

Evidence-based Synthesis Program (ESP)



Nurse Managed Protocols in the Outpatient Management of Adults with Chronic Conditions

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Evidence-based Synthesis Program (ESP)



VA Evidence-based Synthesis (ESP) Program Overview

- Sponsored by VA Office of R&D and HSR&D.
- Established to provide timely and accurate syntheses/reviews of healthcare topics identified by VA clinicians, managers and policy-makers, as they work to improve the health and healthcare of Veterans.
- Builds on staff and expertise already in place at the Evidence-based Practice Centers (EPC) designated by AHRQ. Four of these EPCs are also ESP Centers:
 - Durham VA Medical Center; VA Greater Los Angeles Health Care System; Portland VA Medical Center; and Minneapolis VA Medical Center.

Evidence-based Synthesis Program (ESP)



- **Provides evidence syntheses on important clinical practice topics relevant to Veterans, and these reports help:**
 - develop clinical policies informed by evidence,
 - the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures, and
 - guide the direction for future research to address gaps in clinical knowledge.
- **Broad topic nomination process – e.g. VACO, VISNs, field – facilitated by ESP Coordinating Center (Portland) through online process:**

<http://www.hsrd.research.va.gov/publications/esp/TopicNomination.cfm>

Evidence-based Synthesis Program (ESP)



- **Steering Committee** representing research and operations (PCS, OQP, ONS, and VISN) provides oversight and guides program direction.
- **Technical Advisory Panel (TAP)**
 - Recruited for each topic to provide content expertise.
 - Guides topic development; refines the key questions.
 - Reviews data/draft report.
- **External Peer Reviewers & Policy Partners**
 - Reviews and comments on draft report
- **Final reports posted on VA HSR&D website and disseminated widely through the VA.**

<http://www.hsrd.research.va.gov/publications/esp/reports.cfm>

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Current Report

Effects of Nurse Managed Protocols in the Outpatient Management of Adults with Chronic Conditions

Background

- **Management of chronic illness**
 - **75% of every health care dollar spent in the U.S.**
- **Substantial morbidity and mortality:**
 - **Diabetes mellitus**
 - **Hypertension**
 - **Hyperlipidemia**
 - **Congestive Heart Failure (CHF)**
- **Require long-term medical management**

Background

- **Majority of care in outpatient settings**
- **Gaps between care recommended and care delivered**
 - **Despite clinical practice guidelines**
- **Shortage of primary care clinicians is one barrier to the provision of comprehensive chronic disease care**
- **Impetus to develop strategies for expanding roles and responsibilities of other team members**

Background

- Patient Aligned Care team (PACTs)
- Adaption of Patient Centered Medical Home
- Chronic Care Model
- Core principles:
 - Team-based care
 - Patient-centered
 - Coordinated care across the health system and community
 - Enhanced access to care
 - Systems-based approach to quality & safety

Nurses



- Institute of Medicine (IOM):
 - Expand nurses' roles to practice to the full extent of their training
- Evidence: effectiveness of nurses providing patient education about chronic disease as well as secondary prevention strategies
- Nurses are ideally suited to meet increasing demands for chronic care
- Work in multidisciplinary teams
- With clearly defined protocols & training:
 - Order relevant diagnostic tests
 - Adjust routine medications
 - Appropriately refer patients for medical evaluation

Purpose

- To synthesize the current literature describing the effects of nurse-managed protocols for the outpatient management of adults with common, chronic conditions such as diabetes, hypertension, hyperlipidemia, and CHF

Methods

1. Topic development
2. Systematic searches for literature
3. Study selection
4. Data abstraction
5. Quality Assessment
6. Data Synthesis
7. Peer Review

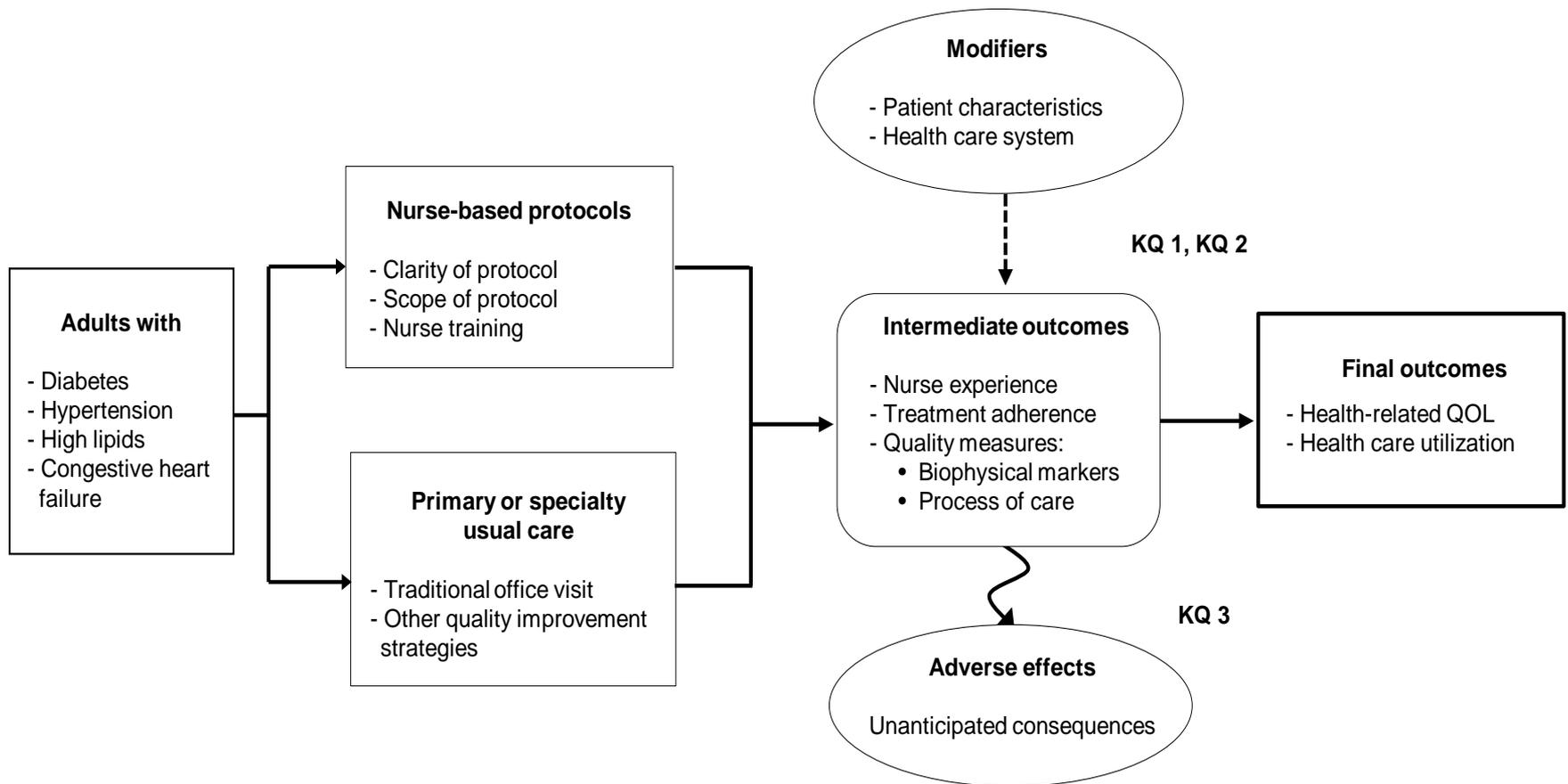
Key Questions

- **Key Question 1:** For adults with chronic medical condition, do nurse-managed protocols compared with usual care improve the following outcomes?
 - Nurse staff experience (e.g. satisfaction)
 - Treatment adherence
 - Quality measures such as
 - Biophysical markers
 - Process of care measures
 - Resources utilization

Key Questions

- **Key Question 2:** In studies of nurse-managed protocol, how well do participating nurses adhere to the protocol?
- **Key Question 3:** Are there adverse effects associated with the use of nurse-managed protocols?

Analytic Framework



Search Strategy

Databases: English-language publications in MEDLINE, Embase, PsycINFO, CINAHL, Cochrane Controlled Trials Registry.

January 1, 1980 - December 12, 2012

Search terms: Included terms for RN protocols, nurse protocols, and randomized controlled trials (RCTs).

Supplemental searches: Bibliographies of individual papers & systematic reviews; used MeSH Analyzer; Clinicaltrials.gov

Study Eligibility Criteria

Study design: Interventions that used nurse-managed protocols compared with usual care in the outpatient setting

Population: Adults \geq 18 yrs w/ diabetes, hypertension, hyperlipidemia, CHF, or combination

Interventions: Involve RN or LPN/LVN functioning beyond usual scope of practice which **MUST** include adjustment of medications

- Based on a written protocol

Comparators: Usual outpatient care or other quality-improvement

Study Eligibility Criteria

Outcomes:

- **KQ 1 must report on at least 1:**
 - Nursing staff experience
 - Treatment adherence
 - Lab or physiological markers (e.g. HbA1c)
 - Performance metrics
 - Utilization of medial resources
- **KQ 2: Fidelity of the nurse-managed protocol**
- **KQ 3: Adverse effects**

Setting: Outpatient setting

Quality Assessment

We assessed the risk of bias by applying the quality criteria described in the Agency for Healthcare and Research Quality (AHRQ) *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.

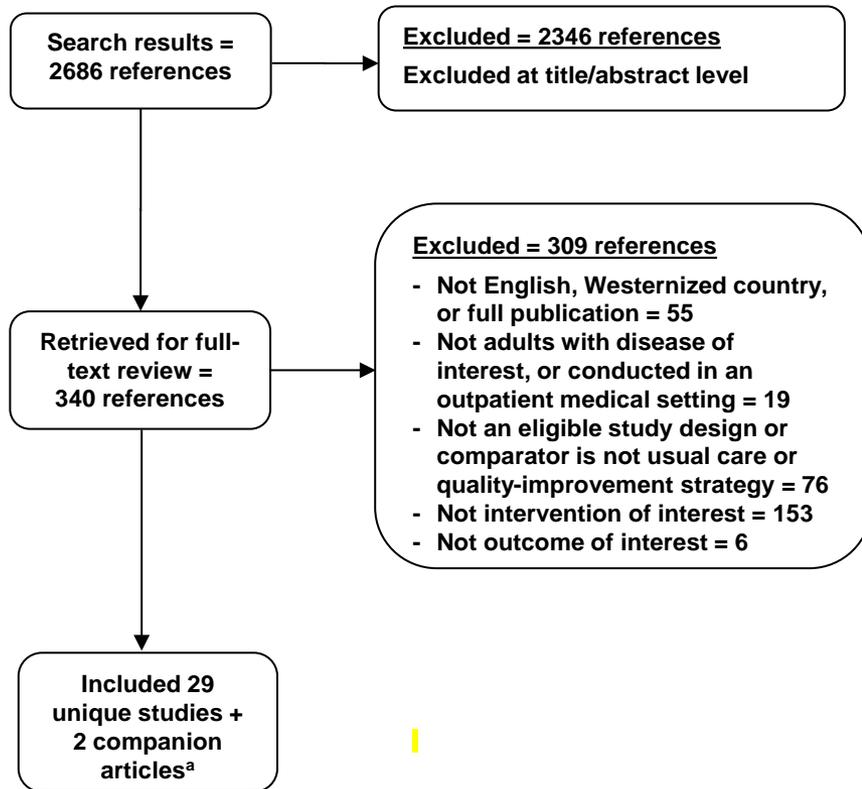
For RCTs, we abstracted data on adequacy of randomization and allocation concealment, comparability of groups at baseline, blinding, completeness of followup and differential loss to followup, whether incomplete data were addressed appropriately, validity of outcome measures, completeness of outcomes reporting, and conflict of interest.

Assigned quality score of Good, Fair, or Poor to individual RCTs.

Rating the Body of Evidence

GRADE Working Group criteria for assessing overall body of evidence:

- **High**--Further research unlikely to change confidence in estimate of effect.
- **Moderate**--Further research likely to have an important impact, and may change the estimate.
- **Low**—Further research very likely to have an important impact, and is likely to change the estimate.
- **Insufficient**—Evidence on an outcome is absent or too weak, sparse, or inconsistent to estimate an effect.



Results: Study Characteristics

- **Eligible studies:**
 - **29 unique studies**
 - 18: management of elevated cardiovascular risk (diabetes mellitus, hypertension, hyperlipidemia)
 - 10: CHF
 - 1: resource utilization of older adults with chronic conditions
 - **26 RCTs**
 - **Risk of bias**
 - Low (n=10)
 - Moderate (n=16)
 - High (n=3)
 - **None conducted in VA settings**

Results: Study Characteristics

- **Eligible studies:**
 - All studies (N=29): nurse had autonomy to titrate medications
 - 20 studies: nurse independently initiated new medication
 - Protocol to guide the nurses
 - Limited to an algorithm describing medication titration
 - 1 study described scope of practice and interactions with the team physician
 - All studies used an RN or equivalent – No LPNs

Study Characteristics	Cardiovascular Risk Studies
N studies (N patients)	18 studies (23,004 patients) ^b
Study design: N studies (%)	
RCT	16 (89%)
Non-RCT	2 (11%)
Setting: N studies (%)	
General medical	12 (67%)
Medical specialty	3 (17%)
Primary clinic and specialty	2 (11%)
Telephone- and clinic-delivered care	1 (5.5%)
Intervention target: N studies (%)	
Glucose	12 (67%)
Blood pressure	15 (83%)
Lipids	14 (78%)
Intervention delivery: N studies (%)	
Clinic visits	15 (83%)
Primarily telephone	3 (17%)
Balance of visits and telephone	–
Nurse training: N studies (%)	
Specialist (i.e., clinical certification or diabetes nurse educator)	3 (17%)
Received study-specific training	10 (55%)
Case manager	1 (5.5%)
Not described	4 (22%)
Medication initiation: N studies (%)	12 (67%)
Education or behavioral strategies: N studies (%)	
Education	16 (89%)
Specific behavioral strategy (e.g., motivational interviewing)	3 (17%)
Self-management plan	9 (50%)

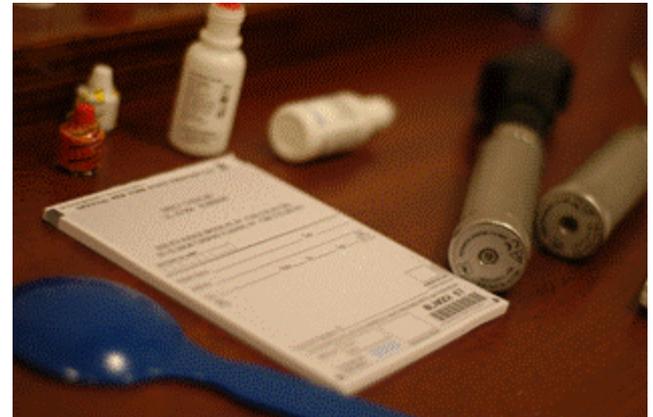
Study Characteristics	Cardiovascular Risk Studies
N studies (N patients)	18 studies (23,004 patients) ^b
Patient characteristics	
Age: median (range)	58.3 (34.7 to 72.1) ^c
Sex: N patients (%) ^d Female Male	4126 (47%) 4716 (53%)
Race: N patients (%) Black Hispanic White Other Not reported	52 (0.2%) 653 (2.8%) 2280 (9.9%) 636 (2.8%) 19,383 (84.3%)
Disease severity: median (range) HbA1c (%) SBP (mm Hg) DBP (mm Hg) LDL (mg/dl)	8.1 (8.0 to 8.2), NR=16 149.4 (119 to 161.3), NR=4 80 (69 to 87.7), NR=4 124.9 (85.3 to 131.5), NR=10

Study Characteristics	CHF Studies
N studies (N patients)	10 (2836)
Study design: N studies (%)	
RCT	10 (100%)
Non-RCT	–
Setting: N studies (%)	
General medical	–
Medical specialty	3 (30%)
Telephone- and clinic-delivered care	6 (60%)
Not reported/unclear	1 (10%)
Intervention delivery: N studies	
Clinic visits	4
Primarily telephone	5
Balance of visits and telephone	1
Nurse training: N studies (%)	
Specialist (i.e., clinical certification or diabetes nurse educator)	4 (40%)
Received study-specific training	5 (50%)
Case manager	–
Not described	1 (10%)
Medication initiation: N studies (%)	8 (80%)
Educational or behavioral strategies: N studies (%)	
Education	9 (90%)
Specific behavioral strategy (e.g., motivational interviewing)	3 (30%)
Self-management plan	5 (50%)

Study Characteristics	CHF Studies
N studies (N patients)	10 (2836)
Patient characteristics	
Age: median (range)	72 (53 to 80)
Sex N patients (%)	
Female	988 (35%)
Male	1870 (65%)
Race: N patients (%)	
Black	988 (35%)
Hispanic	1870 (65%)
White	–
Other	–
Not reported	–
Disease severity: median (range)	
NYHA, class I-II (%)	50 (40.9 to 62)
NYHA, class III-IV (%)	50 (38 to 59)
Not reported	7 studies

Results: KQ1

- **Key Question 1:** For adults with chronic medical condition, do nurse-managed protocols compared with usual care improve the following outcomes?
 - Nurse staff experience (e.g. satisfaction)
 - Treatment adherence
 - Quality measures such as
 - Biophysical markers
 - Process of care measures
 - Resources utilization



Results: KQ1

- **Elevated Cardiovascular Risk:**

- Positive effect on improving:

- HbA1c 0.4%
- SBP/DBP 4 mmHg & 2mmHg
- Total cholesterol 9 mmol/l
- LDL 12 mmol/l

- More patients reached target goals in total cholesterol and BP

- BP: 16 per 1000 patients
- Total cholesterol: 106 per 1000 patients

Results: KQ1

- **CHF:**
 - Lower all-cause mortality
 - 36 fewer deaths per 1000 patients
 - More patients prescribed ACE or ARB
 - 18 per 1000 patients
 - Decrease CHF-related hospitalizations
 - 32 per 1000 patients



Results: KQ1

- **Effects on nursing staff satisfaction:
not reported**
- **Treatment adherence:**
 - Infrequently reported
 - Pattern of improved adherence to lifestyle goals
- **Educational preparation to assume
this expanded nurse role was not
well reported**

Results KQ 2

- **Key Question 2:** In studies of nurse-managed protocol, how well do participating nurses adhere to the protocol?

Results: KQ 2

- Indirect evidence (e.g. improved outcomes) suggests that nurses adhere to protocols
- Direct evidence (e.g. through fidelity check) is insufficient to establish how well nurses adhere to protocols when engaged in delivering nurse-managed care
- 2 of 29 studies reported increased nurse adherence to treatment protocols
- Conclusion: insufficient data

Results KQ 3

- **Key Question 3:** Are there adverse effects associated with the use of nurse-managed protocols?



Results: KQ 3

- Adverse events were reported in only one study
- Evidence was insufficient to establish if there are adverse effects associated with the use of nurse-managed protocols

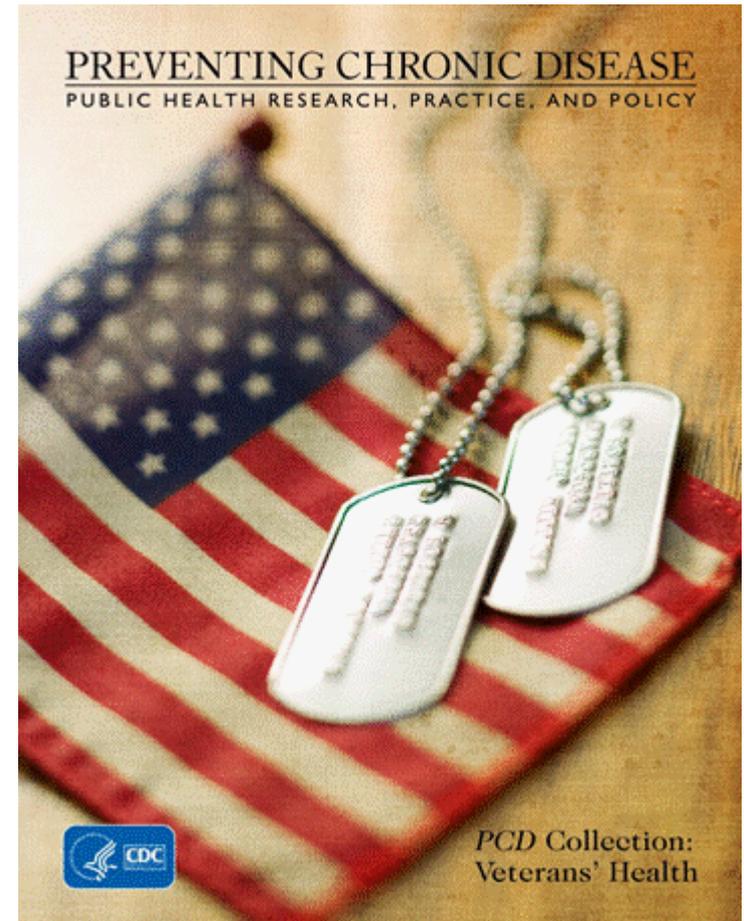
Summary of Strength of the Evidence



Outcome	Strength of Evidence Domains				Effect Estimate (95% CI)	SOE
	Number of Studies (Patients)	Study Design/ Risk of Bias	Consistency Directness	Precision Publication Bias		
Nurse-managed protocol intervention vs. usual care—cardiovascular risk studies						
Hemoglobin A1c	8 (2633)	RCT/Moderate	Inconsistent Direct	Precise None detected	MD = -0.40 (-0.63 to -0.17)	Moderate
Systolic blood pressure	12 (10,224)	RCT/Moderate	Inconsistent Direct	Precise Possible bias	MD = -3.68 (-5.67 to -1.69)	Moderate
Diastolic blood pressure	12 (10,224)	RCT/Moderate	Inconsistent Direct	Precise None detected	MD = -1.56 (-2.57 to -0.55)	Moderate
Blood pressure at goal	10 (9707)	RCT/Moderate	Inconsistent Direct	Precise None detected	OR = 1.41 (1.12 to 1.78) RD = 77 more per 1000 patients (24 to 133 more)	Moderate
Total cholesterol	9 (3494)	RCT/Moderate	Inconsistent Direct	Imprecise None detected	MD = -9.37 (-17.87 to -0.87)	Low
LDL cholesterol	6 (1119)	RCT/Moderate	Inconsistent Direct	Imprecise None detected	MD = -12.07 (-24.10 to -0.03)	Low
Cholesterol at goal	11 (9221)	RCT/Moderate	Inconsistent Direct	Precise None detected	OR = 1.54 (1.14 to 2.08) RD = 106 more per 1000 patients (33 to 174 more)	Moderate
Nurse-managed protocol intervention vs. usual care—congestive heart failure studies						
Mortality	10 (2836)	RCT/Low	Inconsistent Direct	Precise None detected	OR=0.71 (0.52 to 0.96) RD=36 fewer per 1000 patients (5 to 62 fewer)	Moderate
Total hospitalizations	6 (2352)	RCT/Low	Inconsistent Direct	Imprecise None detected	OR=0.83 (0.62 to 1.10) No significant difference: RD = 32 fewer per 1000 patients (76 fewer to 18 more)	Low
CHF-related hospitalizations	5 (2231)	RCT/Low	Consistent Direct	Precise None detected	OR=0.62 (0.49 to 0.80) RD=42 fewer per 1000 patients (22 to 57 fewer)	High
ACE/ARB prescribed	6 (2050)	RCT/Low	Consistent Direct	Imprecise None detected	OR=1.15 (0.90 to 1.46) No significant difference: RD = 18 more per 1000 patients (15 fewer to 45 more)	Moderate

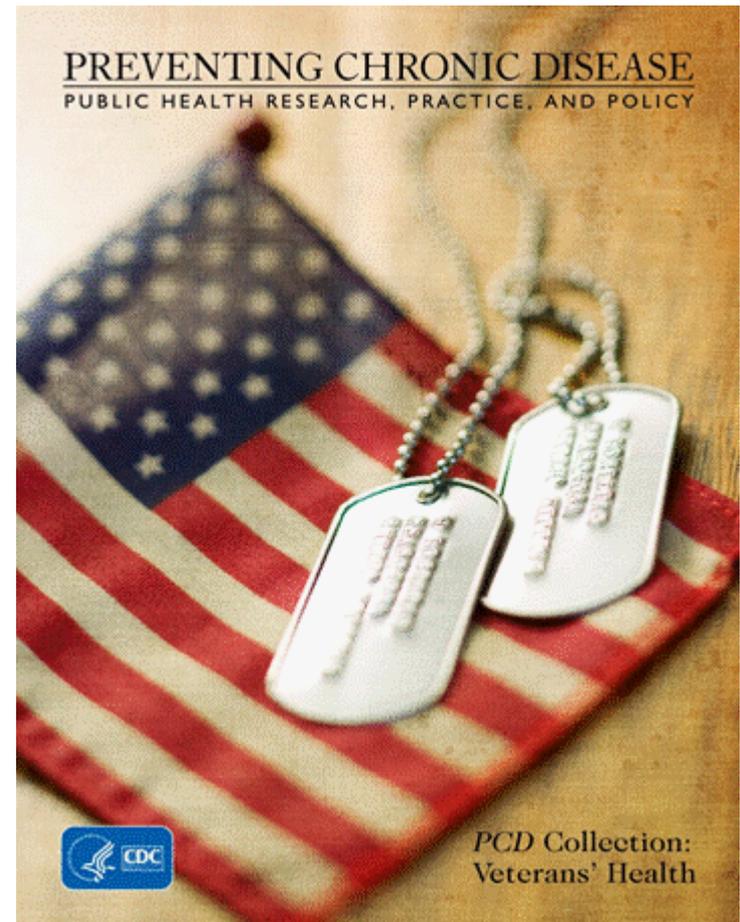
Conclusions

- **With the implementation of PACTs, VA will play a critical role in reconfiguring team-based care models to expand the responsibilities of team members**
- **Nurses are in an ideal position to collaborate with other team members in the delivery of more accessible and effective medical care for Veterans with chronic disease**



Conclusions

- **Results suggest that nurse-managed protocols have positive effects on the outpatient management of adults with stable, common chronic conditions such as type 2 diabetes, hypertension, hyperlipidemia, and CHF**



Limitations

- Lack of detailed description of protocols
- Limited reporting of:
 - Intervention intensity
 - Patient treatment adherence
 - Nurse protocol adherence
 - Health related quality of life
 - Resource utilization
 - Staff satisfaction
 - Educational level and supervision of nurse
- Only RNs were used
- Outcomes varied across studies and contributed to unexplained variability

Strengths

- Highly structured and systematic review of extant evidence.
- Limiting the review to evidence gleaned from published, peer-reviewed, RCTs allowed us to focus on “quality” over “quantity.”
- Multidisciplinary team included expertise in internal medicine, clinical psychology, epidemiology, acupuncture research, family medicine, and integrative medicine.

Recommendation for Future Research

- **Patients with complex disease or multiple chronic diseases**
- **Narrowly focused (e.g. BP) or multi-target interventions (e.g. HbA1c, lipids)**
- **Patient and staff satisfaction**
- **Patient and staff experiences**
- **Fidelity to the intervention protocol**

Evidence-based Synthesis Program (ESP)

Questions?



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The full report and cyberseminar presentation is available on the ESP website:

<http://www.hsrd.research.va.gov/publications/esp/>