



April 13, 2009

The Federal Coordinating Council
for Comparative Effectiveness Research

Dear Madams and Sirs:

The failure of patients to properly adhere to medication therapy is recognized as a major factor contributing to morbidity, mortality, and cost of healthcare. It is known that interventions to improve adherence have beneficial return on investment, in both monetary and human terms.

Below we propose programs to evaluate the effectiveness of adherence assistance and monitoring. Please recognize that if these studies document previous literature they will be cost neutral or even generate significant ROI.

Sincerely,

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Does of Medication Therapy Adherence Assistance and Monitoring Influence the Quality and Cost of Healthcare?

1- The Issue

Failure of patients to properly adhere to prescribed medication therapy is “America’s other Drug Problem.” Poor adherence to therapy is costly in both economic and human terms.

Impact of Patient Non-Adherence

- ✓ More than 50 % of all prescription medications are taken improperly
- ✓ Non-Compliance causes:
 - ✓ 10% of all hospital admissions
 - ✓ 23% of all nursing home admissions
 - ✓ 125,000 heart patient deaths annually
 - ✓ Non-Compliance has been called “The Other Drug Problem”

The 125,000 estimated deaths from non-compliance in heart disease alone rival the annual death rates for other major killers.

Disease	U.S. Deaths Annually
Heart Disease	700,142
Cancer	553,768
Stroke	163,538
Chronic Lower Respiratory Disease	123,013

**National Center for Health Statistics, CDC 2002*

Economics of Non-Adherence

- ✓ *The Task Force for Compliance*, which was established by 20 major pharmaceutical companies in 1992, estimates the direct and secondary cost of non-compliance to be more than \$100 billion annually.
- ✓ *Understanding Medicare Reform*, published by the American Pharmacists Association in 2004 estimates that the annual cost of morbidity and mortality from drug-related problems in ambulatory patients was \$76.6 billion in 1995 and increased to \$177.4 billion in 2000.
- ✓ Health care costs for patients who do not adhere to therapy can be much greater than the cost for those who adhere. For example with diabetes patients the difference can be more than \$4,000 per year, with hypercholesterolemia patient the differential approaches \$5,000. Some studies report that intervention to improve adherence to therapy in congestive heart failure patients can reduce the average annual cost of health care by almost \$5,000.

II. Primary Objectives

- ✓ Implement Medication Therapy Adherence Programs that help patients become adherent.
- ✓ Implement recognized and accepted approaches for improving patient adherence: *“Strategies that appear to have some effect on long term regimens involve a combination of counseling, reminders, self monitoring, feedback and supportive care” (Haynes, McDonald et al The Cochrane Data Base of Systematic Reviews Vol. 1 2005 Interventions for Helping Patients Follow Prescriptions for Medications)*
- ✓ Establish health quality and cost-benefit effectiveness of Medication Therapy Adherence Programs.
- ✓ Reduce healthcare costs for chronically ill patients.

III. Secondary Objectives

- ✓ Create full and part-time jobs for high school graduates and those pursuing higher education.
- ✓ Encourage career paths for training as nurses, social workers, pharmacists and doctors.

- ✓ Provide assistance in underserved communities.
- ✓ Provide proof of principal and establish guidelines for services, in the private and public sector, to as many as 48 million patients taking 3 or more medications each day.

IV. Priorities for Investigation

Poor adherence can cause severe medical and economic consequences in virtually every disease state treated by medication therapy. Poor adherence is a major factor for transplant rejection, failure to adhere to statin therapy leads to arterial disease, the list goes on. Here we propose three areas where we believe significant benefit to patients and to society can be achieved:

a. Can Medication Therapy Adherence Intervention Slow Progression of HIV Disease from Early to Late Stage?

HIV infected patients adherent to anti-retroviral therapy demonstrate slower progression to advanced disease and are less likely to develop drug resistant virus. Adherent patients also experience longer and better quality of life at much lower healthcare cost. Approaches to improve and monitor patient adherence should be evaluated and implemented. Short-term comparisons can be performed using viral burden and virus typing end points. Long-term studies should look at quality of life and cost effectiveness. If adherence intervention slows progression from early to late disease by only 1 year, with 1 million patients the savings could be \$25 billion or more.

b. Determine the Effectiveness of Self-Administered Adherence Intervention in Helping Control Type II Diabetes.

Type II diabetes can be controlled by medication therapy coupled with behavior modification. For effective control patients must adhere to medication therapy. Adherent patients achieve better quality of life and may also realize healthcare cost savings as great as \$7,000 per year. Patients will be provided with portable electronic reminder devices that allow remote monitoring. These devices will remind patients when to take medication and log performance. Stored data will be uploaded to a central database for review. If in the short-term favorable relation between A1c and adherence is established, studies will be extended to evaluate cost effectiveness,

c. Interventions for Improved Adherence and Persistence to Medication Therapy in Medicare Patients

Failure of patients to adhere to medication therapy causes an annual economic burden of 100's of billions of dollars. No systematic study has been performed comparing effectiveness of different adherence interventions. There is no data driven implementation of programs to improve patient adherence. Various interventions for adherence should be compared. A subset of the most effective would be examined for cost effectiveness and impact on quality of life. Medicare provides a population of patients whose medication usage is known and where cost of medical care can be traced. Medicare approval of adherence interventions would have impact the entire healthcare system

V. Program Details

- ✓ Enroll 100,000 patients covered by Medicare, Medicaid or the Veterans Administration into a Medication Therapy Adherence program over the course of 18 months.
- ✓ Patient Medication Therapy Records, Adherence Reminders, Adherence Monitoring, and first tier review will be accomplished using the NexDose Medication Therapy Management platform (See www.nexdose.com)
- ✓ Data entry, patient monitoring, scheduling and patient referrals will be performed by hires.
- ✓ Resolution of medical issues will be effected by patient physicians in cooperation with a program affiliated healthcare care professional.
- ✓ The program may include patient incentives in the form of cash rewards or medication discount coupons.



VI, Required Resources

- ✓ Adherence management is estimated to require 6.5 hr entry level employee time and 1.0 hr. healthcare professional time per year.
- ✓ Equipment and data management will include: a) One NexDose Digital Assistant per patient, a 3+ year life is projected to the digital assistant; b) An annual subscription to NexDose On-line services; c) A lap top computer with internet access will be required for every 250 patients, a 3+ year life is anticipated for hardware.
- ✓ Facilities will be included as an element in the services subcontracts negotiated with personnel providers. Personnel providers may include pharmacies, physicians, hospitals, community organizations, or faith based organizations.

Resource	Cost/100,000 patients (\$ Millions)
Adherence Technicians Healthcare Professionals	11.7 8.5
NexDose Digital Assistant (Year 1) NexDose On-Line Service	9.9 11.9*
Personal Computer & Internet	0.4
Patient Incentives	5.0
TOTAL	47.4

** Nearly 80% of this amount will be expended to outside contractors, and in-house staff. If we assume labor, facilities and overhead at average \$40/hr, this number reflects more than 140 jobs.*

V1. Program Evaluation

- ✓ The program should be considered successful even if the return on investment (ROI) remains neutral (1/1). In this circumstance the cost savings in medical care will be diverted to job creation and the improvement of patient quality of life.
- ✓ The potential ROI resulting from this program could in some chronic disease conditions be as large as 10/1. If the program achieves only a modest average ROI of 1.5/1 the impact of job creation and savings in the cost of healthcare become profound.
- ✓ In 2004 it was estimated that 48 million Americans take 3 or more medications daily. If only 25% of this population are deemed as candidates for a Medication Therapy Adherence Program, and if the ROI is 1.5/1, a net savings in medical care costs in the public and private sector of \$2.8 billion could be achieved (The ROI for Pharmacy based adherence programs reported in the literature are as large as 12/1 and 5.9/1). These savings are beyond the cost of the Medication Therapy Adherence program.

	Pilot Program (100,000 patients)	Public/Private Sector (12 Million patients)
Jobs:		
Adherence Technicians	312	37,440
Healthcare Professionals	48	5,760
Ancillary	140	16,800
Cost//Job/Year	\$ 94,800	\$ 81,400
Healthcare Cost Savings (\$ Millions at 1.5/1 ROI)*	23.7	2,441
Savings /Job/Year**	\$ 142,200	\$ 122,100

* Corrected for the cost of provided services.

** Un-corrected for the cost of provided services.

