Emerging Role of the Pharmacist in Promoting Medication Adherence

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Presentation Objectives

- Name the four major forces impacting health care in the next 3-10 years
- Describe how the forces are changing business models for manufacturers, distributors and pharmacy
- Describe *Project ImPACT* and benefits of on-going pharmacist interventions on persistence and compliance

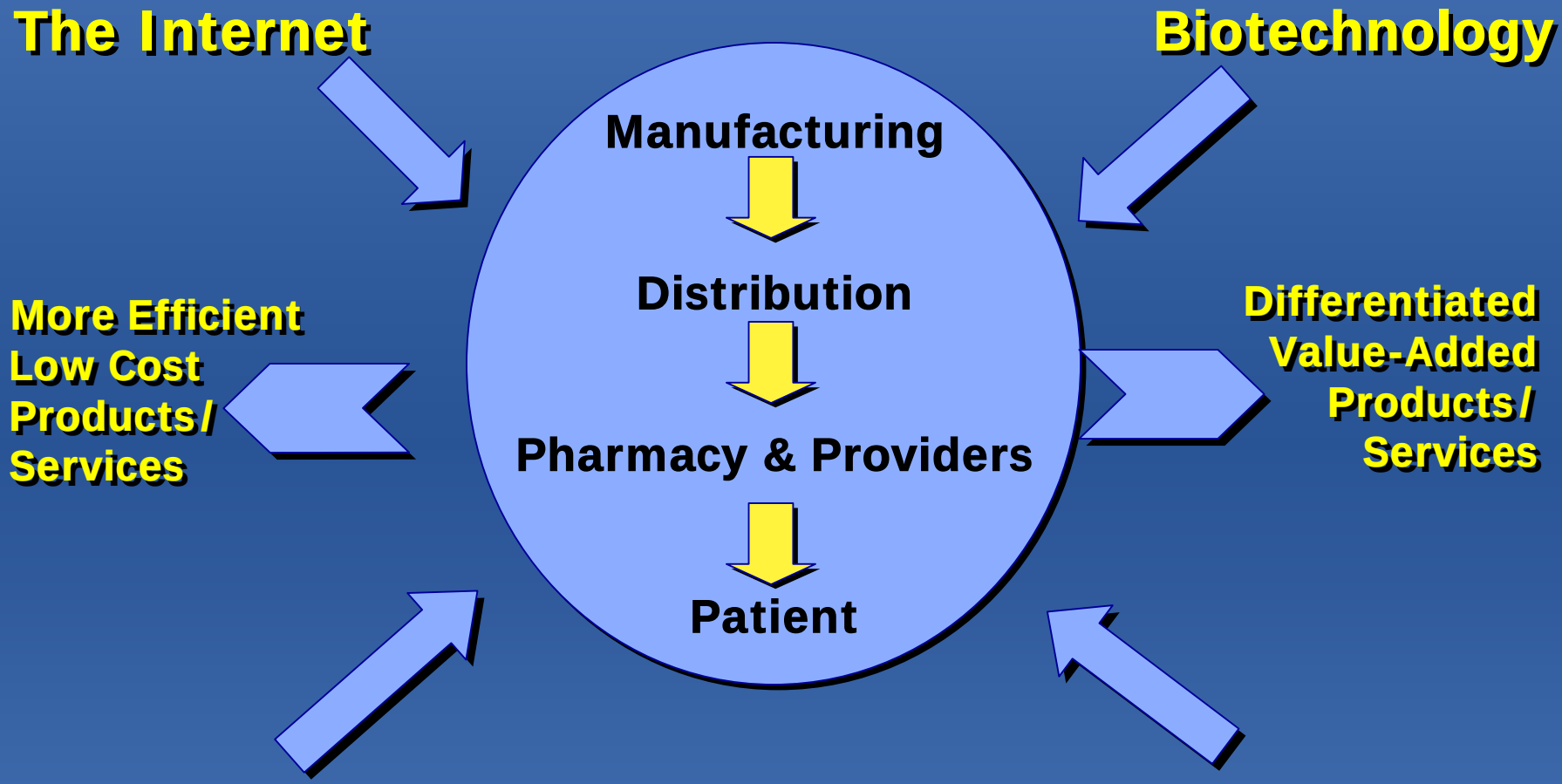
Presentation Objectives

- Describe the *Asheville Project* and its basis for a business model that results in increased medication adherence and positive clinical and economic outcomes for diabetes
- Discuss incentives for patients, providers and payers that re-align the health care system to get the most from medication technology
- Explain the state of development of patient-care oriented business models in pharmacy

Scanning Horizons: The Four Forces

- Biotechnology explosion
- Telemedicine/Internet explosion
- Rising use of alternative therapy
- Rising consumer activism
- Treatment will move:
  - from disease to prevention
  - from institutions to home
- Will blur lines between distribution/delivery--redefining getting product to the right place at the right time to the right provider to the right patient

Major Forces Impacting Healthcare Industry Structure



Promises and Implications BIG*

Promise:

- Rapid technological innovation and vast number of new targets identified: epilepsy, deafness, color blindness, muscular dystrophy--by 2010, a dozen predictive tests
- Today 150 targets, tomorrow 5-10,000
- Rapid acceleration in pace of new therapeutic introductions
- Drugs and treatments that are more tailored to specific patients

Implications:

- *Development* becomes a bottleneck
- Shorter product life cycles
- Market fragmentation
- Blurring distinction between “product” and “service”

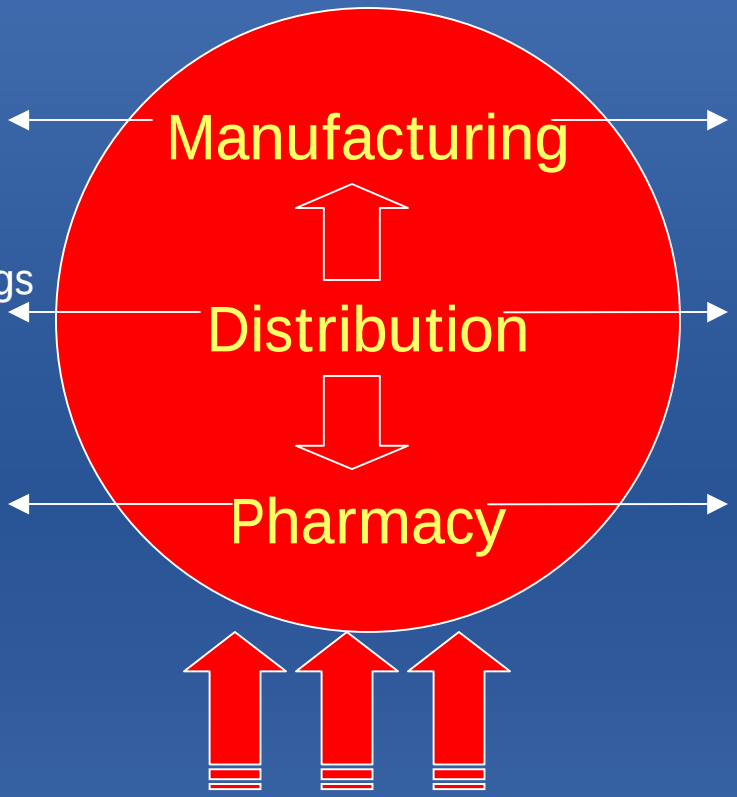
* Gary Pisano, HBS 3/2000

Industry Response to Major Forces: Transformation to New Business Models

More Efficient Low Cost Products/Services

Generic Products
Contract Manufacturing

Integrated Electronic Catalogs
Labeling & Packaging
Repackaging
Bar coding
Central Fill
Unit-of-Use Packaging
Central Adjudication
Integrated Order Systems
Automated Dispensing Systems
Refill Management Systems
Electronic Prescribing & Rx Routing



Differentiated, Value-Added Products/Services

R&D: Individualized Medicines:
Biotech and pharmacogenomic
Biotech Technology Firms:
Diagnostics & Drug Delivery
Contract Research/Sales Organizations

Reimbursement Consulting
Third-Party Logistics/Outsourcing
Specialty Distribution Services
Lot Number/Product Tracking
Compliance Packaging

Patient Registries
Medication Management & Rx Care Services
Monitoring/Testing Services

Economic Pressure/Price Transparency Steamroller:
Changing consumer buying patterns & expectations
Consumer frustration with access to care
Continued payor frustration with cost of care
Legislative/Regulatory solutions proposed

project ImPACT Hyperlipidemia

Project ImPACT: Hyperlipidemia

397 patients collaborate with pharmacists & physicians in 12 states from March 1996 through October 1999.

Improve **P**ersistence **A**nd **C**ompliance with **T**herapy

J Am Pharm Assoc 2000;40:157-65.

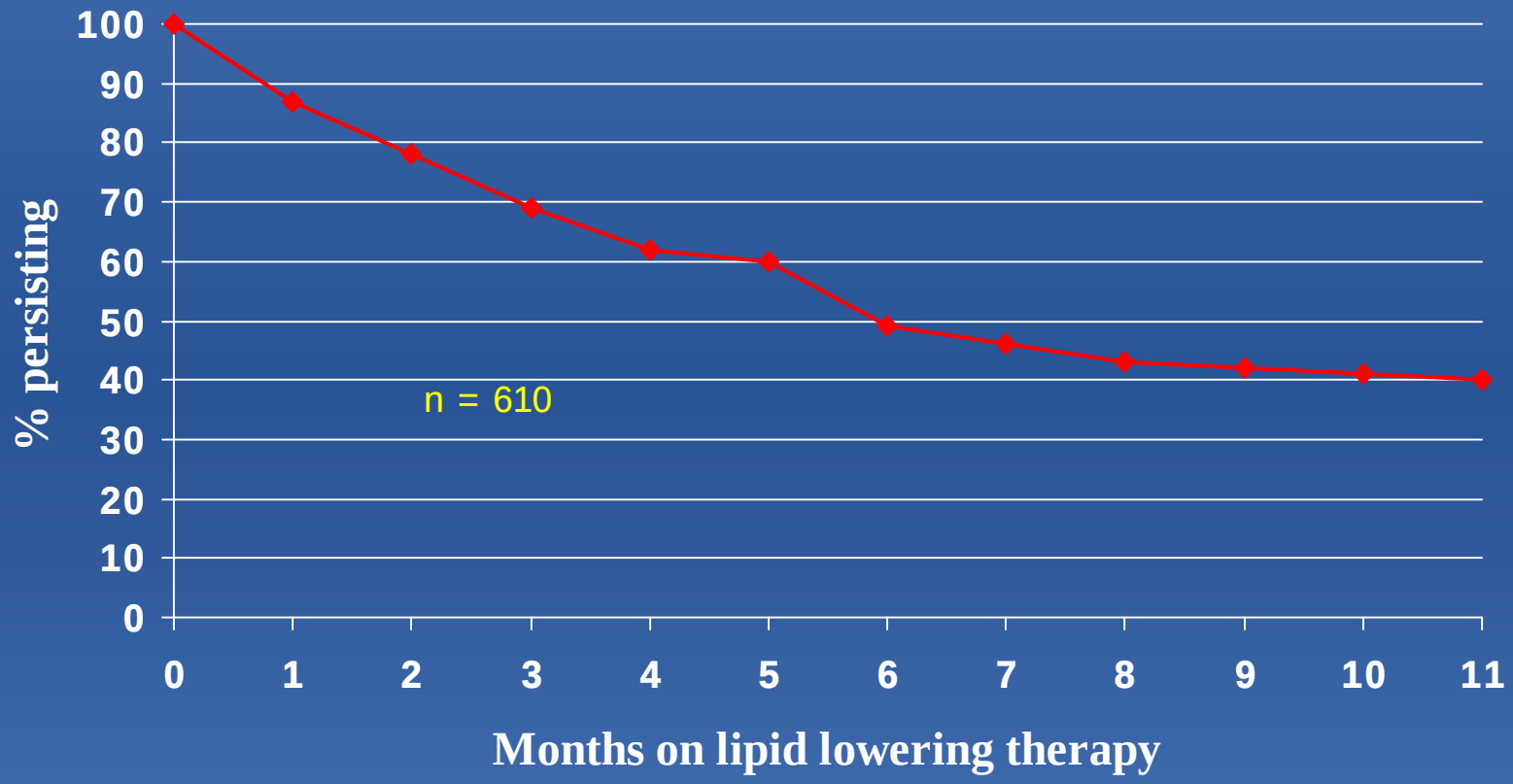
Coronary Artery Disease

- CAD is the leading cause of death in both men and women in the U.S.
- 6 million Americans have symptomatic CAD
- 1.5 million heart attacks per year in the U.S.
- Approximately 500,000 die annually from myocardial infarctions
- CAD causes more deaths in women than all forms of cancer
- CAD is the most common cause of death among the elderly

Hyperlipidemia is a major risk factor

- Hypercholesterolemia has been associated with increased risk of CAD in virtually all large-scale epidemiologic studies
- Major dyslipidemias can be diagnosed in more than 80% of patients with established premature CAD
- CAD is directly related to plasma levels of LDL cholesterol: elevated LDL levels = higher risk
- CAD patients with elevated LDL cholesterol levels are 12 times more likely to die from heart disease than CAD patients with desirable levels

Patients Discontinuing Therapy



Simons, et al MJA 1996; 164:208.

project ImPACT Hyperlipidemia

Primary Objectives

- Improve patient persistence and compliance with lipid-lowering therapy
- Increase communication and the flow of clinical information among patients, pharmacists, and physicians
- Improve the cholesterol levels of individual patients over time
- Increase the population of patients who reach and maintain their NCEP lipid goals

Pharmacy Site Selection Criteria

- Private or semiprivate area for patient consultation
- Technician support
- Documentation system for recording, tracking, and reporting patient care interventions
- Experience with patient-focused disease state management programs
- Demonstrated communication skills
- Ability to implement point-of-care testing technologies

Pharmacies by Practice Setting

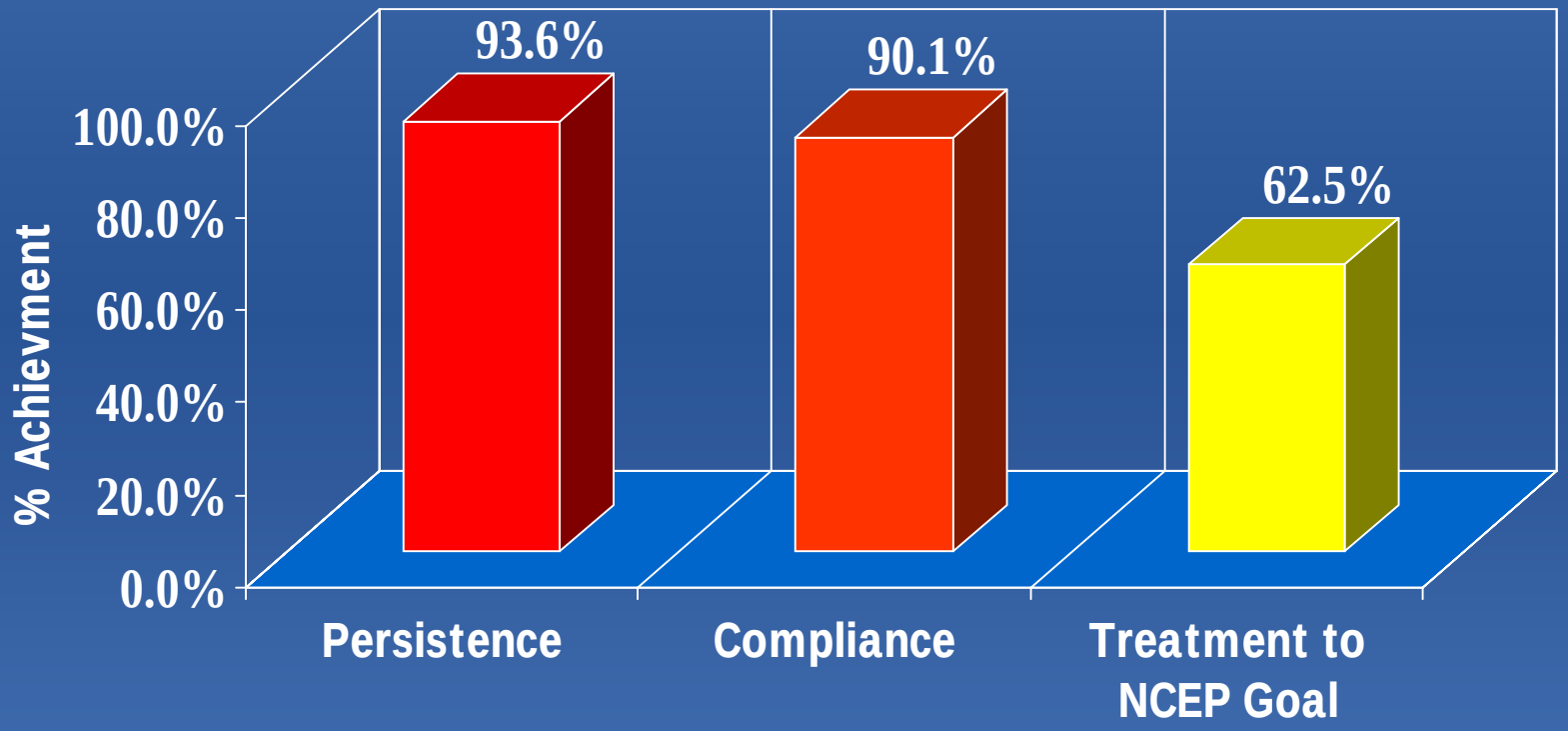
Independent	14
Chain - professional	3
Chain - grocery store	1
Home health / home infusion	2
Clinic pharmacy	4
Health maintenance organization / managed care	2
Total Pharmacies	**26**

Patient Enrollment

- Adult patient (over the age of 20 yrs)
- Newly diagnosed with dyslipidemia, or already receiving lipid-lowering medications but poorly controlled
- Referred by primary care physician, or if self referred, has agreement of primary care physician to participate
- Provided informed consent to participate

Project ImPACT: Hyperlipidmia

Results for 397 patients, 26 sites, 12 states over two years



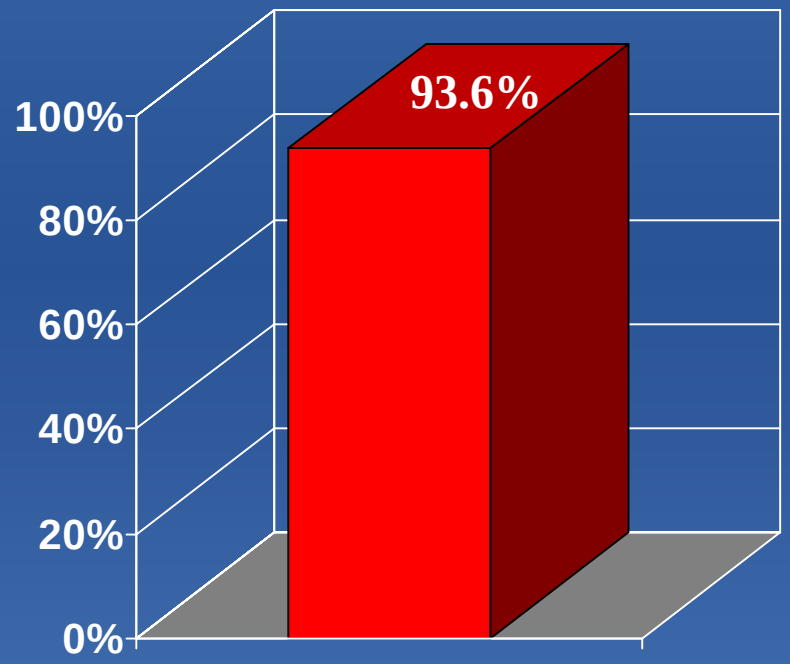
J Am Pharm Assoc 2000;40:157-65.

Project ImPACT: Hyperlipidemia Medication Persistence Results

DEFINITION:

Persistence was defined as the percentage of patients who started on medication just prior to or during the project, remained on medication subsequently and continued on medication as of their last study visit.

(i.e. 323/345)

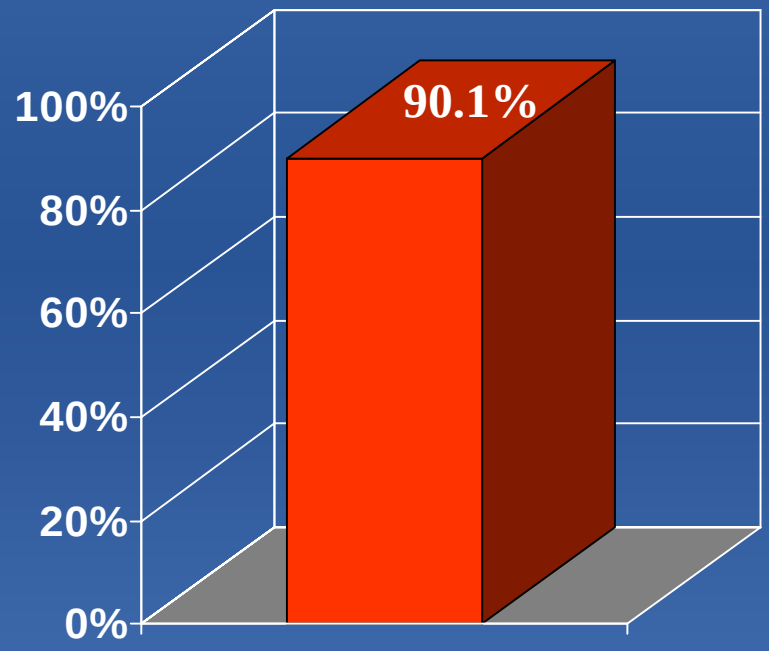


J Am Pharm Assoc 2000;40:157-65.

Project ImPACT: Hyperlipidemia Medication Compliance Results

DEFINITION:

Any patient who missed doses for 5 days or more or who missed a scheduled refill visit by more than 5 days was deemed to be noncompliant at that visit. Compliance (as a %) was calculated by dividing the number of visits at which patients were compliant by the total number of visits. (i.e. 2539/2817)



J Am Pharm Assoc 2000;40:157-65.

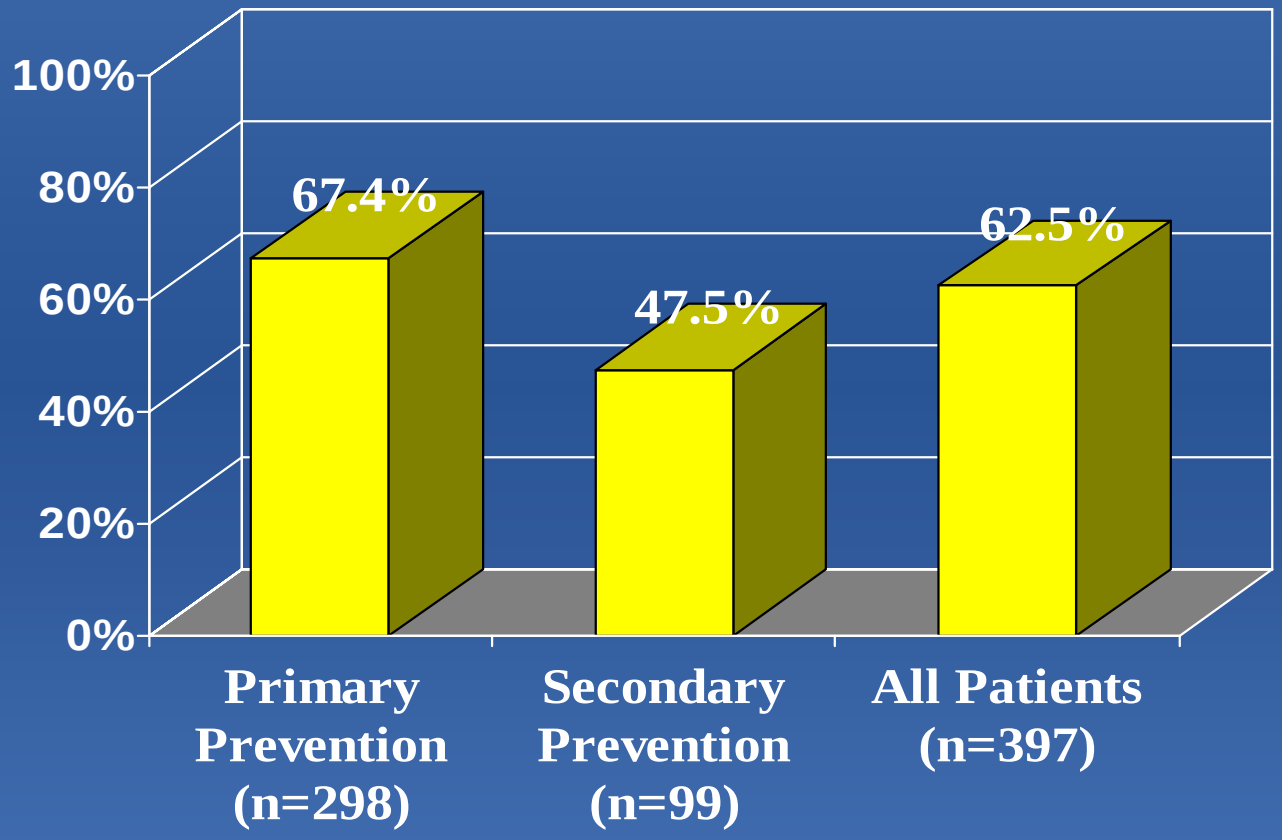
Project ImPACT: Hyperlipidemia Fasting Mean Lipid Levels

Measure	Beginning mg/dL (SD)	Midpoint mg/dL (SD)	Ending mg/dL (SD)	Mean Change	*P* value*
TC	**238.0 (46.7)**	**216.7 (44.3)**	**207.5 (41.1)**	**-30.5 (3.9)**	**< .0001**
TRG	**216.6 (111.3)**	**199.1 (95.7)**	**195.0 (91.3)**	**-21.6 (14.1)**	**< .0001**
HDL-C	**43.1 (14.1)**	**46.6 (15.6)**	**49.2 (16.5)**	**+ 6.1 (1.7)**	**< .0001**
LDL-C	**153.7 (41.3)**	**130.4 (37.8)**	**119.8 (35.7)**	**-33.9 (4.0)**	**< .0001**

* Change calculated as ending measure less the beginning measure (mean duration of 24.6 months) and compared using a two-tailed Student *t* test for paired data.

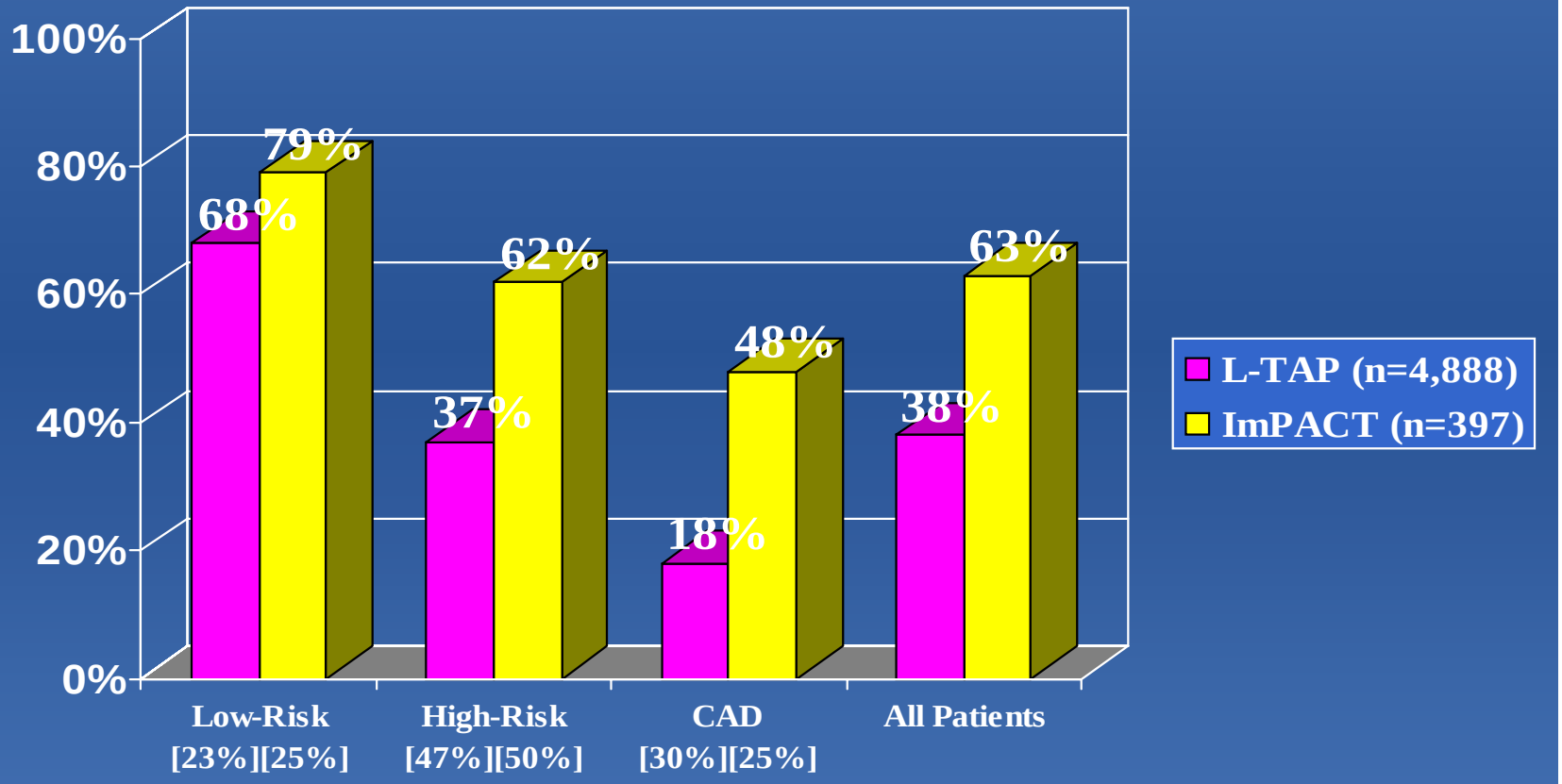
J Am Pharm Assoc 2000;40:157-65.

Project ImPACT: Hyperlipidemia
Achievement of NCEP LDL-C Goals



J Am Pharm Assoc 2000;40:157-65.

Achievement of NCEP LDL-C Goals L-TAP vs. ImPACT: Hyperlipidemia



Arch Intern Med 2000;160:459-467.
J Am Pharm Assoc 2000;40:157-65.

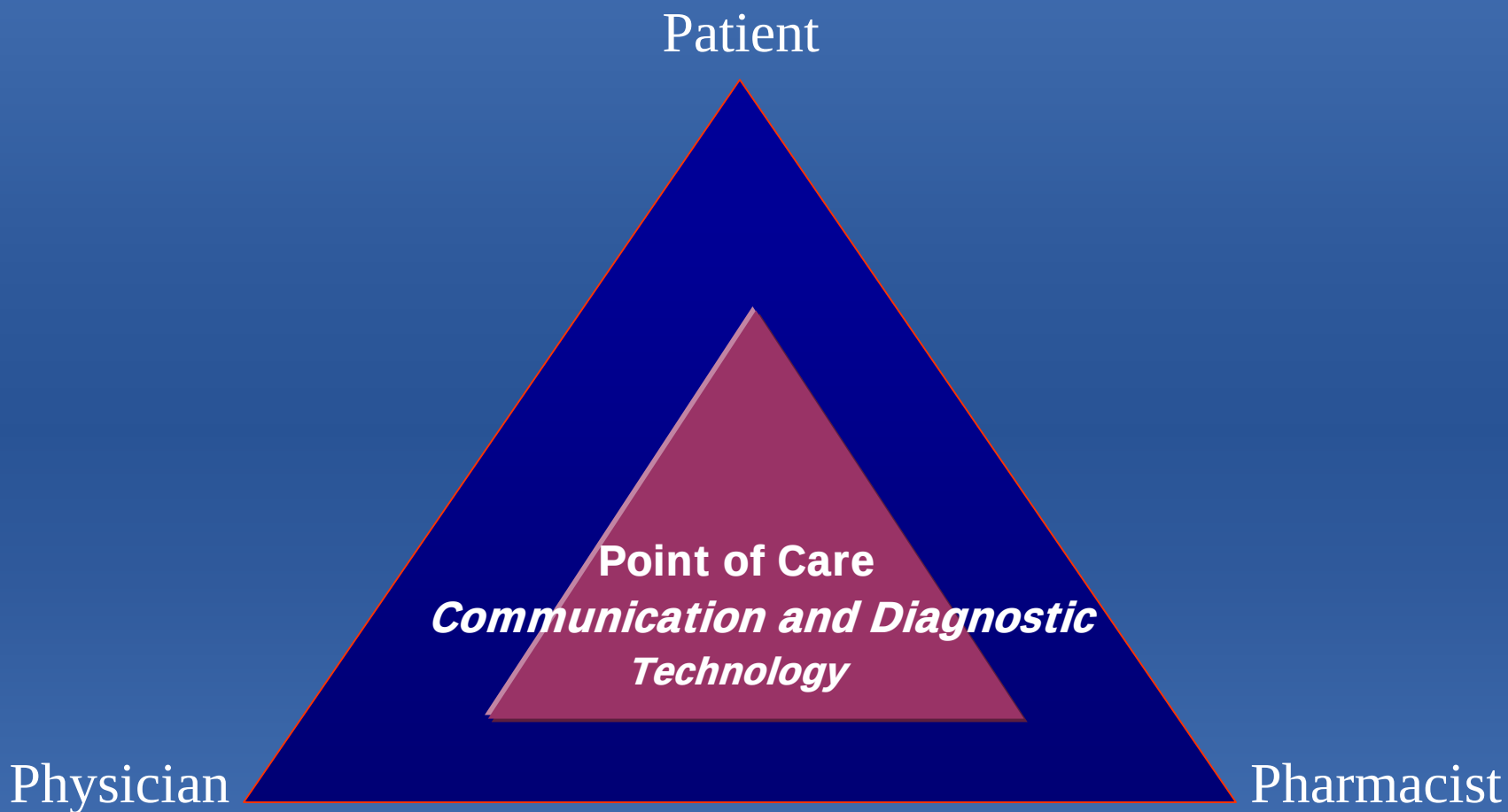
Patient Results Summary

- The 93.6% persistence and 90.1% compliance with lipid modifying therapy by patients receiving services from project pharmacists exceed all historical norms.
- Acceptable persistency and compliance may have lead to the lipid profile improvements and 62.5% achievement of NCEP goals in patients receiving pharmacist's services.
- The 22.1% LDL-C reduction and 14% HDL-C increase translates to a potential CAD event reduction of 30% to 40% in this population based on recent RCTs.
- The pharmacists' services appear to be well received by patients and primary care physicians.

Process of Care Overview

- Patient identified as being at risk
  - multiple points of identification
- Physician signs Certificate of Medical Necessity validating patient requirement for services
- Patient visits the pharmacist at regular intervals
  - objective measures obtained
  - compliance with therapy is checked
  - patient communication and education
- Communication follow up with physician

Point of Care Technology



- Collaborative practice with enhanced communication

Collaborative Practice
is based on mutual goals to...

- Improve Patient Care
- Improve communication and feedback between
  - patient and pharmacist
  - pharmacist and physician
  - physician and patient
- Increase the availability of objective measures to demonstrate improved outcomes (surrogate markers like compliance, risk reduction, etc.)
- Reduce total cost for care to the system over time (absolute endpoints)

Intervention Observations

- Pharmacist interventions with physicians
  - Coordination of care
  - Adverse drug reactions
  - Drug interactions
  - Drug dosing
  - Drug selection
  - Side effects
- Physicians accepted recommendations for therapy optimization in 76.6% of cases (e.g. 265/346)

Practice Model Observations (1)

- Consistently produced an environment that resulted in a high level of collaboration through:
  - Regular communications between and among all involved parties
  - Referral of patients by pharmacists to physicians and other providers (family practitioners, internal medicine physicians, cardiologists, dietitians, nurse practitioners, and endocrinologists)
  - Referral of patients to pharmacists by physicians and other providers (family practitioners, internal medicine physicians, cardiologists, and nurse practitioners)

Practice Model Observations (2)

- Consistently produced an environment that resulted in a high level of collaboration through:
  - Increased availability and use of objective clinical measures
  - Sharing treatment data and pertinent lifestyle and clinical information with patients and physicians
  - Periodic evaluation of the patient's progress toward lipid goals, and, if necessary, consultation and intervention with the patient's physician
  - Timely adjustments in the patient's treatment plans.

Process of Care Observations (1)

- 12% - Community Screening Events
- 13% - Patient Self-Referrals
- 15% - Physician Referrals
- 60% - Pharmacist Identification

Process of Care Observations (2)

- Pharmacist's time spent with patients for pharmaceutical care visits
  - Initial visit
    - 30 to 60 minutes (mean = 45 minutes)
  - Follow-up visits
    - 10 to 30 minutes (mean = 22 minutes)

Payment Observations

- Average assigned value of services:
  - $55 per visit
    - $28 – counseling
    - $27 – lipid profiles

Source	*# asked*	*# paid (%)*	*$ requested*	*$ paid*
Patients	232	174 (75%)	$ 55	$ 35
Third-parties	121	64 (53%)	$ 55	$ 30

Project ImPACT: Hyperlipidemia Conclusions……

- Pharmacists working collaboratively with physicians and patients can improve management of dyslipidemia
- Patients achieved medication compliance and persistence rates significantly higher than previously reported
- This model offers a sound strategy to empower patients & improve outcomes

J Am Pharm Assoc 2000;40:157-65.

Chronic Health Management(CHM): Diabetes

The Benefits of Empowering Consumers

Business Model for Employers/Payers and Providers

Empower the Patient. Improve the Outcomes. Control the Costs.

Rationale for the *CHM:Diabetes* Business Model

- Only 55% of people with diabetes remain on therapy after 12 months
- Only 50% of prescribed doses for cardiovascular disease (e.g., hypertension, CHF) are actually taken
- There are significant knowledge deficits in 50-80% of individuals with diabetes
- Each $1 spent on outpatient diabetes education saves $2-3 in hospitalization costs

Diabetes-Related Costs*

- 62% of health care expenditures for diabetes are due to hospitalizations, average cost of $11,076 per hospitalization in 1997
- 8.3 sick-leave days annually
- 1.7 sick-leave days for employees without diabetes
- $47 billion in productivity forgone due to disability, absence, and premature mortality
- Diabetes beneficiaries cost $4,410/year more than the average employee or dependent

American Diabetes Association. Economic Consequences of Diabetes mellitus in the US in 1997

Strengthening the Patient “Link”

- In 150 years, we have not changed the way medications are prescribed and dispensed while dramatic changes in medications have occurred...
- The Patient is the:
  - Applier
  - Utilizer
  - Determiner...of the outcomes associated with medication “technology”
- Patients on drug therapy ultimately “manage their own care”.

A *CHM: Diabetes* Model Encourages Self Management by the Person with Diabetes

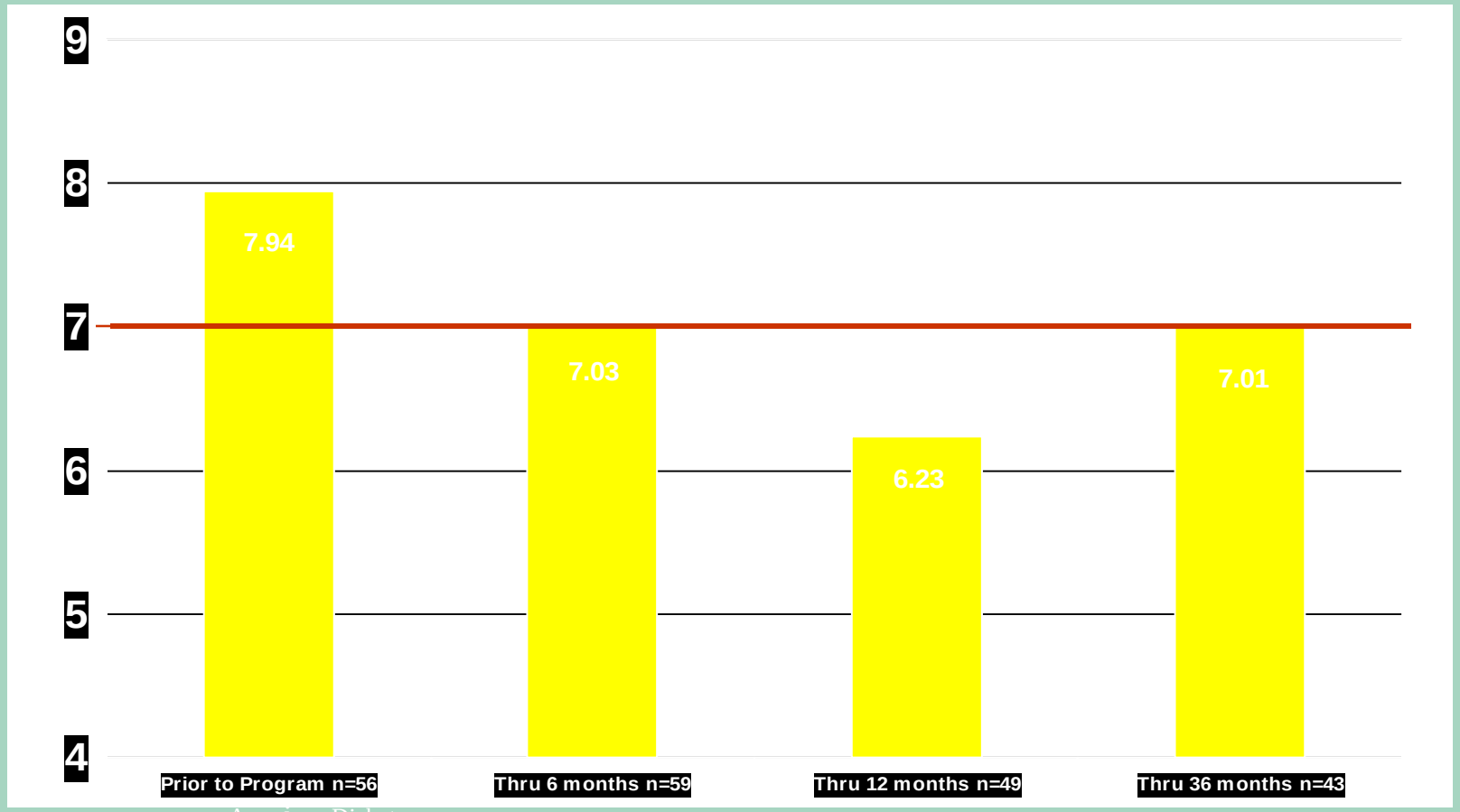
- Pharmacists trained in diabetes provide an ongoing training program for people with diabetes that qualify those who meet with their pharmacist on an on-going basis for reduced co-pays for diabetes medications
- This on-going program demonstrates that the patient has the knowledge, skills and motivation to be in control of their disease
- Follow-up monitoring document patients are continuing to meet their self-management goals
- Incentives for providers to manage *health*
- Pharmacist/CDE/MD reimbursement for patient education, training and monitoring

The “Asheville Project”

- Program began in 1997 with 49 people with diabetics employed by the City of Asheville working with community RPh’s, the Diabetes Education Center and physicians
- Now over 500 patients from 2 employers are enrolled for diabetes, asthma, hypertension and lipid therapy management
- All patients continue to have improved outcomes, increased QOL, & increased medication adherence
- 50% reduction in sick days in the first year
- Average net savings of $2,000 per person with diabetes each year from year 2 on

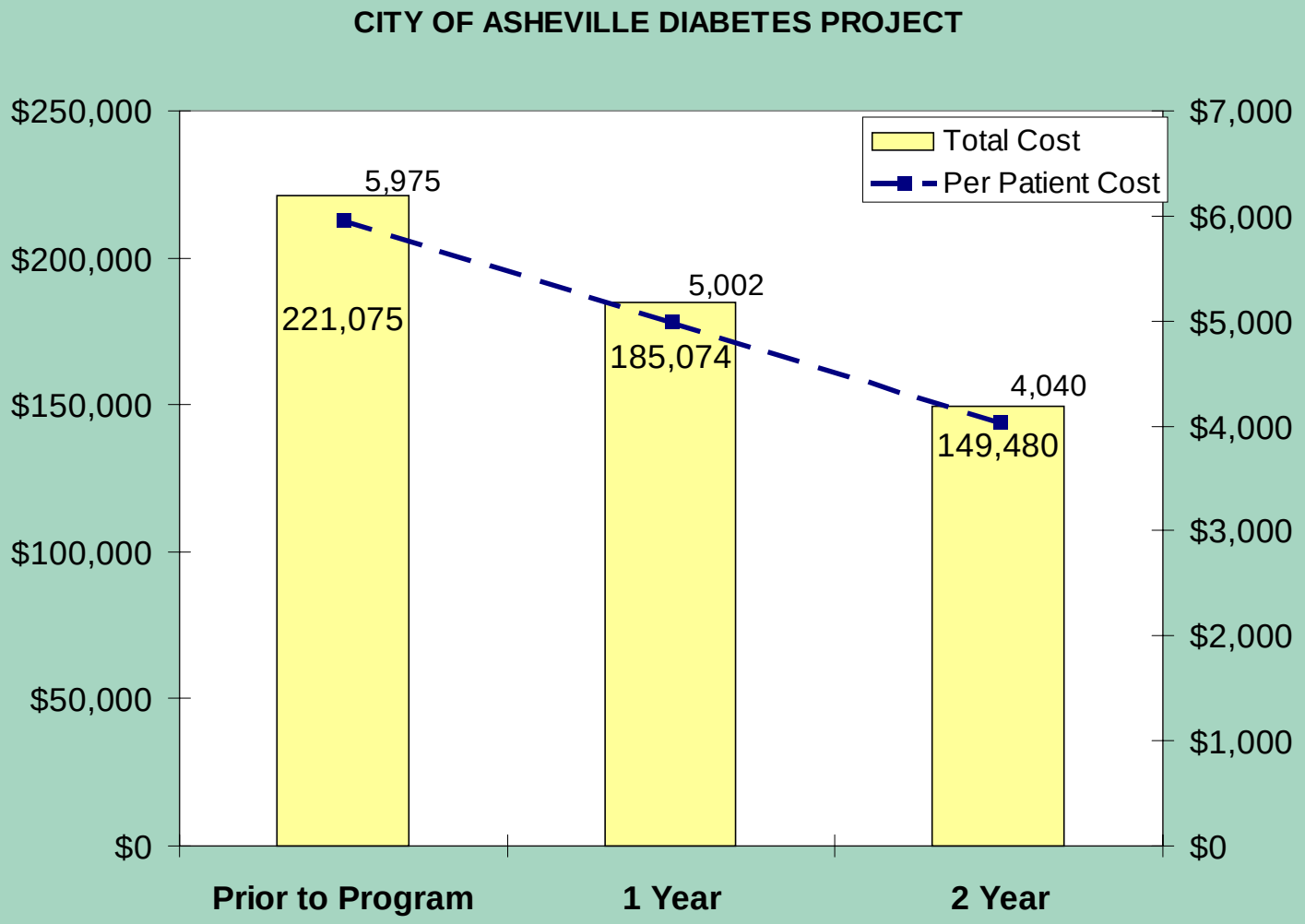
Asheville Project
DIABETES
CLINICAL IMPROVEMENT

Hemoglobin A1c (%)

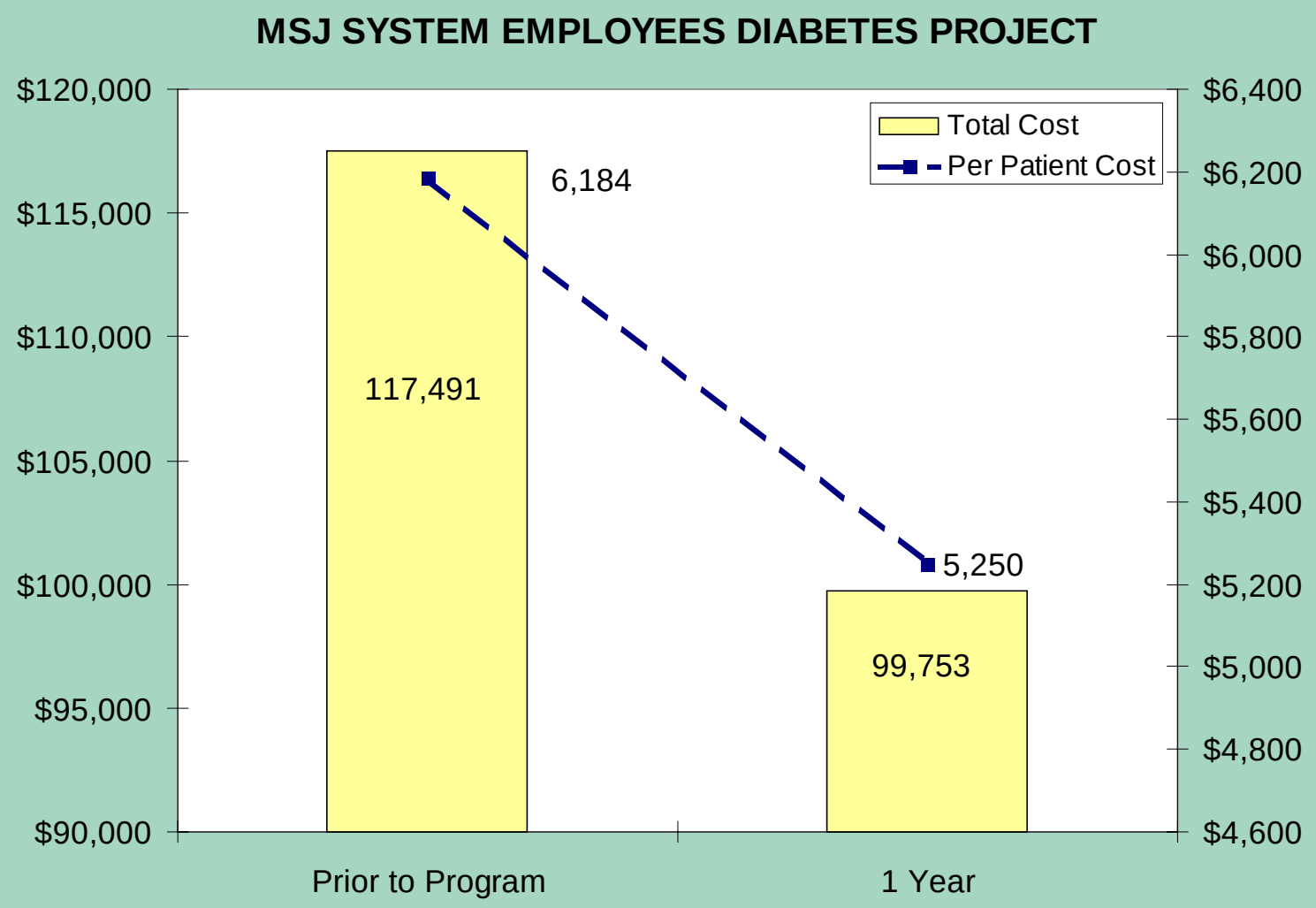


Source: Bunting, BA : Presentation on Outcomes of Asheville Project for Robert Wood Johnson Grant, May 2001

HEALTH CARE COSTS



HEALTH CARE COSTS



Asheville Project: Analysis of Changes in Health Care Costs

Cost Item	Baseline Year	Year Two	% Change
Inpatient Medical	$88,569	$19,059	-78%
Outpatient Medical	95,118	66,845	- 30%
Prescription Medication	34,043	55,155	+62%
Patient Education	0	14,831	NA
Total Costs	$217,730	$155,890	-28%

Base on data from Cranor, CW, Outcomes of Community Pharmacy-based Pharmaceutical Care Services for Patients with Diabetes. Preliminary Results of doctoral dissertation, July 2000, n=29.

Empower the Patient. Improve the Outcomes. Control the Costs.

CHM: Diabetes

Assumptions for initial costs for 100 Enrollees for 1st Year

Projections	Calculations
Enrollment: 100	125 covered lives x 80% enrollment = 100
Pharmacist/CDE counseling services: $34,000	100 x $100 (initial 60-minute session) x 1 month = $10,000 100 x $40 (monthly 30-minute session) x 6 visits = $24,000
Cost for diabetes education: $17,500	50% of 100 patients x $350 (total cost for comprehensive visit to diabetes center)= 17,500
Diabetes-related Rx/year: 3600	100 patients X 3 diabetes Rx per patient X 12 months= 3600 (67% increase in compliance from 2 rx/month/patient incl. Test strips)
Waived copay For prescriptions: $54,000 Medication cost for improved compliance$72,000 Total inc. Rx Cost $126,000	3600X $15 (average copay for brand name Rx) = $54,000 1200 X $60,00(average cost of medication/Rx) = $72,000
Laboratory monitoring: $14,500	100 x $45 (3 HbA_{1C} tests [months 0, 6, 12] x $15 each) = $4,500 100 x $100 (2 lipid panels [months 0, 12] x $50 each) = $10,000

Adapted from: *Diabetes Community Health Project*,, North Carolina Center for Pharmaceutical Care

Empower the Patient. Improve the Outcomes. Control the Costs.

CHM: Diabetes

Assumptions for Cost Savings

Projections	Calculations
Savings from reduction in hospital admissions: $287,872	A 40% reduction of diabetes-related hospital admissions = prevention of 26 hospitalizations/year, 26 x $11,072* (average cost of a diabetes-related hospitalization)
Fewer workdays missed per year: 650	100 x 6.5 days (average increase in workdays)
Second year costs: decrease	No initial consultation with pharmacist Fewer returns to the diabetes education center

Adapted from: *Diabetes Community Health Project,* North Carolina Center for Pharmaceutical Care

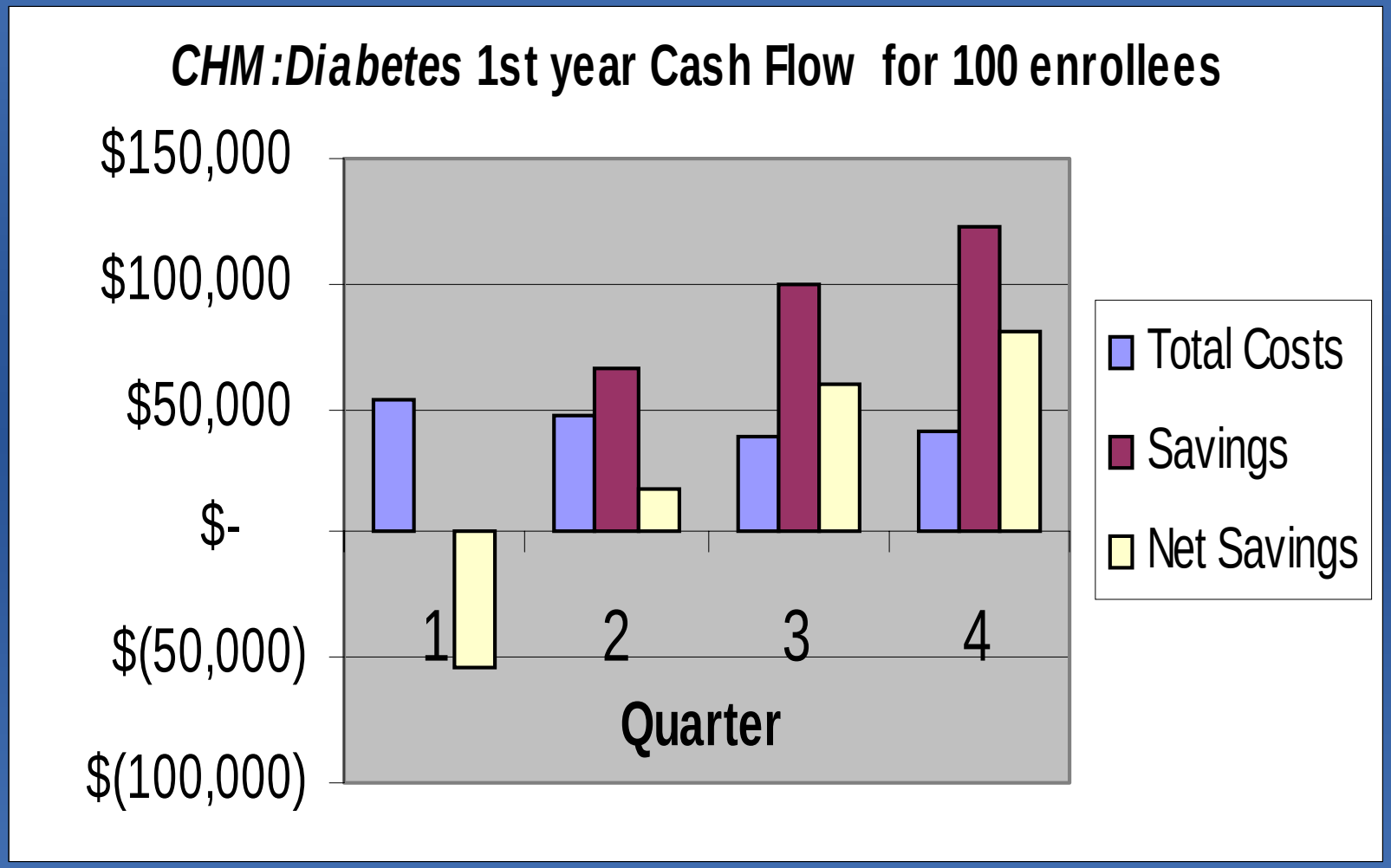
* American Diabetes Association. Economic consequences of diabetes mellitus in the US in 1997.

Summary of projected economic outcomes for 100 people with diabetes

- Initial costs: ~$192,000
- Gross savings: >$287,872 in the first year
- Net savings: >$ 95,872
- Reduced absenteeism and improved productivity
- Second year net savings increase

CHM:Diabetes

Break even point occurs in 3rd quarter of program



Empower the Patient. Improve the Outcomes. Control the Costs

The *CHM:Diabetes* Model

How does it work?

Identify participants, inform them about incentives and direct them to *CHM::Diabetes* education, testing and monitoring centers

Pharmacist /CDE Provide initial education and testing

Refer participants with poor blood glucose control (HgA1c>8.0%) to diabetes education center for intensive training program

Pharmacist/CDE shares findings with patient's physician

Participant returns for follow-up appointments

Pharmacist/CDE consults physician as required

Track clinical, economic, and quality-of-life outcomes

Adapted from the Diabetes *Community Health Project*, North Carolina Center for Pharmaceutical Care

Empower the Patient. Improve the Outcomes. Control the Costs

The *CHM:Diabetes* Model

Who will pay?

Participating pharmacist/CDE provides initial education, testing, and follow up services

Pharmacist/CDE bills employer/insurer, employees receive incentives for initial 6 months to see if they meet program requirements and employer is notified if participant is not keeping appointments

Employer/payer reimburses pharmacists/CDEs for services (employers/payer may want to negotiate risk sharing arrangements with providers for initial year of program)

Adapted from the Diabetes *Community Health Project,* North Carolina Center for Pharmaceutical Care

Empower the Patient. Improve the Outcomes. Control the Costs

The *CHM:Diabetes* Model

Getting Started

Employer/insurer identifies covered lives with diabetes and notifies patients about *CHM:Diabetes* incentive

Network of *CHM:Diabetes* education/monitoring centers is identified to meet patient population needs or education/monitoring is done on-site

Patients select from options provider sites and make initial appointments for education and program enrollment

Follow up visits are schedule and ongoing monitoring is documented to maintain *CHM:Diabetes* incentives

Adapted from Diabetes *Community Health Project*, North Carolina Center for Pharmaceutical Care

Advantages of the *CHM:Diabetes Model*

***CHM:Diabetes* Model**	**"Traditional" Disease Management Programs**
Face-to-face counseling is customized for individual patients.	Impersonal counseling is generic and for a mass audience.
Caregiver is a specially trained pharmacist/CDE who knows the patient's history.	Service is often limited to information about the prescription without the benefit of a complete medical history.
Patient and caregiver work together to set and follow up on specific goals.	Follow-up on generic benchmarks is often conducted via postcard/impersonal telemarketing techniques.
Educational counseling is targeted to each patient's needs and individual goals.	Educational materials are often irrelevant to many patients and inappropriate for low literacy levels.

Adapted from Diabetes *Community Health Project*, North Carolina Center for Pharmaceutical Care

CHM:Diabetes Model
Requirements for Patients

- Agree to meet with a qualified Pharmacist or CDE on an ongoing basis for education, monitoring and set personal goals for diabetes self-management
- Demonstrate proper use of blood glucose monitoring equipment and administration of medications
- Meet at least quarterly with a qualified pharmacist or CDE to set self-management goals have scheduled HbA1c tests and eye exams to maintain the incentive

CHM:Diabetes Model Requirements for Providers

- Pharmacists must be a CDE or BCPS
  - or pass the NISPC Diabetes exam
  - or have completed an ACPE level Diabetes Certificate Training Program
- RN's or RD's must be a CDE
- MD's must have qualified office staff
- Have private consultation rooms for patient education
- Maintain documentation and report outcomes

CHM:Diabetes Model
Requirements for Employers/Payers

- Willingness to invest in employees' health to enhance QOL, reduce sick days and lower hospitalization costs
- Capability to (or use a PBM) identify potential enrollees and provide reduced/waived co-pay prescription cards
- Access to data management systems that track total health care costs for enrollees
- Provide payment to pharmacist/CDE providers, preferably via electronic payment

CHM:Diabetes Model
Role of the Physician

- Physicians are responsible for overall care of patient and changes in therapy
- The *CHM:Diabetes* program is complementary to scheduled or referred physician visits
- A physician office can establish education, and monitoring services
- Physicians will receive summary reports after each patients session with pharmacist/CDE
- Physicians will be notified about the program by the employer/payer when patients enroll
- Data from the Asheville project indicate that physician outpatient visits increase.

What do people say about the *CHM:Diabetes* Model?

- Focus Groups/meetings have been held with
  - Patients
  - Pharmacists/CDE's
  - Managed Health Care Companies
  - Employers
  - Physicians
  - PBMs
  - National Quality Assurance Association Executive

Key Findings

- Everyone we have talked to thinks this a good idea
- No major “red flags” have been identified
- The key to maintaining diabetes control is the on-going relationship with the pharmacist/CDE
- The waived co-pay incentive is significant and consumers will participate to achieve the incentive

Key Findings Continued

- This program will be best driven in the marketplace by employers
- The collaborative team approach to supporting diabetes self-management is needed
- Education/Testing/Monitoring should be able to be provided by all health care providers who qualify (CDE, RPh and MD)

Key Findings Continued

- Existing education materials for patients and provider diabetes training programs are sufficient for program implementation
- Employers will realize both financial and humanistic benefits
- Education and training should include stress management in addition to nutrition, foot care, exercise, medication, monitoring and diabetes disease state knowledge

Comments from Patients

- “The program saved my life”
- “The program reminded me of things and reinforced things I knew”
- “It is the positive reinforcement of good habits since I know I will be meeting with my pharmacist each month”
- “I probably wouldn’t have signed up without the incentive”

Comments from Pharmacists/CDE's

- "Two issues affect a patient's success; 1) If the individual views their health as a priority and, 2) the willingness of the health care professional to take time with patients"
- "What we know can make a difference. Our profession has become a commodity business. We get paid for counting by 5's. The revenue is attached to the commodity and not to what I can impart to patients. This is frustrating. I want to get paid for for using my head"

Comments from Physicians

- “This is where the rubber meets the road. This would help the patient have the medications they need and be compliant.”
- “The big strength of this is continuity. People see the same pharmacist over and over and feel less hopeless”
- “The concept is very tangible; people are given responsibility for managing diabetes, and it is clear what would disqualify them from participating in the program.”

Comments from Physicians Cont.

- “Marketing to physicians is best done by patients. Physicians act positively to programs the patients have researched and bring to them.”
- “A successful approach to marketing would be if an employer sent a letter endorsing the program.”
- “It is the patient that we are all here to serve, not just the bottom line.”

Comments from Employers

- “Every company needs this!”
- “The program works only work if it takes into consideration differences in literacy and cultural biases.”
- “Employers should have a menu of options so they could select the criteria used to decide whether or not an employee retains the incentives.”

Employers Comments Cont.

- “Empowerment of diabetes self management will result in reduced absenteeism and lower overall health care costs for employers.”
- “Employers will experience real life stories about how this program has changed peoples’ lives.”

CHM: Diabetes
Benefits All Stakeholders

- Patients- incentive for self management
- Physicians- patient knowledge assessment and monitoring to individualize care plans
- Pharmacists/CDE- opportunity to educate patients and obtain reimbursement
- Managed Care/Insurers- tool to motivate beneficiaries to manage their health and collect Hedis data
- Employers/Payers- mechanism for giving employees incentives to stay healthy
- Rx Industry/PBMs- increased adherence leads to improved medication outcomes

Summary of *CHM:Diabetes* Model and Benefits

- The *consumer* ultimately manages their own care
- Incentives establish accountability for consumers to manage their health on a continuous basis
- Providers are reimbursed to keep consumers healthy
- Consumer Health and Productivity increase
- Net savings of $1,000/patient/year will be achieved in the first year (break even at 8 months) and savings increase in the second year

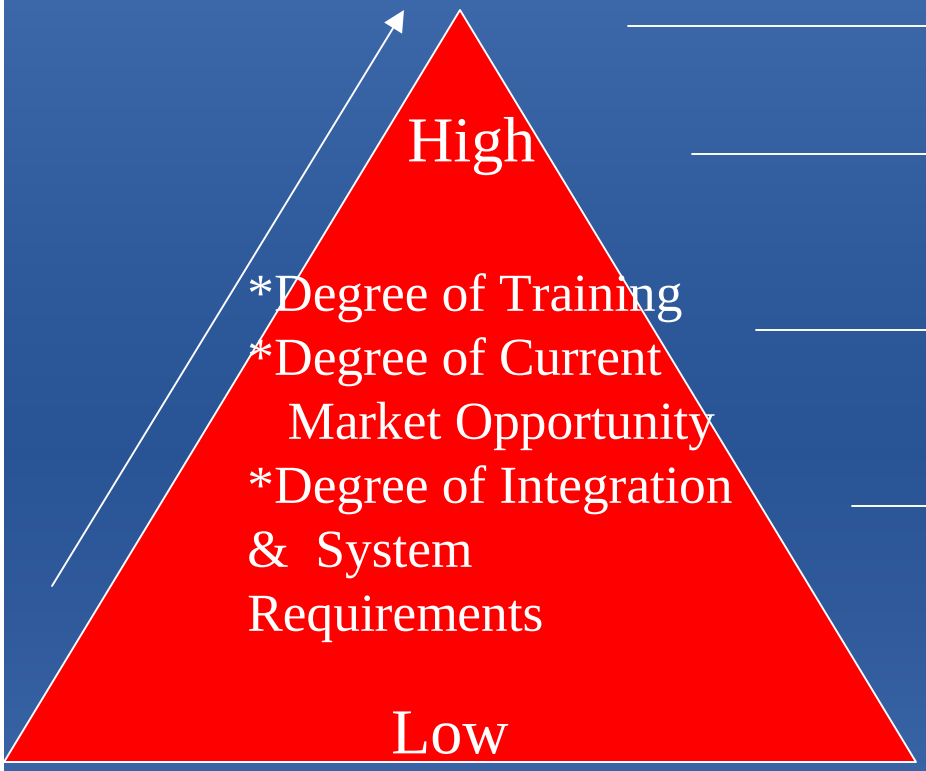
Learnings from *Project ImPACT and the Asheville Project*

- On going patient interaction with pharmacists increases adherence significantly - 90%
- Medication use increases
- Physician contact/communication increases
- Hospitalizations and crisis care costs decrease

Learnings from *Project ImPACT and the Asheville Project (continued)*

- Sick days decrease
- Outcomes improve
- Patients and Physicians love it
- Employers are appreciated by employees
- Patients are empowered and in control

Pharmacist Care Intensity: State of Business Model Development



- Risk-Management Services: Under Conceptual Discussion by APhA, ASHP, NCPA, NACDS, AMCP, FDA, PhRMA—Not Operational
- Collaborative Practice Model: Exists in pockets, not "mass-market" ready, reimbursement spotty-cash/self-insured employer based. E.g. Asheville Project; Project ImPACT: Hyperlipidemia, Osteoporosis
- Screening/Prevention/Risk Assessment Programs: More available; no scalable, widely available reimbursement. E.g. NCPA Men's Health Initiative; Immunization Programs
- Compliance/Adherence/Persistency Programs: Becoming common, especially manufacturer sponsored. Payment based on letters/calls but difficult for independents to participate due to data integration
- "Average" service received in "today's" pharmacy: includes OBRA counseling. Payment based on product dispensed not service offering.

Questions?