposed pilot study evolves and culminates.
CHECKLIST

TYPE OF APPLICATION (Check all that apply.)
- NEW application. (This application is being submitted to the PHS for the first time.)

RESUBMISSION of application number:
- (This application replaces a prior unfunded version of a new, renewal, or revision application.)

RENEWAL of grant number:
- (This application is to extend a funded grant beyond its current project period.)

REVISION to grant number:
- (This application is for additional funds to supplement a currently funded grant.)

CHANGE of program director/principal investigator:
- Name of former program director/principal investigator:
- Name of former institution:

FOREIGN application Domestic Grant with foreign involvement
- LIST COUNTRY (IES) Involved:

INVENTIONS AND PATENTS (Renewal appl. only)
- NO
- YES

1. PROGRAM INCOME (See instructions.)
All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

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2. ASSURANCES/CERTIFICATIONS (See instructions.)
In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

3. FACILITIES AND ADMINISTRATIVE COSTS (F&A)/INDIRECT COST. See specific instructions.
- DHHS Agreement dated: ___________________________ No Facilities And Administrative Costs Requested.
- DHHS Agreement being negotiated with ___________________________ Regional Office.
- No DHHS Agreement, but rate established ___________________________ Date ___________________________

CALCULATION* (The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information.)

a. Initial budget Period: Amount of base $53,461.70 x Rate applied 28% = F&A Costs $14,969.28
b. 02 year: Amount of base ___________ x Rate applied ________% = F&A Costs ___________
c. 03 year: Amount of base ___________ x Rate applied ________% = F&A Costs ___________
d. 04 year: Amount of base ___________ x Rate applied ________% = F&A Costs ___________
e. 05 year: Amount of base ___________ x Rate applied ________% = F&A Costs ___________

TOTAL F&A Costs $14,969.28

*Check appropriate box (es):
- Salary and wages base
- Modified total direct cost base Off-site, other
- Other base (Explain):

Study Team wages based on annual salaries, Consultant fees based on hourly rates.

4. DISCLOSURE PERMISSION STATEMENT: If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)? Yes ☒ No

Page 16
A Medication Reconciliation Educational Intervention To Improve Adherence In A Medically Underserved Population: A Pilot Study

Research Plan

The proposed quasi-experimental one group pretest post-test pilot study will test the effects of a medication reconciliation educational intervention in improving adherence in a medically underserved adult population. Previous studies have found consistent evidence of improvements in medication adherence with multi-component adhering-aiding programs that include medication education. Findings in previous studies have linked medication reconciliation, medication education, medication adhering-aiding programs, and medication self-management with decreased hospitalizations, decreased days in the hospital, and decreased outpatient visits at a cost to savings ratio ~1:10, with long-term results (National Council on Patient Information and Education, 2007; Agency for Health Care Research and Quality, 2008). However, limited evidence was found on whether these programs would be effective in all populations, especially the medically underserved. Medically underserved adults can benefit from interventions offering disease and medication education, while addressing the behavioral aspect of medication taking (Jackson, 2011).

CHAPTER ONE: INTRODUCTION

Background and Significance

Prescribed medications, a critical aspect of care, are important to the well-being of persons with chronic diseases. Medications are the single most important medical advancement to prevent illness, disability, and death (adultmedication.com, 2012). Medically underserved older adults with multiple medical problems (co-morbidities), benefit the most from taking medications and risk the most from not taking it as prescribed.
(Whitney and Glazier, 2004). According to the World Health Organization [WHO] (2003), in the U.S. providers write 1.8 million prescriptions annually and 50% are not taken correctly. Of all prescribed medications, 12% are never filled, 12% are never taken in spite of being filled, and 29% of patients quit taking them. Of the remaining 47%, 22% take less than the provider ordered, leaving only 25% of patients taking medications as prescribed (American Heart Association, 2012). According to Pound et al. (2005) when patients are placed on multiple medications, they become reluctant and decrease the amount taken leading to Adverse Drug Events (ADE).

**Implications of medication non-adherence.** Medication adherence is defined as the extent to which a person’s behavior in taking medication follows the provider’s recommendations (Jackson, 2011; Mann, 2009; World Health Organization, 2003). Non-adherence means the person does not take medications as indicated. It is a prevalent, dangerous problem costing between $100-$289 billion annually in avoidable health care spending (Agency for Healthcare Research and Quality, 2012; Jackson, 2011; New England Health Institute [NEHI], 2009). NEHI (2009) illustrated the economic impact of medication non-adherence in healthcare, in the Summary of Cost of Illness for Drug-Related Morbidity and Mortality, see figure 1. Non-adherence affects many areas of the health care continuum. Consequences of non-adherence can be devastating.
causing unnecessary hospital admissions and death. For example findings of a study by Spertus et al. (2006, p. 2803) elucidated to the high rates of poor adherence to Clopidogrel after drug-eluting stent placement; 13.6% of patients quit taking the medication 30 days after stent insertion creating a nine fold risk of death. Pronovost, Weast, and Schwarz (2003) state that one out of five deaths or injuries are associated with ADE, defined as injury resulting from use of a drug harm caused by a drug (ADE and Over Dose) and harm from using a drug (including dose reductions and discontinuation of drug therapy), are preventable (p.201). Some ADE are due to medication errors but most are not.

Vira, Colquhoun and Etchells (2006) found that ADE cause 7-12% of all permanent disabilities. Ten percent of all unnecessary hospitalizations are attributable to medication non-adherence (Barnsteiner, 2008; Jackson, 2011; Kuzuya et al., 2008). Hospitalized patients usually have at least one medication discrepancy (South Carolina Hospital Association, 2012) defined as an unexplained difference in the medication regimen that can either lead to non-adherence or cause patient harm. Wong et al. (2008) found that 41.3% of patients had at least one unintentional medication discrepancy when returning home from a hospitalization; of these, 29.5% had the potential to cause patient discomfort or clinical deterioration if not corrected. Not only are patients with chronic medical conditions hospitalized due to non-adherence and ADE, they are also discharged with medication discrepancies leading to non-adherence, injury, or re-hospitalizations.

**Populations at Risk.** Populations at risk for medication non-adherence are medically underserved older adults who present a significant problem to public health.

**Medically underserved adults.** Jackson (2011) states that poor adherence to medication regimens is a problem among older adults, especially medically underserved elders.
Anderson and Horvath, (as cited in Mishra, Gioia, Childress, Barnet and Webster, 2011), estimate that one in four U.S. adults have more than two chronic medical problems; by the age of 65, the prevalence increases dramatically to 70%. To treat coexisting problems patients see multiple providers who prescribe multiple medications, often not communicating with each other (Walsh and Cussen, 2012). According to Leonhardt et al. (2008), over 60% of persons over the age of 65 take at least five different medications, 15% take at least 10.1. Additionally older adults have normal age related declines in cognitive, physical, and systematic functions, such as memory problems, limited dexterity, and changes in drug metabolism (Walsh and Cussen, 2012). This makes the handling of complex medication regimens a taxing process. Complex medication regimens coupled with an inability to self-manage the regimen, places the elderly at risk for ADE. The consequences could be pronounced if they never developed self-management skills or patterned behaviors for taking medications.

Kurzuya et al. (2008) found that lack of help with medication management is linked to hospitalizations. Several studies have correlated poor self-management skills to medication non-adherence (Jackson, 2011; Kurzuya et al., 2008; Mishra et al., 2011). Medically underserved older adults have multiple chronic illnesses (co-morbidities) requiring the use of multiple medications. Other reasons cited in the literature for non-adherence in medically underserved adults include: suboptimal communication, limited knowledge of the disease process and usefulness of the prescribed medications, lack of support, and fear of side effects and ADE (Mishra et al., 2011). Also, having limited incomes and problems with transportation make it difficult to afford multiple copays or access health care services (McCallum, 2010; Whitney and Glazier, 2004). Kaplan, Bhalokar, Brown, White, and
Brown (2004) found non-adherence is prevalent in economically disadvantage groups with scarce resources causing poor health outcomes.

Evidence supports that medically underserved adults need help managing their medications and care. According to Whitney and Glazier (2004), a patient’s medication-taking process occurs in three stages: (1) access to medications, (2) retaining medications and (3) compliance with the prescribed regimen. These stages happen in an ordered sequence; the latter cannot be achieved without the former two. In order for a patient to adhere to the medication regimen, barriers related to obtaining and retaining medications cannot exist.

Mojtabai and Olfson, (as cited in Mann, 2009), found a direct relation between amounts of insurance coverage and medication adherence among Medicare beneficiaries; patients with full coverage had a 3% non-adherence rate, patients with partial coverage had a 5% rate, and patients no coverage had a 12% rate. Mann (2009) cited another study by Gibson et al. about the effects of medication copays and adherence finding that the higher the copay, the lower the rates of adherence; specifically for every ten-dollar increase in the copay there was a 3% decline in adherence (p. 12). Gellad, Haas and Safran (2007) found non-adherence was higher in uninsured seniors with low incomes having multiple medical problems (p. 1572).

**Interventions to Improve Adherence.** Providers need to recognize patients at risk for non-adherence and implement interventions to improve adherence and prevent ADE. According to Johnson et al. (2010), there is evidence that medication reconciliation is an effective and safe practice in reducing ADE. Lindquist, Gleason, McDaniel, Doeksen, and Liss (2008) found that increasing medication adherence promises improvements in public
health and savings in healthcare costs. However, improving adherence requires a collaborative teamwork approach. Leonhardt et al. (2008) found interventions that promote a relationship between the patient and provider must occur to facilitate a collaborative approach to medication management. According to Mishra et al. (2011), national and international patient safety experts recommend involving patients in the medication process through a joint effort with the provider; this positive relationship is a significant facilitator in adherence.

Medication reconciliation interventions promote a positive relationship between the provider and the patient (Pronovost et al., 2003). Listening to the patient’s medication concerns are teachable moments when fears about side effects and ADE can be tempered with knowledge about their real frequency. It also creates an opportunity to engage patients in their medication self-management by assisting them to plan reminders and routines for taking medications at home. If patients perceive that medications promote health and well-being, while preventing complications, they will be more likely to become involved in planning routines for remembering to take medications. According to MacLaughlin et al. (2005), those who understand their disease and the perceived need for treatment and medication will work towards planning routines and reminders to adhere.

**Significance to Nursing.** Given the compromised health of the medically underserved, assisting them to strengthen adherence by planning reminders and routines for taking medication at home is a potentially significant contribution to nursing practice. Nurses are able to educate their patients about ways to prompt, tailor, or cue medication reminders. Nurses already educate patients across the healthcare continuum; they are in a position where they can include medication self-management as part of patient
Little is known about interventions that improve medication adherence particularly among vulnerable populations. Medically underserved adults are at risk for medication non-adherence. They can benefit from effective nurse-delivered medication adherence interventions to develop medication-taking skills and improve their medication knowledge and beliefs, in order to increase adherence and prevent ADE.

**Problem Statement**

Voluminous research on adherence over four decades has explored over 200 factors affecting adherence, but none can consistently predict adherence (Vermeire, Hearnshaw, Royen, and Denekens, 2001). A developing credence from the literature is that individual barriers exist (Bohlman, Panzer, Hamlin and Kindig, 2004). A patient’s ability to adhere is dependent on their personal struggles, perceptions, personal choice to adhere, and patterned behaviors.

Medication non-adherence is significant in health care because medications are a critical aspect of care. Medications prevent illness, disability, and death if taken correctly. When medications are not taken correctly unnecessary disease progression, complications, hospitalizations, lower quality of life, and premature death occurs.

Significant to public health is the impact medication non-adherence has on older adults, especially those who are medically underserved who lack finances, health insurance coverage, and access to health care (Jackson, 2011). Medically underserved adults have different experiences, therefore it is necessary that providers understand the patients’ beliefs about prescribed medicines, correct any misinformation, and aid the patient in planning routines for taking medications.
Data links medication reconciliation, education, adhering-aiding programs and self-management with decreased hospitalizations, days in a hospital and outpatient visits at a cost to savings ratio ~1:10 with long-term results (Agency for Health Care Research and Quality, 2008; National Council on Patient Information and Education, 2007). Educational interventions addressing disease and medication knowledge, medication safety, and self-management are effective in improving adherence (Bohlman et al., 2004). However, earlier studies have not evaluated the effects of such interventions in medically underserved adults who are known to have “high usage of medical services to treat serious problems” (Whitney and Glazier, 2004, p. 6). Additional research needs to test the utility and efficiency of the above interventions in medically underserved populations.

**Specific Aims and Objectives**

This Evidence-Based Practice Pilot Study addresses the effect of a medication reconciliation educational intervention on medication adherence in medically underserved adults seeking healthcare at a free clinic project in a small coastal community in southern California.

**Primary Aim.** The primary aim of this EBP pilot study is to improve medication adherence in medically underserved adults seeking healthcare at a free clinic project in Southern California, using methodologies as described by Johnson (2002) in the Medication Adherence Model (MAM).

**Secondary aim.** The secondary aim is to intercept medication discrepancies that can potentially cause harm and lead to medication non-adherence. The aims will be accomplished by meeting the following objectives:

**Objective 1.** Institute an evidence-based medication reconciliation educational intervention
to improve medication safety, medication self-management, communication, and access to accurate medication education.

**Objective 2.** Evaluate the effectiveness of the intervention using a pretest/post-test pilot study approach that will measure the following outcomes:

a) Medication Ratio to identify statistical differences in medication adherence using manual pill counts,

b) Medication Knowledge Assessment Form (see Appendix E) to assess medication knowledge pre and post intervention,

c) Medication Discrepancy Tool (MDT), (see Appendix D) to identify statistical differences in improvements to medication discrepancies pre and post intervention.

The primary outcome of interest is medication adherence. Educational interventions addressing disease and medication knowledge, medication safety, and self-management skills are effective in improving adherence. Given the tumultuous and unstable lives of the medically underserved, information obtained from this study will provide insight into the need for disease and medication education, as well as the need for establishing patterned behaviors for medication taking to improve adherence.

**Hypothesis.** A medication reconciliation educational intervention will improve medication adherence and intercept medications discrepancies in medically underserved adults. The Hypothesis is directional.

**Research Questions.**

**Question #1.** Does a medication reconciliation educational intervention improve medication adherence in medically underserved adults?

**Question #2.** Does a Medication reconciliation educational intervention intercept
medication discrepancies?

**EBP Model**

The evidence-based practice model used to design the intervention for this project and provide the scheme for grading the literature review is the Model for Change to Evidence-Based Practice. The model guides practitioners through a systematic process of developing and integrating evidence-based practice change (Rosswurm and Larrabee, 1999). Derived from theoretical and research literature related to evidence-based practice, utilization, standardized language, and change theory; the model supports evidence-based practice changes derived from quantitative and qualitative data, clinical expertise, and contextual evidence. There are 6 steps in the Model for Change to Evidence-Based Practice: 1) Assessing the need for change in practice 2) Linking the problem to an intervention and outcome, 3) Synthesizing the best possible evidence to decide whether the strength of the evidence supports a change in practice, 4) Designing the practice change, 5) Implementing and Evaluating the change, and 6) Integrating and Maintaining the change in practice. For the purpose of this pilot study, steps one thru four are relevant. Because this project is a grant proposal, steps five and six will apply once funded.
CHAPTER TWO: LITERATURE REVIEW

Introduction

The proposed pilot study aims to show improvement in medication adherence rates in medically underserved adults obtaining care at a parish free clinic project in Southern California after receiving a medication reconciliation educational intervention. Many studies have examined interventions to improve medication adherence and intercept medication discrepancies; however, few have focused on medically underserved adults who are at a high risk for the consequences resulting from medication non-adherence. This literature review will summarize the evidence found in earlier studies for interventions done to improve medication adherence and studies of interventions for intercepting medication discrepancies in adults 40 years and older.

Search Strategy

Computer based searches of English-language literature were conducted using MEDLINE (1994-2012), CINAHL (1994-2012), PUBMED (1994-2012) as well as GOOGLE SCHOLAR (2000-2012). MeSH terms included medication adherence, medication non-adherence, medication reconciliation, medication discrepancies, adverse drug events, medication communication, and health literacy, medication self-management, measuring medication adherence, medication education, adhering-aiding strategies and adhering-aiding tools, pill boxes, medication bags, medication lists and medication reminders. Each of these terms was further limited with the keywords medically underserved, older adults 40 years and over, and medication intervention or intervention studies. The retrieved citations’ abstracts were reviewed for relevance.

A total of 104 articles were found. Eligible articles were reports of intervention studies
geared at improving medication adherence, medication discrepancies and/or having an outcome measure of adherence or reduction in medication discrepancies. Included were many randomized clinical trials (RCT) to look at the most rigorous research in this area of science. Out of 125 reports screened, 47 were reviewed and 36 included in this project. Articles selected had published dates between: 1994-2012. The studies enrolled sample sizes from 30 to 2.17 million participants. The total enrolled sample size for all studies reviewed was over 2,194,453 participants. One (1) systematic review and one (1) meta-analysis reported the total number of studies reviewed (N=20, N=33 respectively) and not the total amount of participants for all studies reviewed. Studies reviewed generated from USA (N=25), Belgium (N=1), Ireland (N=2), Canada (N=4) and Spain (N=1), England (N=1), Netherlands (N=1), Japan (N=1).

### Literature Inclusion/Exclusion Criteria

Eligible studies involved multimodal interventions for improving medication adherence in persons 40 years and older who had co-morbidities and took multiple medications. Additional studies included involved interventions that intercepted medication discrepancies in settings throughout the health care continuum. Studies had to have either an outcome measure of adherence or reduction in medication discrepancies and be reported in the English language. When an article did not report outcomes of interest, consideration was given to studies listed in the reference section of the article. Studies using single interventions were excluded because they failed to improve medication adherence. Articles not meeting inclusion criteria were also excluded. Refer to Table 1 for inclusion/exclusion criteria.
Table 2.1a. Primary Review Inclusion Criteria

1. Study reported in English between 1994 and 2012 because medication adherence (MA) behavior has changed little since 1994, although prescribed medications have improved.
2. Mean age of sample was at least 41 years.
3. Participants had 2 or more chronic medical conditions.
4. Participants were taking 3 or more prescribed medications.
5. Studies involving interventions to improve medication adherence.
6. Studies involving adhering aiding strategies to improve adherence.
7. Studies involving interventions to intercept medication discrepancies.
8. Studies having an outcome measure of adherence or reduction in medication discrepancies

Table 2.1b. Primary Review Exclusion Criteria

1. Studies or reports not meeting inclusion criteria or involving
2. Single interventions

Scheme for Grading Evidence.

The scheme for grading the evidence (Figure 2) is taken from the Worksheet for Critique (Appendix A) of the Model for Change to Evidence-Based Practice, adapted from the rating scale used by the United States Preventative Services Task Force (Rosswurm and Larrabee, 1999).

The strength of the evidence for interventions and strategies to improve medication adherence was given an average rating and the references for each element is included. A summary of the studies reviewed is included in appendix A-1.

Summary of Evidence for each of the major elements of the intervention.

One third of the studies were RCT (N=12), five (N=5) were meta-analysis, one (N=1) was a systematic review, one (N=1) was a well-designed controlled study without
randomization, one (1) was a well-designed quasi-experimental study, thirteen (N=13) were
descriptive studies and four (N=4) were evidence from expert opinion. Twenty seven
(N=27) studies did not report using any theoretical framework to guide the design or
delivery of the intervention. The remaining studies reported a range of theoretical models,
including Johnson’s (2002) Medication Adherence Model (Fung, 2009; Hsu, Mao, and Wey,
2010; Lehane and McCarthy, 2005), Health Belief Model (Hamilton, 2003), Health
Communication Model (Schoenthaler et al., 2009), Transtheoretical Model (Martin et al.,
2011), Bronfenbrenner’s Ecological Model of Behavior (Mishra et al., 2011), Health
Decision Model (Brosworth et al., 2008), To Err is Human (Pronovost et al., 2003). One
meta-analysis of RCT reviewed (N=20) studies, two-thirds of the studies (N=15) used the
Transtheoretical Model and (N=5) used the Social Cognitive Model in their study
design/implementation.

**Adherence measurements.** After decades of research in the area of medication
adherence, there is no true “gold standard” for measuring adherence, though some methods
have greater limitations than others (Lavsa, Holtzworth and Ansani, 2011; Melnikow and
Kiefe, p. 97, 1994; Osterberg and Blaschke, 2005; Vermeire et al., 2001). Direct measures,
such as blood draws are most accurate but invasive, costly, and do not consider each
person’s pharmacokinetics. Only one (1) study reviewed used serum samples for HIV RNA
levels and CD4+ T cell count as part of the adherence-monitoring visit each month, along
with unannounced visits to do pill counts. Indirect measures of adherence were
predominately used in N=36 of the studies reviewed. These included self-reported
adherence (N=16); pill counts (N=8); electronic monitoring, using the medication event
monitoring system (MEMS) caps (N=3); prescription refill data (N=2); one (1) study used
both MEMS and pill counts; one (1) study used self-report and pharmacy refill records; and one (1) study used five (5) different adherence measures: MEMS, urine markers, pill counts, self-report, and a doctor estimate. Additionally, of the 36 studies included, nine (N=10) either measured adherence based on the patient having a support system or acknowledged that a support system is important in determining adherence rates.

**Self-reports.** According to, Vermeire et al. (2001), medication adherence self-reports are vulnerable to overestimates of adherence and under-estimates of non-adherence. It is the most commonly used measured of adherence, but it is subject to recall and self-presentation bias, yet used in the following studies reviewed: Bosworth et al., 2008; Calvert et al., 2012; Fung, 2009; Gellard et al., 2007; Hamilton, 2003; Hsu et al., 2010; Johnson and Shalansky, 2006; Kaplan et al., 2004; Lehanne and McCarthy, 2005; Leonhardt et al., 2008; Lewis, Schenthaler, and Ogedegbe, 2012; Mishra et al., 2011; Ryan and Lauver, 2002; Schoenthaler et al., 2009; Vermeire et al., 2001; Whitney and Glazier, 2004. Of the 36 references resulting from the search, 16 met inclusion criteria and included one (1) meta-analysis (n=20), one (1) systematic review (n=33), four (4) RCT (n=107, n=636, n=439, n=143), and 10 comparative correlation and other descriptive studies (n=510, n=20, n=73, n=350, n=14,829, n=594, n=64, n=94, n=50, n=253) (Evidence = Grade II b).

**Pill counts.** Pill counts are the most common objective, quantifiable, and easy to perform method for measuring adherence (Van Onzenoort et al., 2010). However, researchers have varying views regarding its accuracy. Osterberg and Blaschke (2005) found this measuring method is subject to problems because patients can throw away pills or switch medications. Lewis et al. (2012) did not use pill counts in their study for predicting medication adherence factors in African American men, instead a self-reporting method was used.
Once the study ended the authors realized that medication adherence was underreported, and recommended that future studies use an unbiased method of measuring adherence such as pill counts. In a RCT study by Martin et al. (2011) of rural low-income adults with hypertension (n=434), manual pill counts offered an objective measure of adherence strengthening the study. Those same conclusions were found in other studies using pill counts as the measure of adherence (Conn et al., 2009; Hamilton, 2003; Kogos, 2004; Kurzuya et al., 2008; Lee, Grace and Taylor, 2006; Martin et al., 2011; Peterson et al., 2007; Van Onzenoort et al., 2010). Of the 36 references resulting from the search, eight (8) met inclusion criteria and included one (1) meta-analysis (n=33), five (5) RCT (n=107, n=30, n=533, n=228, n=434), one (1) well designed controlled study without randomization (n=249), and one (1) correlation study (n=1772) (Evidence = Grade Ib).

Medication Event Monitoring System (MEMS) track cap. The MEMS is a Medication Electronic Monitoring System that electronically records the date and time the medication container was opened to compile dosing histories of oral medications. The number pills missing from the container equals the number of times it was opened in a 24 hour period (called “event”); adherence is then calculated as the proportion of days the event occurred correctly (Hamilton, 2003; Pladevall et al., 2010; Van Onzenoort et al., 2010). Measuring adherence with MEMS is time consuming, expensive, resource intensive, and may not be suitable for all medications/formulations (Vermeire et al., 2001). As with pill counts, evidence in the literature for the using MEMS was conflicting. Pladevall et al. (2010) used MEMS in their intervention to improve adherence to anti-hypertension medication (n=877). During the study, 45 containers malfunctioned, resulting in over inflation measurements. Although the manufacturer replaced the defective containers and developed an algorithm to
find and remove invalid readings, about 5% of the readings were still invalid. Van
Onzenoort et al. (2010) also used MEMS in their study in addition to pill counts. Their
findings alluded to participants knowing the MEMS tracked their adherence. The
researchers concluded deviant behavior occurred. Of the 36 references included, three (3)
met inclusion criteria (Hamilton, 2003; Pladevall et al., 2010; and Van Onzenoort et al.,
2010) and were all RCT (n=107, n=877, n=228) (Evidence = Grade Ib).

**Prescription refill records.** The prescription refill record is another available option to
measure medication adherence; however, its validity is dependent on the completeness of
the pharmacy database and counting tables given to patients. Refill records have been
known to overestimate adherence (Vermeire et al., 2001). Calvert et al. (2012) used 143
prescription refill records to measure adherence to cardiovascular medications: aspirin, beta-
blockers, and statins, post hospitalization. The patients randomized to the intervention
group received in-hospital counseling, attention to adherence barriers, and communication
of discharge medications with the pharmacy and primary treating provider. Six months
after discharge, participants had overestimated their adherence; only 80% had six-month
refill records. In another study by Vanelli et al. (2009), 2.17 million prescription refill
records were instrumental in collecting data retrospectively to find patients at a higher risk
for discontinuing their medications in the first 30 days of filling their prescriptions. Of the
36 references reviewed, three (3) met inclusion criteria (Calvert et al., 2012; Johnson and
Shalansky, 2006; and Vermeire et al., 2001) and included one (1) systematic review (n=33),
one (1) RCT (n=143) and one (1) correlation study (n=2.17 million) (Evidence Grade=Ib).

**Other adhering measurements.** Other adhering measurements used less often were urine
markers and provider estimations of adherence (Hamilton, 2003). In a double-blind RCT,
Hamilton (2003) evaluated various adherence measurements in 107 participants which included an unreliable provider estimate of adherence. Providers in that study were already treating the participants before the study, making the estimate biased. Another adherence measure evaluated urinary potassium markers. Instructions were given to the participants on how to take the potassium marker and how to collect their urine for 24 hours. This measure was inadequate; not all patients could take the urine markers. Instead it burdened the participants because of the complex instructions. This caused undue hardship for many patients. Some of the participants forgot the instructions, did not refrigerate the urine, and turned in small specimens. This method was not adequate or efficient. Peterson et al. (2007) used monthly serum samples to measure HIV RNA levels and CD4+ T cell count at baseline of the adherence-monitoring visit each month, in addition to pill counts. Of the 36 references reviewed, two (2) met inclusion criteria (Hamilton, 2003; and Peterson et al., 2007) and included one (1) RCT (n=107), and one (1) well designed controlled study without randomization (n=245) (Evidence Grade=IIb).

Medication Reconciliation. Medication reconciliation is the process used by providers to check for medication errors. It is a three-step process to 1) verify medications use, 2) identify discrepancies, and then 3) rectify errors (Johnson et al., 2010; Leonhardt et al., 2008; NEHI, 2009; Pronovost et al., 2003; Vira et al., 2006; Walsh and Cussen, 2012). It ensures medication safety and prevents medication non-adherence. When medication discrepancies are not corrected, patients are at risk of being harmed. All studies reviewed reported statistically significant improvements in both medication discrepancies and patient safety. Pronovost et al. (2003) used a medication reconciliation intervention to decrease medication discrepancies when patients were transferred out of an intensive care unit. Using
a survey created by the primary investigator, medical records were randomly selected for medication reconciliation. At the start of the intervention, 94% of files had medication discrepancies. The prescribing providers and pharmacy staff worked diligently to prevent discrepancies. After 24 weeks there were no discrepancies found in any of the records. In summary, using medication reconciliation is an effective and efficient way to decrease medication discrepancies with minimal cost (Pronovost et al., 2003).

In a study by Vira et al. (2006), newly hospitalized patients were randomly selected for a medication reconciliation. Sixty percent of the sample (n=60) had one intentional medication discrepancy and 18% had at least one clinically important discrepancy. The discrepancy was not detected with normal clinical practice. The medication reconciliation intervention intercepted 75% of the clinically important discrepancies before harm occurred (95% CI 56-94). The previous two studies show the efficiency of a medication reconciliation intervention in a hospital setting; however, even in a community setting the intervention has favorable outcomes.

In a pharmacy setting, Johnson et al. (2010) used a medication reconciliation intervention and found an average of six medication discrepancies per patient. Those with more than one provider had more discrepancies than patients treated by a sole provider. The study found a need for medication reconciliation in outpatient settings where this valuable intervention has been under represented in research studies. Additionally, medication reconciliation interventions were found to promote adherence to the medication regimen (Walsh and Cussen, 2012). Of the 36 references resulting from the search, six (6) met inclusion criteria (Johnson et al., 2010; Leonhart et al., 2008; Provonost et al., 2003; Vira et al., 2006; Walsh and Cussen, 2012; Wong et al., 2008) included; three (3) RCT
(n=600, n=60, n=50); one (1) quasi-experimental study (n=594), and two (2) descriptive studies (n=150, n=100) (Evidence=Grade IIa).

**Educational Interventions.** Medication education was the most common component of the interventions reviewed (N = 16). The education involved information about medications, healthy lifestyles (Kogos, 2004), medication adherence (Calvert et al., 2012) and disease management (Bosworth et al., 2008; Vermeire et al., 2001). According to MacLaughlin et al. (2005), increased medication knowledge and belief in its’ effectiveness on disease management improves adherence. An educational intervention to increase adherence to hypertension medication was successful not only in improving adherence but also in decreasing systolic blood pressure (SBP) by as much as 6.9 mm/Hg, and low density lipoprotein (LDL) levels by as much as 4.8 mg/dL (Lee et al., 2006). Medication education included the purpose, dosage, side effects, ADE, and administration times (Hamilton, 2003; Lee et al., 2006; Leonhardt et al., 2008; Pladevall et al., 2010). According to Tanner (2004), knowledge is a prerequisite for medication adherence; however, education alone is generally not adequate to achieve adherence. Further, purely educational interventions are useful when non-adherence is deliberate; otherwise, behavior-based interventions with oral and written medication education are more effective in improving adherence (Tanner, 2004; Melnikow and Kiefe, 1994).

In a study conducted by Pladevall et al. (2010), the patient and family received medication education, a practice supported by Brosworth et al., 2008; Conn et al., 2009; DiMatteo, 2004; Kurzuya et al., 2008; Lewis et al., 2012; NEHI, 2009; Pound et al., 2005; Mishra et al., 2011; and Tanner, 2004. Family members are invaluable supporters when promoting adherence behavior; their role can influence medication adherence. The
educational intervention in Pladevall et al. (2010), consisted of constantly assessing for symptoms of ADE and offered adhering aiding tools to reinforce self-management behaviors. Bosworth et al. (2008) provided calendars to help participants keep track of their medications. Other studies joined the educational intervention with other adhering-aiding strategies such as blister packs (Lee et al., 2006; NEHI, 2009), medication bags, medication lists, and wallet medication cards (Calvert et al., 2012; Leonhardt et al., 2008; NEHI, 2009) to improve adherence. Some studies found statistically significant improvements in adherence after participants received pill boxes as adhering-aiding tools (Calvert et al., 2012; Conn et al., 2009; Fung, 2009; Peterson et al., 2007; Tanner, 2004). Multiple studies found the main reason for non-adherence was forgetfulness, and adhering-aiding tools were instrumental in assisting patients with medication reminders (Calvert et al., 2012; Hamilton, 2003; Hsu et al., 2010; Lehane and McCarthy, 2005; NEHI, 2009; Peterson et al., 2007; Pladevall et al., 2010; Ryan et al., 2002).

The settings for the educational interventions included outpatient clinics, community centers, libraries (Leonhardt et al., 2008), patients’ homes (Martin et al., 2011; Peterson et al., 2007), pharmacies (Calvert et al., 2012; Johnson et al., 2010; Lee et al., 2006) and involved the use of feedback and tailored interventions (Ryan and Lauver, 2002). Of the 36 references resulting from the search, 16 met inclusion criteria (Bosworth et al., 2008; Calvert et al., 2012; Conn et al., 2009; Hamilton, 2003; Johnson et al., 2010; Kogos, 2004; Lee et al., 2006; Leonhardt et al., 2008; Lewis et al., 2012; MacLaughlin et al., 2005; Martin et al., 2011; Pladevall et al., 2010; Pound et al., 2005; Ryan and Lauver, 2002; Van Onzenoort et al., 2010; Vermeire et al., 2001) and included one (1) systematic review (n=33) two (2) meta-analysis; (n=37, and n=33), eight (8) RCT (n=107, n=30;
n=533; n=636, n=877, n= 228, n=434, n=143); one (1) controlled study without
randomization (n=245), (1) one quasi-experimental study (n=594), three (3) cross-sectional
studies (n=94, n=100 and n=253); and one (1) expert opinion (Evidence=Grade Ia).

Support with medication self-management. In a meta-analysis of the literature from 1948
to 2001, DiMatteo (2004) found 122 studies correlated social support either structurally or
functionally with patient adherence to medical regimens. The study established significant
average r-effect sizes between adherence and practical, emotional, and uni-dimensional
social support; family cohesiveness and conflict; marital status; and living arrangement of
adults. Assistance with activities of daily living and independent activities of daily living
had the highest correlation with adherence. In her review, DiMatteo (2004) found that
adherence was 1.74 times higher in patients from cohesive families and 1.53 times lower in
patients from families in conflict. In a RCT, Kogos (2004) instituted a multi-component
intervention, one of which was a support group. Participants in the treatment group had
higher adherence rates than those in the control group based on the pill counts used to
measure medication adherence.

In another meta-analysis by Conn et al. (2009) involving 33 studies across 11,827 older
adults, tools and stimuli prompting participants to take their medications and
administration by a family member or caregiver were instrumental in improving
medication adherence. A third meta-analysis by Pound et al. (2005), involving 37 studies,
found the main reason people do not take their medications as indicated is due to concerns
about medications. The Author concluded that doctors need to make sure patients get
proper education, feedback, and that support is available to make sure patients can self-
manage their medications.
Tanner (2004) provided evidence that support for older adults dealing with chronic illnesses is important. Individuals must comply with an increasingly burdensome self-management protocol over time. The irreversible nature of chronic diseases requires supportive care and the ability to self-manage medication regimens to keep function and prevent further disability. Adherence to complex medication regimens for chronic illnesses is often difficult for older adults to manage; for this reason support and help with self-management is very important (Bosworth et al., 2008; Kurzuya et al., 2008; NEHI, 2009).

Of the 36 references resulting from the search, ten (10) met inclusion criteria (Brosworth et al., 2008; Conn et al., 2009; DiMatteo, 2004; Kurzuya, 2008; Lewis et al., 2012; Mishra et al., 2011; NEHI, 2009; Pound et al., 2005; Tanner, 2004; Vermeire et al., 2001) and included one (1) systematic review (n=33) three (3) meta-analysis (n=40, n=122, n=37), two (2) RCT (n=40 and n=636), three (3) descriptive studies (n=1772, n=50 and n=253), and one (1) expert opinion (Evidence Grade=Ib).

**Synthesis of Review**

Measuring medication adherence is challenging because adherence is an individual behavior. All measures seem to have pros and cons; the most widely used in the studies reviewed were self-reports. Researchers who used self-reports to measure adherence concluded that participants exaggerated adherence when compared to other adherence measures in the same study (Calvert et al., 2012; Hamilton, 2003).

Studies involving medication reconciliation reported statistically significant improvements in both medication discrepancies and patient safety. The evidence strongly supports the importance and effectiveness of medication reconciliation in decreasing medication discrepancies with minimal cost. In the studies reviewed, existing
medication discrepancies were not found in normal clinical practice (Johnson et al., 2010; Leonhardt et al., 2008; Pronovost et al., 2003; Vira et al., 2006; Walsh and Cussen, 2012; Wong et al., 2008). They were only found when performing a medication reconciliation intervention. The most compelling evidence of the effectiveness of medication reconciliation was found in a study by Pronovost et al. (2003). At the start of the intervention 94% of files had medication discrepancies; at the end (24 weeks later) no discrepancies were found.

Medication education-based interventions improved medication adherence in 53.3% of the studies reviewed. While this success rate is better than what was found in other medication adherence reviews, educational interventions alone are likely to be insufficient. To improve medication-taking behaviors, educational interventions may best be used as a part of a multifaceted intervention (NEHI, 2009; Osterberg and Blaschke, 2005; Pound et al., 2005; Ryan et al., 2002;). According to the literature reviewed, collaborative and multimodal interventions are more effective in improving adherence than programs that are single modal and not collaborative (Melnikow and Kiefe, 1994; NEHI, 2009; Vermeire et al., 2001). Feedback and support as part of an educational intervention seemed to stimulate the patient to want to adhere to the medication regimen. Support and follow-up given by providers, particularly adherence feedback, showed promise as an intervention (Johnson, 2002) and would benefit from further testing in the medically underserved population.

In older adults, support from providers of care, family members, friends or support from adhering-aiding tools (pill boxes, medication lists, and medication bags) helped to increase adherence rates (Bosworth et al., 2008; Conn et al., 2009; DiMatteo, 2004;
Kogos, 2004; Kuruzuya et al., 2008; Leonhardt et al., 2008; NEHI, 2009; Pound et al., 2005; Tanner, 2004). Supportive systems are invaluable, external motivators for adherence (Mishra et al., 2011). Having support assists patients with managing and using their adhering-aiding tools, while helping to tailor medication routines (DiMatteo, 2004; Mishra et al., 2011; Tanner, 2004). In addition, support helps to ease medication concerns (Pound et al., 2005) and provides medication reminders and feedback on self-management skills (NEHI, 2009).

Summary

Based on available evidence, a multimodal intervention is the focus of this pilot study. According to the literature, teaching the patients solely about their medications will not increase adherence. However, patient education is a key component to any adherence-improvement plan. Evidence indicates that with increased medication knowledge, belief in the effectiveness of medications, and proper feedback and support, medication adherence rates increase. Additionally, medication reconciliation is effective in detecting medication discrepancies and ensuring medication safety, accuracy of the medical record, and increased adherence. The proposed pilot study will include medication and disease education, medication reconciliation, and help with medication self-management, including feedback. Participants will receive adhering-aiding tools: a medication list for the wallet and refrigerator, a medication bag, and pillbox to help with medication self-management.

Finally, due to the simplicity and objectivity offered manual pill counts will be used to measure adherence in this pilot study thus preventing recall bias, as well as exaggerated results.
CHAPTER THREE: RESEARCH DESIGN AND METHODS

Setting Site

The selected site for the proposed pilot study is the CSUSM SON Student Health Care Project in Ocean Beach, CA. The Community of Ocean Beach is 1.4 square mile and has approximately 500 homeless people living in the area (Axman, 2012). The patients followed at this clinic are medically underserved- uninsured, underinsured, unsheltered homeless and self-employed small business owners. Data will be collected in a private exam room to ensure confidentiality. In addition to an exam room, administrative offices will be used in this pilot study when evaluating data. The site management team will assist in coordinating appropriate days for the pre-test and post-test.

The facility has affiliations with two major Universities: California State University San Marcos and University of California San Diego, serving as a clinical teaching site for various graduate and undergraduate health care programs (e.g. Nursing, Medicine and Physician Assistant students). The Doctorally prepared Nurse Practitioners give free, convenient, and high-quality primary care services to medically underserved adults living in Ocean Beach, CA and are also educators and mentors offering collegial support. The Nurse Practitioners at the facility impart their skills and knowledge to new investigators, while providing guidance and supervision. This scientifically and academically enriched environment will foster an excellent intellectual opportunity for this new investigator to learn from experts in the field while obtaining invaluable direction, guidance and support, for the proposed pilot study.

Intervention or Practice Change

The proposed intervention is a medication reconciliation educational intervention
Consisting of:

1. reconciliation of prescribed versus actual medications taken;
2. a pill count for all prescribed medication;
3. followed by an educational session to increase knowledge of the medications, disease, and self-management;
4. while tailoring the medication schedule based on personal need.

Additionally, participants will receive adhering aiding tools and instructions on how to use the tools. They will also be asked to either call in or stop by the study site once a month for follow-up and feedback. Most of patients in the proposed pilot study are highly mobile; to prevent attrition, monthly contact is essential. A post-test will follow six months after the pretest to measure adherence and will be used to give feedback to the participants. The goal of the intervention is to increase medication adherence by removing medication discrepancies, increasing medication and disease knowledge, while providing feedback and promoting self-management.

**Theoretical Framework**

Johnson’s Medication Adherence Model [MAM] (2002) will guide the study and infer its findings. Developed to describe the process of medication adherence, MAM guides health care professionals through the process of medication taking in patients with hypertension. Johnson (2002), selected hypertension because of the asymptomatic nature of the disease “affecting about 24% of the population” (p. 184). Hypertension is a common diagnosis found in medically underserved populations including the population for this pilot study. Johnson (2002) believed that if the primary adherence tenets could be explained for one chronic illness than those same tenets would apply to other chronic
medical conditions. According to Johnson (2002), “the structural focus of MAM centers on two underlying reasons individuals do not take their medication: the intentional decisions to miss medications and the unintentional interruptions that cause medications not to be taken” (p. 180).

Mary Jane Johnson (2002) created MAM to describe the process of medication adherence after finding that the Health Belief Model, the Social Learning Theory, Theory of Reasoned Action, Self-Efficacy and Self-Regulation Theory did not focus on factors associated with the process of being adherent to medication regimens in chronic disease. Adherence to medications prescribed to treat chronic illnesses appears to have other attributes when compared to acute illnesses. The MAM has three core concepts, as illustrated in figure 3. that describe the theoretical framework:

1) **Purposeful action** is the decision-process where patients cognitively or intentionally decide to take or avoid medications based on a **perceived need**, medication **effectiveness**, and **safety** (Johnson, 2002). If patients perceive a need to take medications for well-being and to prevent complications, they will take the medications. Those who are either asymptomatic, have normal blood pressure...
readings, or other normal clinical findings, are more likely to stop taking medications.

The proposed pilot study offers an educational intervention targeting *perception* to promote *purposeful action*. The patient will receive information about the disease process and management, purpose and effectiveness of medications, importance of self-management, as well as the frequency of medication complications to target the individual’s medication and disease perceptions.

2) **Patterned Behavior** - is the process by which a person sets up a ritual, habit, or pattern for taking medications by accessing the medication, developing a routine, and remembering to take medications (Johnson, 2002). Sometimes patients want to adhere to the medication regimens but encounter obstacles impeding medication access. Medically underserved adults often have chaotic lifestyles and instability (homelessness) which make it difficult to set up realistic routines that will remind them to take their medications. Assisting these patients in personalizing their medication-taking habits around their chaotic lifestyle may promote adherence (Whitney and Glazier, 2004).

Promoting patient-provider relationships will help providers learn about potential barriers that may impede access to medications in medically underserved adults. Knowledge of such barriers will allow the provider to network with available resources to facilitate access. If patient-provider communication is lacking, linking the patient to potential resources will be impossible.

For the purpose of this pilot study, the selected site: will offer financial assistance to help the medically underserved in accessing medications. The proposed intervention will help patients with planning *reminders* and *routines* for medication-taking at home, while providing evidence
based techniques (tailoring) and reminder tools to improve medication self-management and ongoing medication communication.

3) **Feedback**- is the degree to which information, facts, prompts, or events reinforce the need to keep up, change, or quit medication-taking (Johnson, 2002). Purposeful action and patterned behavior occur as a result of the patient’s response to treatment. According to Johnson (2002), “feedback is the individual’s outcome criteria of the need, effectiveness and safety of the medication” (p. 187). Feedback sources that encourage ongoing medication adherence include: normalizing clinical findings e.g. blood pressure readings, personal responses, media messages, and comments by health care providers or other persons. Patients use the information to check the need for continuing to take or stopping the medication. Information received from feedback sources serve to motivate the patient to adhere and as a reminder that medications are important.

For the purpose of the proposed pilot study, monthly contacts and a post-test educational session will serve as feedback opportunities for positive reinforcement assisting patients to continue their medication self-management and tailored routines.

In summary, purposeful action triggers patterned behavior which affects the degree of medication adherence. The outcome of medication adherence either creates positive or negative reinforcement that directly feeds back to both the patient’s purposeful action and patterned behaviors. This leads to a varied degree of medication adherence.

**Evaluation Methodology**

**Design.** A Quasi-Experimental one group Pre-test Post-test design was selected for this pilot study to determine the effects of an intervention aimed to increase medication adherence. This pilot study seeks to investigate the effects of a medication reconciliation
educational intervention on medication adherence (dependent variable) see figure 4. Although not tested in the pre-test or post-test analysis the independent variables will include age, gender, number of comorbidities, number of medications, and number of treating providers. These variables will be used to describe the demographic representativeness of the sample.

Figure 4. Quasi-Experimental One Group Pre-test Post-test Design

There are limitations with the selected research design. First, the sample is one of convenience. There will be no random selection, and no control group to have as a basis for comparison with persons who would not receive the intervention. Also, the selected site for the pilot study is a single site with a patient base of 52. A risk exists that the patients may not want to take part in the pilot study, making it difficult to get the proposed sample size. A financial incentive will serve to attract participants, e.g. twenty-five dollars at pre-test completion followed by another twenty-five dollars after the post-test. Further, most patients at the proposed site are highly mobile unsheltered homeless adults; there is a high chance that some may not return for the post-test.

The intervention is appropriate for use in any setting or population. The pilot study though generalizes to the same type of clinic setting with the same type of population. Unfortunately in attempting to protect the internal validity, certain inclusion criteria may have restricted the pilot’s study generalizability potential: e.g. two or more chronic
conditions, three or more medications, seeing two or more providers. Additionally, homeless people in shelters or meal programs will not be included if they do not receive care at the selected site.

**Outcome of Interest.** The primary outcome of interest is medication adherence (Dependent Variable). In addition, a secondary outcome of interest is the removal of medication discrepancies to promote medication safety and accuracy of the medical record.

**Sample.** Recruiting participants at the provider appointment will generate a convenience, non-random sample. A Basic Demographic Questionnaire, adapted from the 2010 U.S. Census (see Appendix C1-C3), will help pre-screen participants for the study. Those meeting inclusion criteria: will be ≥41 years, have two or more chronic medical conditions, take three or more medications, receive care from two or more providers, speak English, manage their medications independently, and have no cognitive deficits as verified by the participant’s provider. Additionally, they must keep monthly contacts with the research assistant (RA) and Principal Investigator (PI) for five months after the pretest visit to prevent attrition. A dependent one (1)-tailed t-Test will describe the representativeness of the sample.

**Sample Size. (and power calculation).** A statistical power analysis-G* Power 3.1, (Faul, Erdfelder, Buchner, & Lang, 2009), was used to calculate the sample size.

![Figure 5. Power calculation Graph](image-url)

**t tests** - Means: Difference between two dependent means (matched pairs)

**Analysis: A priori:** Compute required sample size
Program Director/Principle Investigator: Delgado, Virgie S.

**Input:** Tail(s)=One
- Effect size dz=0.3500000
- $\alpha$ err prob=0.10
- **Power** (1-$\beta$ err prob)=0.80

**Output:**
- Noncentrality parameter $\delta=2.1575449$
- Critical $t=1.3048544$
- Df=37
- **Total sample size=38**
- Actual power=0.8028422

A Power: .80, Effect Size: .35, p=< 0.10, yielded a sample size of: 38 + 30% (for loss factor), the sample size will be: N = 38 + 11, for a total of 49.

*Figure 6. Power Analysis Plot*

![Power Analysis Plot](image)

Paired t-test: Effect size of .35, alpha of .10, power of .80, 30% for loss factors = sample size of 49. To compensate for the small sample size, the significance level selected is higher than usual due to the limited number of patients treated at the selected site for the pilot study. When performing pilot studies with small sample sizes, it is common for a researcher to set the significance level higher than usual to compensate for the small sample size. According to Windsor, Baranowski, Clark and Cutter (1994), when the conventional significance level is $p < 0.05$, a pilot study might use a significance level of 0.10 or even 0.20. The purpose of the higher significance level in a pilot study is to avoid abandoning what might otherwise be a promising line of research on the basis of a pilot study that finds no effect for the treatment.
Data Analysis Plan

Manual pill counts will provide a ratio measure of adherence at pre- and post-test. A count of the actual number of prescribed pills in the bottle, divided by the number of pills that should have been taken, since the date medication was filled, will be multiplied by 100, to yield a ratio measure of adherence. Participants will be classified as: (1) “adherent” if the pill count suggested that the patient consumed at least 80% of the prescribed medications or (2) “nonadherent” if the patient consumed less (Martin et al., 2011). Calculating a difference in means will serve to compare means before and after the intervention. Descriptive statistics (frequency, mean, median, mode) will describe the sample. A regression analysis will check for confounding variables. Confounders that will be considered include: age, gender, number of comorbidities, number of medications, and number of treating providers.

Regression equation \( Y = b_1X_1 + b_2X_2 + \ldots + b_5X_5 + A \)

After the post-test using SPSS 20.0, inferential analytic techniques will be used to evaluate the data, specifically an analysis using one tailed dependent t-Test (directional). The anticipated computed value of \( t \) will be more than the tabled value of a one tailed \( t \) using \( \alpha=0.10, t(49) \) and CI 1.30 Confidence level of 90% to figure if group means are definitely different. A change in group means will show the effectiveness of the intervention. The research question asks if the intervention will have any effect on the dependent variable (medication adherence). Although present the independent variables will not be tested in the pre or post-test analysis, they will only be checked as confounding variables in a regression analysis. \( p= < .10, df= n-1 \) or \( 49-1= 48, \ H_1 \neq H_0, \ one (1) tailed dependent t-Test. \)

Organizational Issues

For a detailed explanation of the proposed Budget, see pp. 7-11 above
Instruments

The participant will sign the consent and authorization forms (see Appendix B1-B4), then complete a basic demographic questionnaire adopted from the US 2010 Census. The purpose of the questionnaire is to gather data describing the population: age, sex, race, educational level, living arrangements, and employment status.

A Medication Discrepancy Tool (MDT) by Dr. Eric Coleman (2004) [see Appendix D1-D2] will assess any discrepancies between actual medications taken and those recorded on the medical file. The provider will be immediately notified of all discrepancies found and documented on the MDT. A previous study by Smith, Coleman, and Min (2004) [see Appendix D3], established the psychometric properties of the MDT. Inter-rater reliability (kappa) for the 20 vignettes was 0.56 (15% low agreement, 80% good agreement, and 5% excellent agreement). Intra-rater reliability ranged from 0.58 to 0.69. Dr. Eric Coleman (2004), granted written permission to use the MDT in this proposed pilot study.

At both pretest and post-test, a Medication Assessment Form (adultmedications.com, 2013) [see Appendix E1-E2], will test the participant’s medication knowledge. The use of this form will help the PI identify the medication, disease, and self-management gaps in knowledge and also guide the participant’s educational intervention. Because medication adherence is an individual behavior, participants will receive an individually designed educational intervention based on the identified gaps in knowledge in order to best meet their educational need.

Data Collection

After obtaining informed consent, the participant will complete the demographic questionnaire adopted from the US 2010 Census to get descriptive data representative of the
Program Director/Principle Investigator: Delgado, Virgie S.

population sample. Manual pill counts for each prescribed medication will be obtain at both pre-test and post-test. The MDT (Coleman, 2004) will be used to document medication discrepancies, and then report the discrepancies to the provider for correction. Participants will then receive individualized medication, disease, and medication self-management education based on the identified gaps in knowledge. Finally, participants will receive adhering-aiding tools, along with instructions on how to use the tools to help with their medication self-management (see Appendix F1-F6). The demographic information will only be collected at pretest. Figure 7. Outlines the steps in the intervention.

---

**Figure 7. Medication Reconciliation Educational Intervention**

[Diagram of the steps in the intervention]

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Dissemination plan

Once all data has been analyzed and interpreted, the participants and any other groups (e.g., similar populations at other free clinics or free clinic projects) benefitting from the findings will receive a formal presentation of the pilot study’s results. Using power point presentations and poster formats, the findings will summarize the effects of a multi-component medication reconciliation intervention on medication adherence. Finally, both the Journal of Geriatric American Society and the Journal of Primary Care and Community Health will receive the research manuscripts.
Bibliography and References Cited


Axman, L. (2012). Living unsheltered : Not a hollywood experience but it would make a great horror flick: Odyssey 2012: The emergence of a nursing student-run free healthcare project [PowerPoint slides].


http://proquest.umi.com/pqdweb?did=1798970751&sid=1&Fmt=2&clientId=79356&RQT=309&VName=PQD


Protection of Human Subjects

Inclusion Enrollment Report Not applicable

Protection of Human Subjects

An application for research involving human subjects will be submitted for approval by Institutional Review Board at California State University San Marcos and the School of Nursing. A detailed consent will be provided to each participant outlining all information about the pilot study (see content of proposed consent in Appendix B1-B3). All identifying and personal information will be maintained securely locked in file cabinets, accessible only by the PI and API.

Inclusion of Women and Minorities

Women will be included, if willing to participate in pilot study.

Targeted/Planned Enrollment Table

Included in grant content, refer to page 62.

Inclusion of Children

Not applicable.

Vertebrate Animals

Not applicable.

Select Agent Research

Not applicable.

Consortium/Contractual Arrangements

Not applicable.

Resource Sharing Plan(s) Not applicable.
Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: A MEDICATION RECONCILIATION EDUCATIONAL INTERVENTION TO IMPROVE MEDICATION ADHERENCE IN A MEDICALLY UNDERSERVED POPULATION: A PILOT STUDY

Total Planned Enrollment: 49

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<td><strong>Racial Categories</strong></td>
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<td>Native Hawaiian or Other Pacific Islander</td>
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<td>Black or African American</td>
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<td>**Racial Categories: Total of All Subjects *</td>
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* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”
**Inclusion Enrollment Report**

*This report format should NOT be used for data collection from study participants.*

**Study Title:** A MEDICATION RECONCILIATION EDUCATIONAL INTERVENTION TO IMPROVE MEDICATION ADHERENCE IN A MEDICALLY UNDERSERVED POPULATION: A PILOT STUDY

**Total Enrollment:** 49

**Protocol Number:** PA-12023

### PART A. TOTAL ENROLLMENT REPORT:

by Ethnicity and Race

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<td>29</td>
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</tr>
</tbody>
</table>

**Racial Categories**

- American Indian/Alaska Native
- Asian
- Native Hawaiian or Other Pacific Islander
- Black or African American
- White
- More Than One Race
- Unknown or Not Reported

**Racial Categories: Total of All Subjects**

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<tr>
<th></th>
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<th>Males</th>
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<tr>
<td>More Than One Race</td>
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<tr>
<td><strong>Racial Categories: Total of Hispanics or Latinos</strong></td>
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APPENDIX A- Worksheet to Critique and Grade the Evidence (Rosswurm and Larrabee, 1999)

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<tr>
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<th>Research Variables</th>
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<th>Major Findings</th>
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<td>Descriptive</td>
<td>Findings:</td>
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<td></td>
<td>Level II: Correlational Survey</td>
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<tr>
<td></td>
<td></td>
<td>Level III: Quasi-experimental Experimental</td>
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<td>Limitations:</td>
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<table>
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<td>Type:</td>
<td>Names: #1, #2, #3, #4</td>
<td>I. Meta-analysis of random-controlled trials</td>
</tr>
<tr>
<td>Type:</td>
<td>Acute Care-Hosp</td>
<td>a. One randomized controlled trial w/o randomization b. One other type of well-designed quasi-experimental study</td>
<td></td>
</tr>
<tr>
<td>Age:</td>
<td>Community</td>
<td>III. Comparative correlation &amp; other descriptive studies</td>
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</tr>
<tr>
<td></td>
<td>Nursing Home</td>
<td>IV. Evidence from expert committee report or expert opinion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other:</td>
<td>Feasibility: Could this practice change be implemented easily in your org. &amp; within resources? YES NO</td>
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<tr>
<td>Gender:</td>
<td>Location:</td>
<td>Benefit/Risk: Would the benefits of this change outweigh the risks to patients? YES NO</td>
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## APPENDIX A1-Literature Review: Chart Summary

**Characteristics of Review Studies** for: A Medication Reconciliation Intervention to Improve Medication Adherence in a Medically Underserved Population: A Pilot Study

<table>
<thead>
<tr>
<th>A1. Author</th>
<th>Design/Sample Size Mean Age/Location</th>
<th>Specific Criteria for Measurement</th>
<th>Theoretical Framework</th>
<th>Outcomes</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melnikow and Kiefe (1994)</td>
<td>Expert opinion/review on methodologic issues important in the design, analysis &amp; evaluation of medication (MED) adherence</td>
<td>Evaluated various methods for measuring adherence: direct (MED administration), patient interviews, pill counts, pharmacy records, serum &amp; urine drug levels, urine markers, clinical measurements of biological effects, MEMS</td>
<td>None mentioned</td>
<td>No “golden standard” for measuring adherence. It is preferable to study adherence as a dependent variable (varies over time) Enhancing MED adherence best done by tailoring, MED education (MED EDU) given both verbally &amp; written (more effective)</td>
<td>Pill counts- standard “objective” method of measuring adherence for many years. Gives fairly accurate of average adherence. MEMS: not feasible, time consuming &amp; expensive</td>
<td>Aspire to improve adherence only with those treatments which have reasonable evidence of efficacy</td>
</tr>
<tr>
<td>Vermeire et al. (2001)</td>
<td>Systematic Review- 3 decades of literature 1975-1999 N=33 Mean age: not indicated Location: Belgium</td>
<td>Articles reviewed having adherence as the main topic of the study &amp; the methodological was of good quality</td>
<td>Some studies reviewed reference the Health Belief Model</td>
<td>No “Golden Standard” for measuring adherence, self-reports vulnerable to overestimates, recall &amp;self-presentation bias; refill records overestimate it; Educational &amp; behavior strategies better at improving Adherence, when combined (tailoring, reminders, adhering- aiding tools, support &amp; feedback)</td>
<td>MED EDU aimed at improving treatment understanding enhances adherence (verbal followed by written). Patient beliefs predict adherence. Assistance in improving patterned behavior known to increase adherence.</td>
<td>Article supports multimodal interventions aimed at improving adherence. Support &amp; adhering-aiding tools as well as both verbal &amp; written MED EDU were recommended</td>
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<tr>
<td>A2. Author</td>
<td>Design/Sample Size Mean Age/Location</td>
<td>Specific Criteria for Measurement</td>
<td>Theoretical Framework</td>
<td>Outcomes</td>
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<td>Ryan and Lauver (2002)</td>
<td>Meta-analysis N=20 (sample sizes in each study n=51-1934 Mean age: 50 Location: Wisconsin USA)</td>
<td>Evaluate efficacy of Tailored Informational Interventions (TIs) compared to Standard Informational Interventions (SIs); determine whether efficacy varies by type of behavior, use of feedback, type of delivery channel, dose of the intervention, or time.</td>
<td>Cooper’s method of literature integration</td>
<td>Participants preferred TIs to Sis (felt messages were directed to them personally), read &amp; remembered more information from TIs, saved &amp; shared the intervention: adherence measured via self-reports</td>
<td>TIs more effective than SIs in promoting health behavior outcomes in 50% of studies reviewed. TIs had greater effect when explicit ipsative feedback was provided than with implicit feedback.</td>
<td>Tailored MED EDU info more personal &amp; effective; feedback that focuses on improve adherence</td>
</tr>
<tr>
<td>Pronovost et al. (2003)</td>
<td>Random selection of medical records n= ~240-600 files over 24 weeks Mean age: not indicated Location: John Hopkins ICU, Maryland USA</td>
<td>*Primary outcome variable: % of records with MED errors in transfer patients *Secondary outcome variable: # of times doctor orders were changed, due to errors found. *Staff compliance in collecting MED errors</td>
<td>&quot;To Err is Human&quot; &amp; Conceptual model of Independent Redundancies</td>
<td>% of audited surveys w/errors # of meds errors per wk. prevented through medication reconciliation (MED REC) Staff compliance with med rec each wk.</td>
<td>At baseline 94% of doctor orders were changed due to discrepancies. At Week 24 no med discrepancies were found</td>
<td>MED REC directly associated with a dramatic reduction in MED errors</td>
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<td>Hamilton (2003)</td>
<td>RCT-double blind 3 group n=107 Mean age: 50 Location: Lancaster, MA USA</td>
<td>Measuring adherence to HTN MED using various methods: Self-reports, pill counts, MEMS, urin markers &amp; MD estimates</td>
<td>Health Belief Model</td>
<td>Intervention by groups 1) no intervention 2) Med EDU, 2 visits at study site 3) MED EDU via phone, 2 x 10min each</td>
<td>Lowest level of adherence reported via Self-reports, Forgetfulness most reported reason for non-adherence (46-55%). Urine marker &amp; MD estimates inadequate to measure adherence</td>
<td>MED EDU: purpose, dose, S/E, ADE &amp; dose times. Group receiving MED EDU at site adhered more than those who got it via phone</td>
</tr>
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<tr>
<td>Kaplan et al. (2004)</td>
<td>Mixed Method (Interviews &amp; MED record review) n= 510 Mean age: 50 Location: Bronx, NY USA</td>
<td>Predictors of Adherence w/lipid-lowering MED Adherence measured via Self-reports</td>
<td>None ID</td>
<td>Age &amp; sex adjusted Nonadherence 1- higher frequency in Black &amp; Hispanic 2- Sex, race, ethnicity adjusted Nonadherence associated w/MED s/e, feeling sad, depressed, fair/poor health, primary language other than English, single, divorce status, few &amp; less contact w/friends, children in house &amp; lower education.</td>
<td>Multivariate models predictors of non-adherence: S/E (OR = 3.9, P &lt; 0.01), sad or depressed (OR = 1.9, P =.05), Black (OR = 3.7, P &lt; 0.01, vs. White), Hispanic (OR = 6.3, P &lt; 0.01, vs. White) single or divorced (OR = 2.1, P &lt; 0.01), children in the house (OR = 1.5 per child, P &lt; 0.01) under/uninsured (OR = 2.4, P&lt;0.05).</td>
<td>ID High risk groups: need Multimodal interventions MED EDU &amp; communicate -on</td>
</tr>
<tr>
<td>Kogos (2004)</td>
<td>RCT pretest posttest design, N=30 Mean age: 69 Site: VA hospital in Birmingham, Alabama USA</td>
<td>Pill counts used to measure adherence pre-post test. Intervention: 2 groups met 5 sessions-one group had pill counts, used contracts, enlistment support, monitored feedback &amp; healthy lifestyles, MED EDU. Control group: initial-final pill count, meet 1/wk. discussed other issues</td>
<td>None ID</td>
<td>Calculated portion of prescribed (Rx) MED # of pills dispensed MINUS # of pills in bottle DIVIDED by # of pills expected to be taken per Rx</td>
<td>Adherence better in intervention group: measured by pre- &amp; post-test: pill counts Conclusion support &amp; multicomponent intervention increased MED compliance.</td>
<td>Multimodal intervention-MED EDU &amp; support improved adherence in older adults.</td>
</tr>
<tr>
<td>Whitney and Glazier (2004)</td>
<td>Qualitative using semi-structured interviews, purposeful sampling was used N= 20 Mean age: 45 Location: Toronto, Canada</td>
<td>Factors affecting MED adherence: Content analysis was used to identify, code &amp; categorize themes in data Adherence measure used: Self-reports</td>
<td>None ID</td>
<td>Issues with MED access retaining MED &amp; MED regimen; Homeless under-represented in literature regarding barriers to treatment &amp; MED adherence</td>
<td>Barriers: Accessing MED Retaining MED Following regimen Outreach &amp; support needed</td>
<td>Multimodal interventions Monitor, therapeutic pt-provider relationship, feedback</td>
</tr>
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<td>Dimatteo (2004)</td>
<td>Meta-Analysis</td>
<td>Impact of family &amp; social support on Adherence</td>
<td>None ID</td>
<td>Adherence in patients having family &amp; social support to manage MED and Treatment regimens</td>
<td>Adherence 1.74 times higher in patients with close family ties &amp; involvement; and 1.53 times lower in patients lacking support &amp; Family involvement</td>
<td>Support enhances MED adherence</td>
</tr>
<tr>
<td>Tanner (2004)</td>
<td>Expert Opinion</td>
<td>No measurement, only recommendations for improving adherence</td>
<td>None ID</td>
<td>MED EDU alone not adequate to achieve adherence Behavior-based educational interventions-both verbal &amp; written more effective; pill boxes</td>
<td>Improvements in adherence seen in patients when family received MED &amp; adhering-aiding tools education, eg. pill boxes</td>
<td>Older adults need support and assistance with MED to adhere</td>
</tr>
<tr>
<td>Pound et al. (2005)</td>
<td>Meta-analysis of qualitative studies of lay experiences of meds taking. n= 37</td>
<td>Evaluating the experiences of patients who reject their MED or accept them uncritically</td>
<td>None ID</td>
<td>pts avoid illness by ignoring need for MED &amp; fear of disclosing illness-stigma. Pts take MED minimally due to cost, addiction fear, ADE based on symptoms. Most don’t report actual intake, for fear of being labeled “Bad Pt”.</td>
<td>MD must accept pts modify their MED regimen; therefore communication (comm), MED EDU, patient inclusion in MED regimen is vital to getting pts engaged.</td>
<td>Improved comm &amp; MED EDU vital to improve adherence. Support motivates &amp; engages pts to adhere to meds.</td>
</tr>
<tr>
<td>MacLaughlin et al. (2005)</td>
<td>Expert Opinion</td>
<td>No Measurement, only recommendations for improving adherence</td>
<td>None ID</td>
<td>Increased MED knowledge &amp; belief in its effectiveness in disease management increases adherence</td>
<td>Routine evaluation of MED adherence in the elderly-rarely performed in clinical practice. Patients who understand perceived need to MED adhere better</td>
<td>Knowledge of disease &amp; consequence of not taking MED influences adherence</td>
</tr>
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<tr>
<td>Lehane and McCarthy (2005)</td>
<td>Correlation Study</td>
<td>n= 73, convenience sample Mean age: 52 Location: Ireland</td>
<td>Measured adherence using self-reports</td>
<td>MAM</td>
<td>Intervention-strategies to enhance unintentional non-adherence: MED EDU focused on gaps in knowledge &amp; adhering-aiding tools (pill box); also improve patient-provider relation</td>
<td>High levels of adherence reported mean score 4.75/5.0 53% of patients do not use adhering-aiding tools for MED reminders</td>
</tr>
<tr>
<td>Vira et al. (2006)</td>
<td>Randomized, Prospective study n= 60 Mean age: 56 Site: Community Hospital Location: Canada</td>
<td>MED discrepancies hospital admission and discharge</td>
<td>None ID</td>
<td>36 cases had 1 MED discrepancy (greater than ½ the sample). Med REC intercepted 75% of meds errors before the pt was harmed</td>
<td>60%- had 1 MED discrepancy, 18% had 1 clinically important MED discrepancy. None detected in normal clinical practice, ONLY found when MED REC done</td>
<td>MED REC proven to intercept meds errors which can potentially cause harm to the pts.</td>
</tr>
<tr>
<td>Johnson and Shalansky (2006)</td>
<td>Correlation Study n= 350 Mean age: 50 Location: Canada</td>
<td>Morisky self-reporting adherence &amp; pharmacy refill reports</td>
<td>None ID</td>
<td>Non-adherence to refill MED Adherence calculated # of pills taken divided by # of pills that should’ve been taken x100; &lt;90% indicates non-adherence</td>
<td>Patient’s perception of MED decreases adherence; regimens should be prescribed after asking them about their existing routines. Regimens that disrupt routines lead to non-adherence.</td>
<td>Intervention that assist patients with tailoring MED schedule needed &amp; helpful</td>
</tr>
<tr>
<td>Lee et al. (2006)</td>
<td>RCT n= 533 Mean age: 65 Location: TX USA</td>
<td>Pill Counts measured Adherence Intervention: 1 hour MED education at baseline then 30 mins; use of blister packs &amp; follow-up with pharmacy every two months.</td>
<td>None ID</td>
<td>Adherence measured from phase 1-run in to 8 months Change in B/P &amp; LDL</td>
<td>MED adherence improved 61.2% after phase 1; after phase 2 continued intervention group maintained adherence rate of 95.5%; usual care group decreased adherence-69.1%</td>
<td>MED adherence did not persist after intervention ended in spite of decrease in B/P &amp; LDL levels</td>
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<td>Gellad et al. (2007)</td>
<td>Cross-sectional national survey of Medicare beneficiaries n = 14,829 Mean age: 65 White, Black &amp; Hispanics, on more than 1 med. Location: Boston, MA USA (from 2003 National Survey of seniors, by “Health Institute at Tufts-New England Medical Center)</td>
<td>Adherence measured by self-report (survey was used)</td>
<td>None ID</td>
<td>1) Eval if rate of non-adherence vary by race 2) Eval association between race &amp; ethnicity &amp; non-adherence is moderated by insurance coverage &amp; income</td>
<td>Blacks &amp; Hispanics more likely to report cost-related non-adherence, than Whites (35.1%, 36.5% &amp; 26.7%, respectively p &lt; .001) Race &amp; ethnicity disparities in MED adherence in seniors due to cost concerns</td>
<td>Affordability should be addressed to eliminate racial &amp; ethnicity disparities</td>
</tr>
<tr>
<td>Peterson et al. (2007)</td>
<td>Observational n = 245 Mean age: not identified Location: San Francisco, CA USA</td>
<td>Adherence measured by pill counts and serum samples for HIV RNA levels &amp; CD4+ T cell count, as part of an adherence-monitoring monthly unannounced visits</td>
<td>None ID</td>
<td>Med adherence-primary outcome, measured via monthly unannounced visits</td>
<td>Pillbox organizer use estimated to improve adherence by 4.1–4.5% &amp; decrease in viral load of 0.34–0.37 log₁₀ copies/mL &amp; a 14.2%–15.7% higher probability of achieving a viral load ≤400 copies/mL (odds ratio, 1.8–1.9). All effect estimates were statistically sig.</td>
<td>Pillbox sig improved adherence to antiretroviral therapy &amp; virologic suppression. Est. to be associated with a cost of ~$19,000 per quality-adjusted life-yr</td>
</tr>
<tr>
<td>Leonhardt et al. (2008)</td>
<td>Quasi-experimental trial using 2 waves of cross-sectional data Sites: 5-clinics n = 596 pre, 594 post (intervention) 68 other Aurora clinics (no intervention) n=2,154 pretest n = 2053 post test Mean age: 73 Location: Walworth City, WI USA</td>
<td>Primary outcome: rate of accurate MED lists in the intervention clinics compared to 68 controlled clinics (no intervention)</td>
<td>None ID</td>
<td>Accurate MED list, eliminating MED discrepancies via a community-based initiative providing med rec, tools &amp; resources for patient engagement improved pt adherence and accuracy of the outpatient MED list</td>
<td>After disseminating over 16,600 MED lists &amp; 7,800 med bags at over 80 educational sessions, the rate of accurate MED lists significantly increased from 55 % to 72% (P &lt;.001).</td>
<td>Multimodal intervention of MED &amp; tools to assist patient with self-management can improve engagement &amp; MED adherence</td>
</tr>
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</table>
### A7. Author Design/Sample Size

**Mean Age/Location**

**Specific Criteria for Measurement**

**Theoretical Framework**

**Outcomes**

**Results**

**Comments**

| Bosworth et al. (2008) | RCT  
n= 636 (319 in intervention & 317 in usual care)  
Mean age: 60  
Location: VA Medical Center Durham, NC USA | Behavior intervention to improve adherence & control B/P, adherence measured using self-reports: Morinski Scale | Health Decision Model | Effect of intervention on adherence: Intervention included: disease & MED EDU, importance of patient-provider relation, exercise, ETOH use, smoking, wt management, stress, & ETOH use; support. | MED adherence improved 9% in intervention group. Functional health literacy ability to understand & act on health info- primary component needed to plan & adhere  
Recommend MED EDU for family members of older adults. | Patient receiving social & family support or those having adhering-aiding tools adhere to MED regimen |
|---|---|---|---|---|---|---|
| Kurzuya et al. (2008) | Prospective cohort study  
n= 1,772  
Mean age: 79-81  
Location: Japan (The Nagoya Longitudinal-3yr Study for frail elderly) | Self-reported MED adherence & with difficulty self managing Med; Pill counts measure adherence: Total # of pills taken divided by total # of prescribed pills then assessed according to self-reported average MED adherence x 1mon. Adherence was averaged across the different MED classes 80-100%= adherent < 80%= non-adherent | None ID | 1) Ability to self-manage MED  
2) Assistance with MED management needed & available  
3) Association with unmet MED management assistance & 3yr mortality and hospitalizations in community elderly  
4) MED adherence | Elderly needing but not having help with MED self-management was associated with hospitalizations. Poor MED adherence observed in participant who lacked assistance managing MED | Unmet need for MED assistance-risk factor for hospitalization & non adherence in community dwelling elderly. |
| Wong et al. (2008) | Prospective study  
N= 150  
Mean age: 65  
Location: Canada Tertiary Care teaching hospital | Comparing the MED list for community dwelling elderly newly hospitalized, to correct MED discrepancies; then comparing the MED list again at discharge, against the MD orders | None ID | 1) Determine # of pts w/at least 1 Med discrepancy at hospital discharge D/C  
2) Characterize/assess potential clinical impact of MED discrepancy 31 (29.5%) had potential to cause pt discomfort clinical instability | 70.7% (106) had 1-actual/potential MED discrepancy 41.3% (62) had 1-actual MED discrepancy 55.3% (83)-had at least 1 potential MED discrepancy | Most common discrepancy R/T incomplete Rx (49.5%) & meds omission (22.9%) |
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<tr>
<td>NEHI (2009)</td>
<td>Meta-analysis of RCT of interventions proven effective in improving MED adherence N= 40 Mean age: Not indicated Location: Cambridge, MA USA</td>
<td>Interventions that improve MED adherence were reviewed</td>
<td>None ID</td>
<td>Intervention to improve adherence: Simplified MED regimen, MED &amp; disease education for patient &amp; their family, case management, discharge counseling, reduce MED cost, include patient in MED prescribing, reminders tailoring, enhance patient-provider relation, follow up, target at-risk populations.</td>
<td>Adhering-aiding interventions must address barriers (MED cost, access, gaps in knowledge, daily routine, MED perception, cognitive impairment, forgetting, lack of support with MED management) MED REC: improves adherence, promotes communication, engages both patient &amp; provider. Tools to assist with MED reminders: MED list, pill box, MED cards (studies reviewed showed statistical sig improvements in adherence with use of pillbox)</td>
<td>Multimodal interventions promoting patient-provider relation, MED EDU, reminders &amp; adhering-aiding tools found to improved MED adherence.</td>
</tr>
<tr>
<td>Schoenthaler et al. (2009)</td>
<td>RCT, cross-sectional N = 439 (poorly controlled HTN patients followed in a community clinic) Mean age: 58 Site: New York, USA</td>
<td>Perceived Comm style questionnaire: measured patients’ perception of provider communication (comm) Morisky self-report questionnaire: measured MED adherence</td>
<td>Health Comm. Model</td>
<td>Perceived providers’ comm. Adherence to anti-HTN MED</td>
<td>Collaborative MD comm. associated w/better adherence in African Americans (r = -.15, P =.003), poor MD comm. worse adherence (r= -.12, p =.018)</td>
<td>Patients who rate provider comm. as collaborative reported better adherence</td>
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<tr>
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| Vanelli et al. (2009) | Retrospective study | Comparing the risk of discontinuing MED in first 30 days of filling MED  
\textit{n} = 2.17 Million patients who received prescriptions from 3,821 pharmacies  
Mean age: 50  
Location: USA | Pharmacy records used to measure adherence for patients who’s in-class MED was not dispensed in previous 180 days (ID as naïve), Patients whom an in-class med was dispensed (ID as med experienced) Discontinuation defined as being >30 days late for a scheduled refill. | None ID | MED discontinued during first 30 days after MED filled and the median time to discontinuation (D/C)  
for MED naïve and MED experienced patients prescribed MED for asthma, glaucoma, DN, high cholesterol, CVD, breast CA & osteoporosis. | During the first 30 days of therapy, rates of D/C for med-naïve pts were 17.4% to 42.6% higher than for med-experienced pts, & their median times to discontinuation were 14.2% to 28.9% as long. | MED-naïve patients had greater risk of D/C MEDS during first 30 days than MED experienced patients regardless of MED class |
| Fung (2009)          | Correlation study  | n=64, conveniences sample  
Mean age: 51  
Location: Chicago, IL USA | Relation between MED adherence & factors related to MED adherence in medically-underserved patients with CHF  
Self-reports measured adherence | MAM | 1) overall patient rating of their adherence  
2) Self-reported frequency of non-adherence  
3) sources of getting & taking MED | Patterned behaviors & belief about MEDs were significant predictors explaining 52% of variance in MED adherence, with patterned behaviors accounting for 42% of variance | Nurses can help plan routines for taking MED at home & eval need for assistance with self-management to ensure adherence |
| Conn et al. (2009)   | Meta-analysis of RCT | n= 33  
Mean age: 67  
Location: Columbia, MO USA | Behavioral and cognitive strategies used in interventions to improve adherence, which proved to be more effective in older adults  
Effectiveness of adherence measures | None ID | Improvement in MED adherence using behavioral or cognitive strategies, which produced better adherence?  
Pill counts objective method of adherence, causing greater effect. | Interventions that emphasis behavioral rather than cognitive strategies produced better adherence  
Outcomes: Pill boxes, MED lists, MED EDU for patient & family, MED self-management. Intense intervention needed for patients taking >3 MED  
Older adults need MED support. Pill counts effective | Multimodal interventions improved adherence. MED EDU should be less verbal with written instructions given for patient to refer to at home. |
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<tr>
<td>Hsu et al. (2010)</td>
<td>Cross sectional survey design n= 94, convenience Mean age: 65 Location: San Jose, CA USA</td>
<td>Attributes considered as affecting level of adherence: Gender, marital status, EDU, Insurance, time in US, yrs of HTN Dx, # of HTN MED, Freq of MED taking, cultural or social barriers Adherence measured using self-reports</td>
<td>MAM</td>
<td>Level of adherence to HTN MED among Chinese Any attributes affect rate of adherence</td>
<td>Forgetfulness, ADE language difficulties, cultural barriers were influential factors hindering MED adherence only</td>
<td>Culturally appropriate adhering-aiding strategies needed in elderly of Chinese culture</td>
</tr>
<tr>
<td>Van Onzenoort et al. (2010)</td>
<td>RCT double blind trial with a parallel-group design n=228 Mean age: 57 Location: Netherlands</td>
<td>Med Adherence measured: 1-via MEMS % of days taking correct dosing 2- PILL COUNT-calculated as % of # of Rx pills corrected for the # of returned pills ÷ by the period (in days) x 100%. 90%-acceptable 3-Categories ID: A. Non-adherent by both methods, B. Adherent by MEMS, not pill count, C. Adherent by pill count not MEMS D. adherent by both methods. Patients educated on disease process &amp; MED</td>
<td>None ID</td>
<td>Examine whether decisions concerning HTN MED based on self BP measurement would lead to less MED &amp; associated costs, when compared to decisions based on Office BP measurements The effect of self BP measurement on MED adherence within random subgroups was investigated.</td>
<td>Median adherence per MEMS was lower than by pill count (91.6% &amp; 96.1%; P&lt;0.001). In 107 (47%) &amp; 33 (14%) both methods agreed in defining adherence &amp; non-adherence, 31 (14%) were adherent only by MEMS &amp; 59 (25%) only by pill count. At study termination, patients in the 4 categories reached comparable BP values &amp; reductions</td>
<td>MED, disease &amp; B/P taking EDU helpful in promoting patient engagement, providers involved participants in MED Rx when HTN MED needed to be changed during the study</td>
</tr>
<tr>
<td>Johnson et al. (2010)</td>
<td>Cross-sectional comparison of Patients Electronic Medical Record list &amp; pharmacy MED fill history n= 100 Mean age: not indicated Location: Oklahoma USA</td>
<td>Types and frequencies of MED discrepancies ID through a MED REC intervention in a community pharmacy MED discrepancies ID: duplication, exclusion, inactive MED still on file, differences in MED dose, strength, or dosing regimen.</td>
<td>None ID</td>
<td>Occurrence of MED discrepancies in a pharmacy &amp; determine if any relation between patients who use prescribers &amp; pharmacies out of pharmacy doing the study</td>
<td>Each patient had an average of 6 MED discrepancies, most belonged to the inactive MED category-41% Those with more than 1 prescriber had more discrepancies</td>
<td>Meds REC needed in out-patient settings, especially when patients see more than 1 provider</td>
</tr>
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<td>Pladevall et al. (2010)</td>
<td>RCT-multipurpose cluster-longitudinal Prospective study, lasting 39 mons</td>
<td>Measuring effects of intervention on adherence. Adherence measured using pill counts and MEMs. Intervention: family member appointed to support adherence behavior; an educational sheet at start: info on B/P MED, dose, frequency, S/E, action to take if dose is missed, med running low, 2 questions for pt to answer &amp; bring MD appointment: any problem w/med? Any S/E? along w/B/P readings.</td>
<td>None ID</td>
<td>1-SBP &amp; DBP control at end of 6 month follow-up (f/u) 2-Med adherence over 6months of f/u, 3-additional exploratory outcome, composite endpoint of all-cause mortality &amp; admission to hospital for any cardiovascular event at 5yrs of f/u.</td>
<td>Intervention successful at improving adherence 48% vs. 32% P&lt;0.05, those who adhered had lower SB/P than non-adherent (P&lt;0.05), not significant for DB/P. Intervention patients less likely to have uncontrolled SB/P (odds ratio 0.62%, 95% CI 0.50-0.78) were more likely to be adherent (Odds ratio 1.91, 95% CI 1.91-3.05)</td>
<td>Multifactorial intervention effective in improving both adherence &amp; B/P control but did not appear to improve CV events.</td>
</tr>
<tr>
<td>Martin et al. (2011)</td>
<td>RCT N=434 (Medically underserved)</td>
<td>Examine effectiveness of community-based, multimedia intervention on adherence in adults w/ HTN Manual Pill Counts measured adherence: # of pills taken ÷ by # of pills patient was supposed to have taken per Rx &gt;80 = Adherent &lt; 80 = Non-Adherent offered an objective measure, strengthening the study) ** MED provided free of charge to patients at clinic through a Federal grant but patients needed to pickup MED from clinic.</td>
<td>Trans-theoretical model, used to create intervention to help keep behavior skills for taking MED</td>
<td>Improvements to MED adherence after an EDU intervention focusing on: Individual behavior, Goal setting, Self-monitoring.</td>
<td>Intervention group didn’t differ from control (51% vs. 49%, respectively; p = .67). Clinic type (p &lt; .0001), forgetting MED (p = .01) &amp; difficulty getting to clinic to get MED (p &lt; .001) predicted adherence EDU intervention could not impact adherence because patients could not access MED from clinic-had no transportation.</td>
<td>Multilevel interventions addressing MED access in rural low-income patients &amp; pt-related factors (forgetting) are needed to improve MED adherence.</td>
</tr>
<tr>
<td>A12. Author</td>
<td>Design/Sample Size</td>
<td>Mean Age/Location</td>
<td>Specific Criteria for Measurement</td>
<td>Theoretical Framework</td>
<td>Outcomes</td>
<td>Results</td>
</tr>
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<td>Mishra et al. (2011)</td>
<td>Qualitative study n= 50</td>
<td>Maryland, USA</td>
<td>Participants in groups of 9-11, focus groups to foster understanding of meaning &amp; context from patients view of prescribed MED for &gt;2 chronic conditions. Adherence measured using self-reports</td>
<td>Bronfenbrenner's Ecological Model of Behavior</td>
<td>Patient's perspective of barriers, facilitator to multiple MED taking &amp; strategies for self-care. 4-key areas targeted: knowledge of disease &amp; MED taking, reason for non-adherence, strategies for adherence to overcome barriers</td>
<td>Lack of shared decision with MD in MED management for multiple MED, 49 of the participants could not recall if MD provided MED EDU or helped to design a med Self-management plan</td>
</tr>
<tr>
<td>Walsh and Cussen (2012)</td>
<td>RCT n= 58</td>
<td>Ireland</td>
<td>Ten minute MED REC to detect MED discrepancies</td>
<td>None ID</td>
<td>Detect MED discrepancies, correct them, promote MED safety, accuracy of medical record, identify non-adherence, increase patient-provider comm.</td>
<td>*88% had change to meds due to review. *70% had at least 1-meds terminated. 32% had error in dose Rx. *ALL records had inaccurate actual meds taken by patients (pt) **92% had MED listed-pt not taking **56% were taking over the counter meds, not reported</td>
</tr>
<tr>
<td>Lewis et al. (2012)</td>
<td>RCT n= 253</td>
<td>Pennsylvania, USA</td>
<td>Effects of intervention on MED adherence. Adherence measured using self-reports: Morinsky measure Intervention: MED &amp; disease EDU, needed lifestyle changes, B/P monitoring at home, behavior Counseling</td>
<td>None ID</td>
<td>Primary end point-Assessed at 12 months, participants with adequate B/P control. Secondary end point-assessment of pt, provider, &amp; health care system factors associated with MED adherence.</td>
<td>In a hierarchical regression analysis age self-efficiency, depression, predicted non-adherence, final model accounted for 32.1% of variance (F=7.80), Depressed pts reported the worse adherence</td>
</tr>
<tr>
<td>A13. Author</td>
<td>Design/Sample Size Mean Age/Location</td>
<td>Specific Criteria for measurements</td>
<td>Theoretical Framework</td>
<td>Outcomes</td>
<td>Results</td>
<td>Comments</td>
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<tr>
<td>Clavert et al. (2012)</td>
<td>RCT-single blinded, longitudinal pre &amp; post-test N= 143 71 Randomized to intervention, 72 to control group (Hospital patients w/CAD discharged on ASA, Statins &amp; beta blockers) Mean age: 63 Location: North Carolina, USA</td>
<td>Evaluating the effects of an intervention on adherence. Adherence measured using self-report: Morinsky measure Intervention group In-hospital MED EDU, attention to adherence barriers, MED communication to pharmacy &amp; primary MD, &amp; ongoing assessment by community pharmacist. Usual care group received discharge counseling &amp; letter to Primary MD.</td>
<td>None ID</td>
<td>Primary outcome- self-reported med use at 6mons post hospital discharge, secondary outcome ≥ 75% proportion of days covered for beta blockers &amp; statins through 6mons post discharge.</td>
<td>No difference in self-reported adherence between intervention group &amp; control group 91 vs. 94% respectfully P=&lt;.05 Better adherence of beta blockers &amp; statins in intervention group. Self-reporting was overestimated.</td>
<td>Promoting effective MED taking behaviors through a variety of strategies, EDU adherence aids, support &amp; reminders are effective in improving adherence</td>
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CONSENT AND AUTHORIZATION FORM
FOR INSTITUTIONAL REVIEW BOARD APPROVED RESEARCH

Research Study Title: A MEDICATION RECONCILIATION EDUCATIONAL INTERVENTION TO IMPROVE MEDICATION ADHERENCE IN A MEDICALLY UNDERSERVED POPULATION: A PILOT STUDY

The researchers at California State University San Marcos School of Nursing (CSUSM SON) are conducting a study to examine the effects of a medication review-educational session on taking medication as ordered. My name is Virgie S. Delgado, RN, BSN. I am a graduate nursing education student at the CSUSM SON and primary investigator for this pilot study.

Invitation to Participate
You are invited to participate in the study because you are currently receiving care at the CSUSM SON Student Health Care Project, in Ocean Beach, CA, and have two (2) or more chronic conditions, requiring the use of three (3) or more medications that have been prescribed by two (2) or more health care providers.

This study aims to examine the effects of a medication review-educational session on:
- decreasing medication discrepancies (which is the difference between the actual medications you take to those listed on your medical record), and
- improving medication adherence (your consistency in taking prescribed medications as ordered),

The study will address:
- your medication knowledge,
- the appropriate use of medications, and
- the importance of managing your medications using tools provided to help you take medications safely.

The purpose of this consent form is to provide you with information about the nature of the study to assist you in deciding whether or not you would like to participate.

Requirements of Participation
In addition to this consent, you will complete a basic demographic questionnaire to help us identify the characteristics of those in the study. You will be required to attend two (2) medication review-educational appointments, to be scheduled six months apart for:
- an interview with members of our research team (nurses) and if needed your primary provider, to show us the actual containers of all prescribed and over the
Appendix B2

- counter medications, vitamins and herbal supplements; to be compared by the research team to the medication list in your medical record;
- a manual pill count of all prescribed medications, to obtain the amount of medication taken from the date it was filled;
- discussing your medication understanding, schedule and routines that help remind you to take medications as ordered.

After the first appointment you will need to contact us once a month either via phone or by coming to the clinic, to obtain support and answers to any medication question you may have as you manage your medications at home, using tools provided to you.

Six months after the first appointment, you will return to CSUSM SON Student Health Care Project for a final medication review. This will be done to determine if the intervention was helpful and useful in improving your medication taking skills. All steps followed in the first appointment will be repeated in the second, but you will not need to complete another consent or basic demographic questionnaire. You will inform us if the medication education and tools received were helpful, and if you changed your behavior as a result of the project, or if the information and tools were not helpful. The conversational style medication review-educational session will take 30 – 60 minutes and will take place in a private exam room located on the CSUSM SON Student Health Care Project in Ocean Beach, CA.

Risks

- Emotional distress resulting from self-disclosure
- Loss of Anonymity
- Loss of privacy
- Loss of time and incurring a cost related to transportation and a meal, as a result of attending the medication review-educational session.
- Coercion

Safeguards

- The responses provided will be kept unrelated to your name, to protect your identity.
- Your name on all documents (data sheets, etc.) will be replaced by a code developed by the Primary Investigators to conceal your identity. Your name will never be released to anyone other than the members of the research team, except when limited by the law. In some instances, research results may be disclosed to government agencies, the research sponsor, the IRB or its designee, or a regulatory agency. State statutes may require reporting of child abuse, sexually transmitted diseases, intent to murder, or suicidal thoughts.
- Your data will always be maintained in locked cabinets, in a locked room accessible only by the Primary Investigators. Only the Primary Investigators will analyze data (coded by number and not name), which will be used to publish manuscripts in peer-reviewed journals. Other personnel will not have access to these data. Data will be maintained by the Primary Investigators for at least three years after the completion of the Project. Findings disseminated at conferences or in publications will be expressed in aggregate, ensuring privacy.
The time spent at the medication review-educational session will allow you the opportunity to access a potentially beneficial intervention not otherwise available. A total of $50.00 incentive will be given to compensate you for the loss of your time, and for the transportation and meal expense incurred as a result of participating in the study. The incentive will be paid in two (2) payments: $25.00 at the end of the first medication review-educational session and $25.00 at the end of the second (six months after the first).

You will not be coerced in any way to take part in the study, participation is strictly voluntary. You can withdraw from the study at any time without consequences. The care you receive at the CSUSM SON Student Health Care Project will not be affected in any way regardless of your decision. Only the primary investigators will be aware of your choice to withdraw from the study.

Incentives for Participation:
As indicated above, a $25.00 incentive will be given at the end of both the first and second medication review-educational sessions. Be aware that in order to receive the incentives the study must be completed.

Benefits
- Increasing your knowledge about your diseases, medications and techniques used for remembering to take your medications.
- Satisfaction that the information provided may help others with similar problems and conditions.
- Contributing to clinical research about medication adherence in medically underserved populations.
- Helping students to become researchers.
- Direct monetary incentive.

However, the Primary Investigators cannot guarantee that these benefits will be incurred by all participants.

VOLUNTARY PARTICIPATION:
Participation in this study is voluntary, and you may withdraw from the study at any time without consequence. No one other than the Primary Investigators will know of your choice to stop participating in the study.

CONTACT INFORMATION: The Primary Investigator will gladly answer any questions that you have regarding this study. If you have further questions, please contact Virgie S. Delgado, RN, BSN by phone at (760) 750-4000 (School of Nursing) or via email at delgao45@cougars.csusm.edu. This study has been approved by the California State University, San Marcos Institutional Review Board. Questions about your rights as a research participant should be directed to the Institutional Review Board at (760) 750-4029. You will be given a copy of this form to keep for your records.
Appendix B4

Program Director/Principle Investigator: Delgado, Virgie S.

I agree to participate in this research study.

_________________________________________                  ____________________
Participant’s Name                                                                       Date

_________________________________________                  ____________________
Participant’s Signature                                                                  Date

_________________________________________                   ____________________
Researcher’s Signature                                                                   Date
Appendix C

BASIC DEMOGRAPHIC QUESTIONNAIRE

Patient Screening Questions:

Adopted from the US Census 2010

“Ask about Medicines” Brand and materials used with written permission obtained from the

Patient Information Forum, U.K.  adm@pifonline.org.uk

(Please note inclusion criteria: ≥ 41 years old, ≥ 2 chronic medical conditions, taking ≥ 3 prescribed medications, care being managed by ≥ 2 providers, speaks English and Spanish, managing meds independently, able to keep telephonic contact with our staff monthly for 5 months (until the post-test is done.))

A. Gender
   What is your sex?
   o 1. Male
   o 2. Female
   o 3. Other

B. Age
   In what year were you born? ____

C. Education
   What is the highest degree or level of school you have completed? If currently enrolled, mark the previous grade or highest degree received.
   o 1. No school-8th grade
   o 2. 9-12th grade, no diploma
   o 3. High school graduate or the equivalent (for example: GED)
   o 4. Some college credit, no degree
   o 5. Associate degree (Junior College)
   o 6. Bachelor's degree
   o 7. Master's degree
   o 8. Doctorate degree

D. Employment Status: Are you currently...?
   o 1. Employed for wages
   o 2. Self-employed
   o 3. unemployed
   o 4. A homemaker

C1
5. A student
6. Retired
7. Unable to work

E. Living Arrangement:
Do you live in a house, apartment, or mobile home - __________________________

1. Alone
2. With family
3. In the home of a friend
4. In the home of family
5. Homeless

F. If homeless are you:
1. Staying in a shelter
2. Staying with friends
3. Staying with family
4. Have no shelter

G. Ethnicity
Please specify your ethnicity.

1. Hispanic or Latino
2. African American
3. White
4. Asian Pacific Islander
5. Other, Not Hispanic, AA, White or API

H. Language spoken:
1. English only
2. Spanish only
3. Other language only
4. Bilingual

I. How many medical diagnoses or problems are you being treated for:
1. More than 2
2. More than 3
3. More than 4
J. How many prescribed medications do you take:

- 1. More than 2
- 2. More than 3
- 3. More than 4

K. Do you take over the counter medication, if yes, how many?

- 1. More than 2
- 2. More than 3
- 3. More than 4

L. Do you take herbal supplements, if yes, how many?

- 1. More than 2
- 2. More than 3
- 3. More than 4
- 4. More than 5

M. Do you take Vitamins, if yes, how many?

- 1. More than 2
- 2. More than 3
- 3. More than 4
- 4. More than 5

N. Do you use any tools in the home to assist you in remembering to take your medication?

- 1. Yes, What tool do you use?______________________________
- 2. No

O. If you were selected to participate in our study would you be able to commit to maintaining monthly telephonic or clinic contact with our research staff and would you be able to return to the clinic six months after we initially see you for a repeated medication review?

- 1. Yes
- 2. No

P. If you do not meet criteria for this study and at times forget to take your medications, would you like to receive information on tools you can use to help you remember to take your medications?

- 1. Yes
- 2. No
The following section is to be completed by the research team.

Congratulations you are eligible to participate in the medication review study, you are schedule to attend the medication review on ________________, please bring all of your prescribed, over the counter, herbal supplements and vitamins to the appointment.

Unfortunately based on your responses, at this time you are not eligible to participate in the medication review study. If you’d like we can send you a handy tool to keep with you at all times, which can be presented at your doctor appointments or hospital visit.
MDT is designed to facilitate reconciliation of medication regimen across settings and prescribers.

**Medication Discrepancy Event Description:** Complete one form for each discrepancy.

**Causes and Contributing Factors:** Check all that apply.

*Italicized text suggests patient’s perspective and/or intended meaning*

### Patient Level
1. ☒ Adverse Drug Reaction or side effects
2. ☒ Intolerance
3. ☒ Didn’t fill prescription
4. ☒ Didn’t need prescription
5. ☒ Money / financial barriers
6. ☒ Intentional Non-Adherence
   - “I was told to take this but I chose not to”
7. ☒ Non-intentional non-adherence (ie: Knowledge deficit)
   - “I don’t understand how to take this medication
8. ☒ Performance Deficit
   - “Maybe someone showed me but I can’t demonstrate to you that I can”

### System Level
9. ☒ Prescribed with known allergies/intolerances
   - Conflicting information from different informational sources
   - *For example, discharge instructions indicate one thing and pill bottle says another.*
10. ☒ Confusion between brand & generic names
11. ☒ Discharge instructions
    - incomplete/inaccurate/ ineligible
    - *Either the patient cannot make out the instructions written in lay terms.*
12. ☒ Intentional Non-Adherence
    - “I was told to take this but I chose not to”
13. ☒ Non-intentional non-adherence (ie: Knowledge deficit)
    - “I don’t understand how to take this medication
14. ☒ Performance Deficit
    - “Maybe someone showed me but I can’t demonstrate to you that I can”
15. ☒ Intentional Non-Adherence
    - “I was told to take this but I chose not to”
16. ☒ Non-intentional non-adherence (ie: Knowledge deficit)
    - “I don’t understand how to take this medication
17. ☒ Performance Deficit
    - “Maybe someone showed me but I can’t demonstrate to you that I can”
18. ☒ Intentional Non-Adherence
    - “I was told to take this but I chose not to”
19. ☒ Non-intentional non-adherence (ie: Knowledge deficit)
    - “I don’t understand how to take this medication
20. ☒ Performance Deficit
    - “Maybe someone showed me but I can’t demonstrate to you that I can”

### Resolution:
- Advised to stop taking/start taking/change administration of medications
- Discussed potential benefits and harm that may result from non-adherence
- Encouraged patient to call PCP/specialist about problem
- Encouraged patient to schedule an appointment with PCP/specialist to discuss problem at next visit
- Encouraged patient to talk to pharmacist about problem
- Addressed performance/knowledge deficit
- Provided resource information to facilitate adherence
- Other
Medication Reconciliation Form • Ask about your medicines Program

Date: __________

Patient Name _____________________________________________ Sex: M F

Telephone Number ___________________________________________ Age: ______

ANY Medicine Allergies _________________________________________

Please list ALL medications you currently take (prescriptions, over-the-counter medications, Vitamins, Supplements, Herbal pills, Tablets or Remedies)

<p>| | | | | |</p>
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</table>

For PI Use

<table>
<thead>
<tr>
<th>Medicine #1</th>
<th>Medicine #2</th>
<th>Medicine #3</th>
<th>Medicine #4</th>
<th>Medicine #5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication Name</td>
<td>Dosage/Frequency</td>
<td>MD Name</td>
<td>Exp. Date</td>
<td>Prescribed for?</td>
</tr>
<tr>
<td>Still taken?</td>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Date of last provider visit?</td>
<td></td>
<td></td>
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<tr>
<td>Follow up needed?</td>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
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<tr>
<td>Patient knows purpose of drug</td>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Any Side Effects?</td>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
</tr>
</tbody>
</table>

A) # of pills taken (# dispensed minus pills in bottle)
B) # of pills to date that should've been taken per Rx

Divide A into B then x 100%

>80% Adherent
<80% non-Adherent

Over/Under Use

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</thead>
<tbody>
<tr>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
<td>Yes / No</td>
</tr>
</tbody>
</table>

Med Discrepancy?

MDT completed?

MDT: Medication Reconciliation Tool by Smith, J. D. & Coleman, E.A. (2004) used with written permission for this project.
Appendix D3

A new tool for identifying discrepancies in post-acute medications for community-dwelling older adults.

Smith JD, Coleman EA, Min SJ. (2004).


BACKGROUND: Despite a national focus on the problem of medication safety, few studies have examined the frequency, causes, and factors contributing to discrepancies between the medications prescribed in acute care settings and what elderly patients (age≥65 years) actually take after their discharge.

OBJECTIVE: The aims of this study were to develop a new instrument, the Medication Discrepancy Tool (MDT), for use by multiple practitioners across the continuum of care and to assess the MDT's reliability among nurses, pharmacists, and physicians, all of whom play a part in the formulation and administration of medication regimens for patients in transition.

METHODS: The study was conducted in a vertically integrated health care system and at a geriatric clinic in an academic health center. We applied the MDT to a series of 20 clinical vignettes based on actual cases involving older patients discharged from a community hospital to home. The intrarater reliability of the MDT was assessed by asking clinicians (2 home health care nurses, 2 doctoral-trained geriatric pharmacists, and 2 physicians) to use this tool to rate the clinical vignettes. Reliability comparisons were then made within and across clinical disciplines. Intrarater reliability was also determined.

RESULTS: Across all 3 clinical disciplines, the mean intrarater reliability (kappa) for the 20 vignettes was 0.56 (15% low agreement, 80% good agreement, and 5% excellent agreement). Within disciplines, the kappa statistic was as follows: nurses, 0.68; pharmacists, 0.50; and physicians, 0.64. Intrarater reliability ranged from 0.58 to 0.69.

CONCLUSIONS: By capturing transition-related medication discrepancies, the MDT fills an important gap in national efforts to promote patient safety. MDT items are actionable at both the patient and system level, suggesting that this tool could be used to foster continuous quality improvement efforts.
Appendix E

MEDICATION KNOWLEDGE ASSESSMENT

The Medication Knowledge Assessment is used to assess a person’s knowledge and ability to read and comprehend information necessary for appropriate medication use. Information from the Medication Knowledge Assessment can serve as the basis for a focused knowledge improvement plan.

On the day the Medication Knowledge Assessment is to be conducted, the person should be asked to have all their medication containers available.

ADMINISTRATION

Using the Medication Knowledge Assessment Form, write the name of each medication name in the left column, then ask the person the following questions about each of their medications.

1. Name of the medication. (Can the person read the label?)
2. Why are you taking the medication? (For what disease or condition?)
3. How much are you taking? (Number of pills)
4. When to take the medication? (E.g., morning, before meals, twice a day)
5. Effects to look for. (Both positive and negative)
6. Where do you keep the medication? (To ascertain special storage conditions)
7. When is the next refill due? (And plan or method for obtaining refills.)

Place a check mark next to each question that the person can correctly answer. Use the results from the assessment to identify knowledge gaps and develop a knowledge improvement plan.
# MEDICINE KNOWLEDGE ASSESSMENT FORM

**Name:** ___________________________  **DATE:** _________________________

<table>
<thead>
<tr>
<th>Medication</th>
<th>What is the name of medication?</th>
<th>Why are you taking the medication?</th>
<th>How much do you take each time?</th>
<th>When do you take the medication?</th>
<th>What effects do you look out for?</th>
<th>Where do you keep the medication?</th>
<th>When is the next refill due?</th>
</tr>
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<tbody>
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<td>N</td>
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</table>

P = Positive effects from the medication  N = Negative effects from the medication
APPENDIX F

“Ask about Medicines” Brand and materials used with written permission obtained from the Patient Information Forum, U.K. adm@pifonline.org.uk

Keep a copy of this form on your refrigerator door

(Present to all Healthcare Providers in Clinic, Urgent care, Hospital & Emergency Room)

Date form started:

Name: Address:
Phone Number: Birth Date:
Emergency Contact/Phone numbers:

<table>
<thead>
<tr>
<th>IMMUNIZATION RECORD</th>
<th>(Record the date/year of last dose taken, if known)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TETANUS</td>
<td>FLU VACCINE(S)</td>
</tr>
<tr>
<td>PNEUMONIA VACCINE</td>
<td>HEPATITIS VACCINE</td>
</tr>
<tr>
<td></td>
<td>OTHER</td>
</tr>
</tbody>
</table>

**Allergic To /Describe Reaction:**

Primary treating Provider Name:
Phone number:

**LIST ALL MEDICINES YOU ARE CURRENTLY TAKING:** Prescription and over-the-counter medications (examples: aspirin, antacids), Vitamins, Nutritional Supplements and Herbals (examples: ginseng, gingko). Include medications taken as needed (example: nitroglycerin).

<table>
<thead>
<tr>
<th>DATE</th>
<th>NAME OF MEDICATION / DOSE</th>
<th>How often do you take this medication (Do not use medical abbreviations.)</th>
<th>DATE STOPPED</th>
<th>Notes: Reason for taking / Doctor Name</th>
</tr>
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Refer to back of form for directions, benefits of using the form, and how to get more copies.

F1
Patient:

1. **ALWAYS KEEP THIS FORM WITH YOU.** You may want to fold it and keep it in your wallet along with your driver's license. Then it will be available in case of an emergency.
2. Write down all of the medicines you are taking and list all of your allergies.
3. Take this form to **ALL** doctor visits, when you go for tests and **ALL** hospital visits.
4. **WRITE DOWN ALL CHANGES MADE TO YOUR MEDICINES** on this form. If you stop taking a certain medicine, draw a line through it and write the date it was stopped. If help is needed, ask your Doctor, Nurse, Pharmacist, or family member to help you to keep it **up-to-date**.
5. In the **NOTES** column, write down the name of the doctor who told you to take the medicine(s). You may also write down why you are taking the medicine (Examples: high blood pressure, high blood sugar, high cholesterol).
6. When you are discharged from the hospital, someone will talk with you about **WHICH MEDICINES TO TAKE AND WHICH MEDICINES TO STOP TAKING**. Since many changes are often made after a hospital stay, a new form should be filled out. When you return to your doctor, take your new form with you. This will keep everyone up-to-date on your medicines.

**HOW DOES THIS FORM HELP YOU?**

1. This form helps you and your family members **remember** all of the **medicines you are taking**.
2. Provides your doctor(s) and others with a **current list of ALL of your medicines**. Doctors need to know the herbals, vitamins, and over-the-counter medicines you take!
3. **Helps you**—concerns may be found and prevented by knowing what medicines you are taking.

F2
**ask about your medicines**

- **share** any questions or concerns about the medicines you are prescribed or buying - and ask about other options
- **tell** a health professional about the medicines you are taking
- **tell** them if you think the medicines you are taking aren’t working or are giving you side-effects
- **ask** if you are unsure how to take your medicines or for how long
- **ask** if you need help getting a regular supply of your medicines

The word **medicines** can mean different things to different people

when we use the word *medicines* here, it includes things such as:

- over-the-counter medicines, like painkillers
- creams and ointments
- inhalers or other devices
- vitamins, herbal products or other supplements from the pharmacy, health shop or supermarket

F3
**how do you take your medicines?**

This leaflet is designed to help you understand your medicines better. The chart overleaf is to remind you when and how much to take. It is only meant for medicines you take regularly. There is no need to write down anything you only have occasionally (such as a headache tablet) unless there is a problem with it.

Please show the chart to anyone who prescribes for you. When you discuss your medicines with a health professional take this with you. If your medicine is changed in any way then make sure that it is noted on the chart.

If you go to hospital take this leaflet with you and show the health professional your medicine chart.

Name
Date of birth
Allergies
GP’s name/ phone
<table>
<thead>
<tr>
<th>name of medicine</th>
<th>what I call it</th>
<th>what it’s for</th>
<th>how much to take and when</th>
<th>comments/other information</th>
</tr>
</thead>
<tbody>
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<td>breakfast</td>
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<td>lunch</td>
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<td>evening meal</td>
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<td></td>
<td>bedtime</td>
<td></td>
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