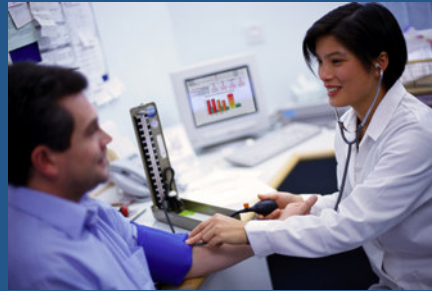
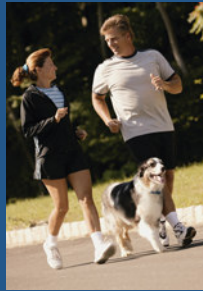
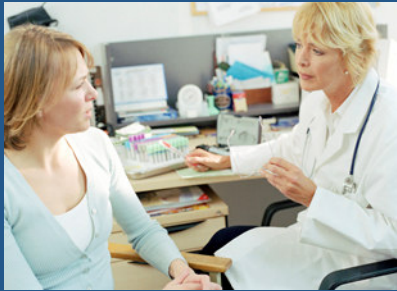




KnowYourNumber™
The Key To Proactive Good Health



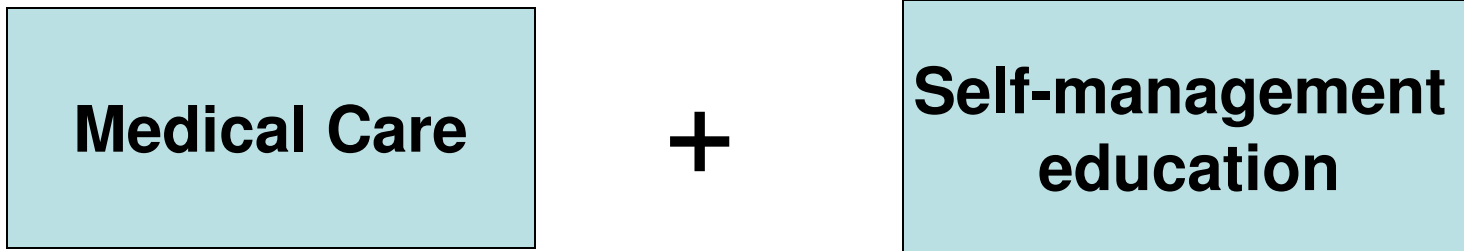
Diabetes and Its Complications

Diabetes and Its Complications

- 16 million are Americans affected
- Serious and fatal complications cost \$92 billion in 1992
 - Blindness
 - diabetes as the leading cause in age 25-74, 27,000 /yr
 - Amputations
 - 28 times higher risk, 54,000/yr
 - Heart disease
 - 2-4 times higher risk, 77,000 die/yr
 - Stroke
 - 5 times higher risk, 11,000 die/yr
 - Kidney disease
 - 1/3 of all kidney failure, 13,000/yr

Care for Patients with Diabetes

To optimize glycemic control and minimize complications



American Diabetes Association

“Diabetes Self-Management Education (DSME) is the cornerstone of care for all individuals with diabetes who want to achieve successful health-related outcomes.”

“Continuing patient education for self-management is an integral component of diabetes treatment. This is particularly so for diabetes; successful management of diabetes is greatly dependent on the patient’s own efforts. Therefore, all people with diabetes must have access to affordable patient education services.”

Diabetes Self-Management Education (DSME)

A process of providing

- Knowledge
- Skills for self-care

DSME Works

- Participants in DSME
 - Decrease in complication rates
 - Fewer emergency room visits and hospitalizations
 - Reduced medication costs

Examples

- 49% reduction of lower extremity amputations, 65% fewer severe ketoacidosis
 - J Am Dieb Ass 1979, 75: 250-7
- 78% reduction in hospital length of stay, saves \$2,319/person/year
 - N Eng J Med 1972, 286: 1388-91

DSME is Paid

Most insurers reimburse for DSME programs that have met accepted standards

National Standards for Diabetes Self-Management Education

Standard 8.

An individualized assessment, development of an educational plan, and periodic reassessment between participant and instructor(s) will direct the selection of appropriate educational materials and interventions.

BioSignia's Diabetes Complication Predication Model: A Useful Tool in DSME

- Individualized complications prediction
- Detail disease stages, 19 predicted stages
- Comprehensive and up to date medical knowledge
- Advanced statistical algorithm: Monte Carlo assimilation
- Interactive animation and simple graphic presentation

Objective of the Tool

- Increase knowledge
- Motivate self-care
- Increase adherence to treatment
- Evaluate effectiveness of treatment

What Does The Model Predict ?

- Cardiovascular
 - Stroke, Heart Disease
- Retinopathy
 - NPDR 1-3, PDR, ME, Blindness
- Nephropathy
 - MA, GPA, ESRD
- Neuropathy
 - Clinical Neuropathy, LEA

How Was It Developed ?

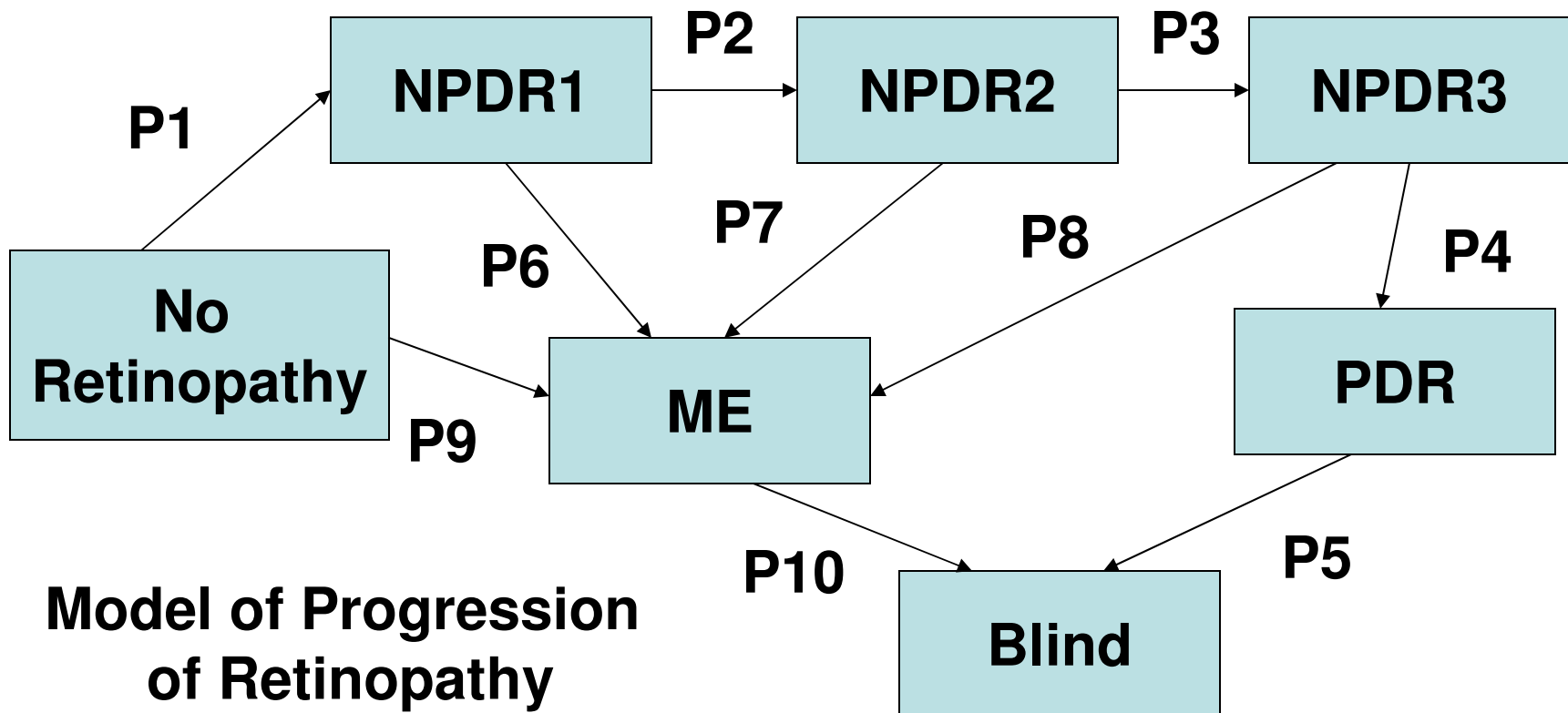
Review of the known epidemiology of diabetes natural history and effects of intervention.

Information sources:

- DCCT
- UKPDS
- WESDR
- Rochester, Minnesota population study

How Was It Developed ?

Probability modeling (Monte Carlo simulation)



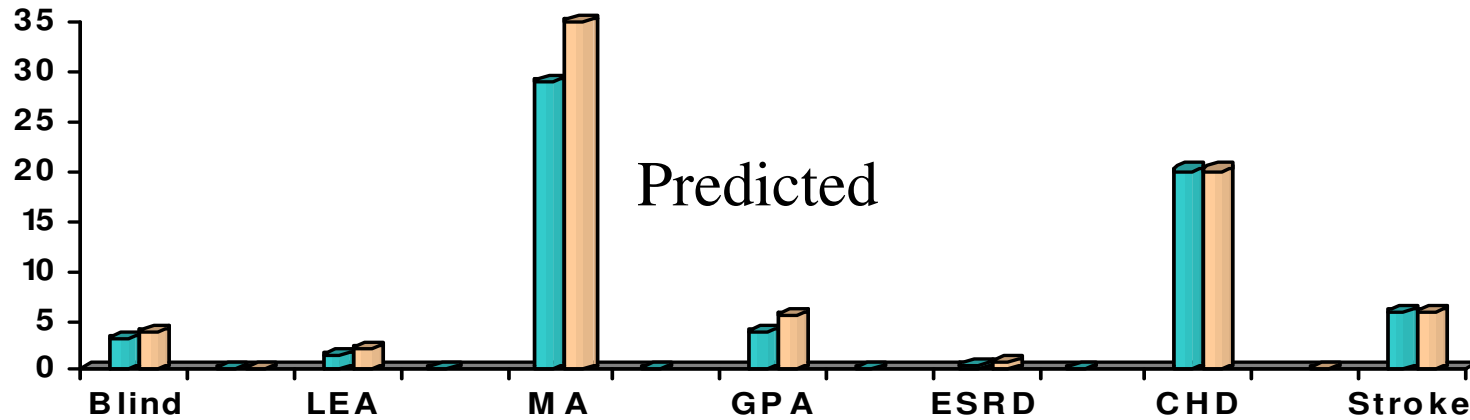
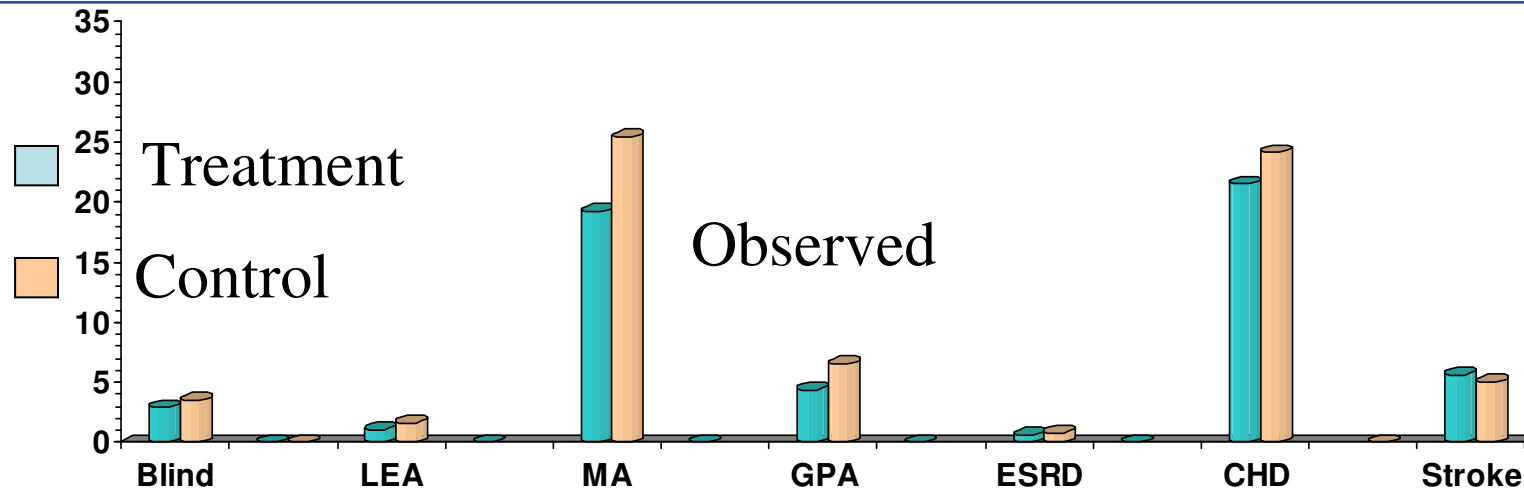
Validation: Question

- Among general population does the model
 - predict complications incidence close to what were observed?
 - predict the effectiveness of interventions close to what were observed?

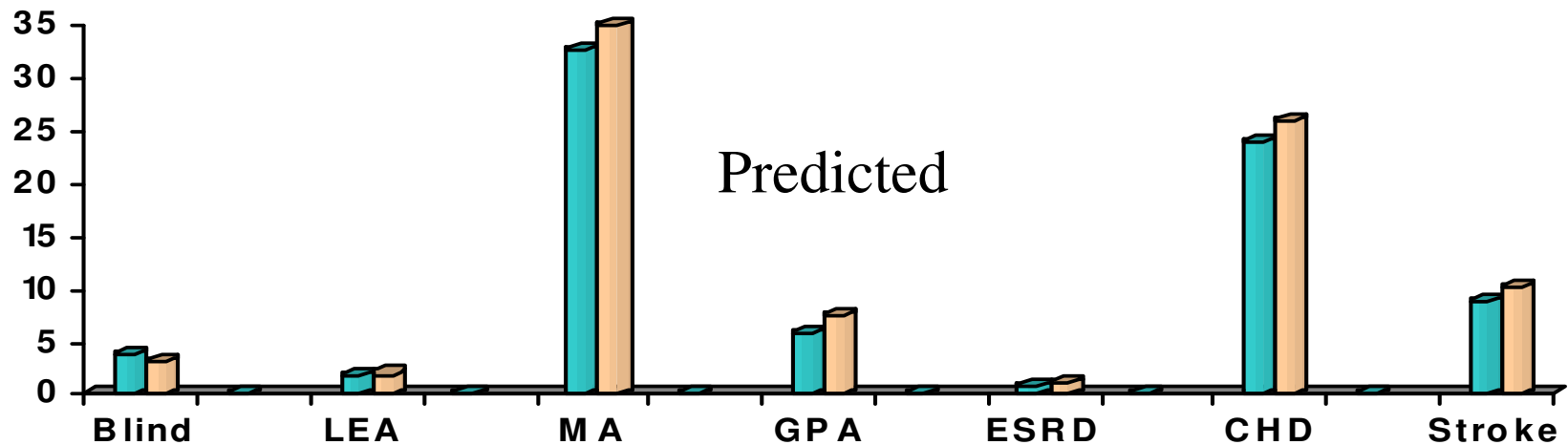
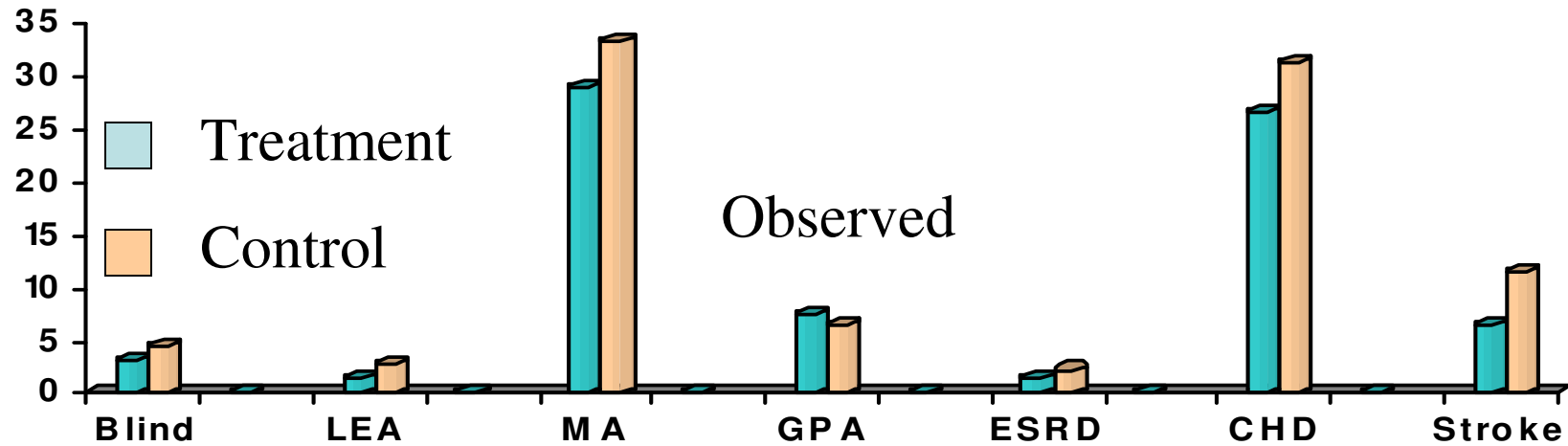
Validation: Population

- UKPDS, glycemetic control trial
 - average 9 year of follow up
 - Treatment (n=2729) with HbA1c=7.0% vs. control (n=1138) with HbA1c=7.9%
- UKPDS, BP control trial
 - Treatment (n=758) with SBP=145 vs. control (n=390) with SBP=155
- DCCT (second cohort)
 - Average 6 year of follow up
 - Treatment (363) with HbA1c=7.0% vs. control (n=352) with HbA1c=9.0%

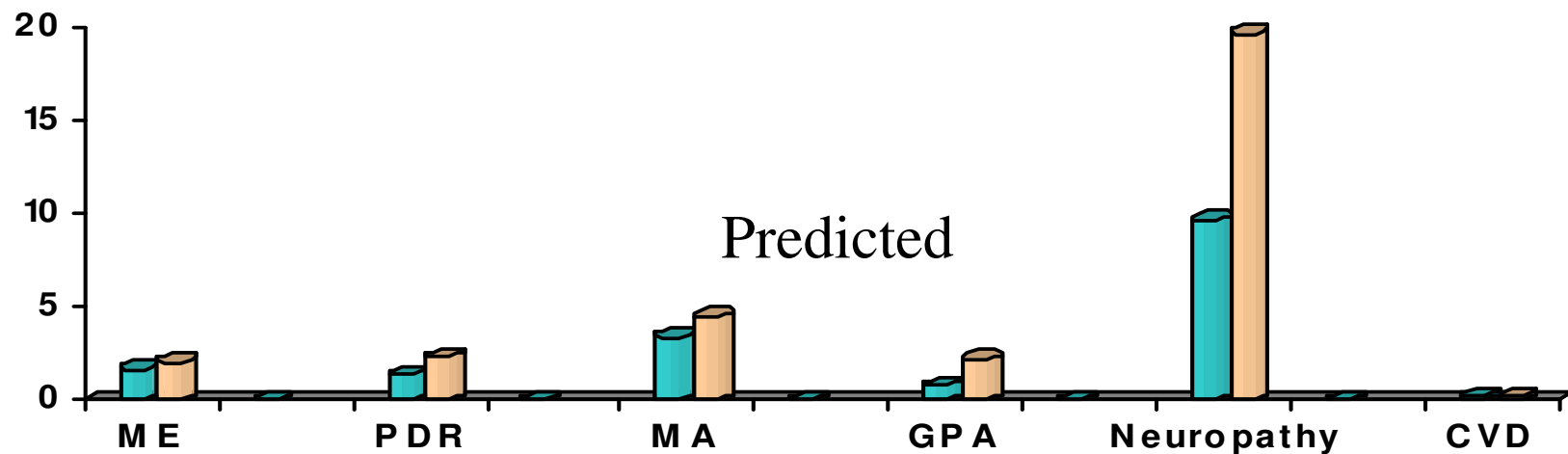
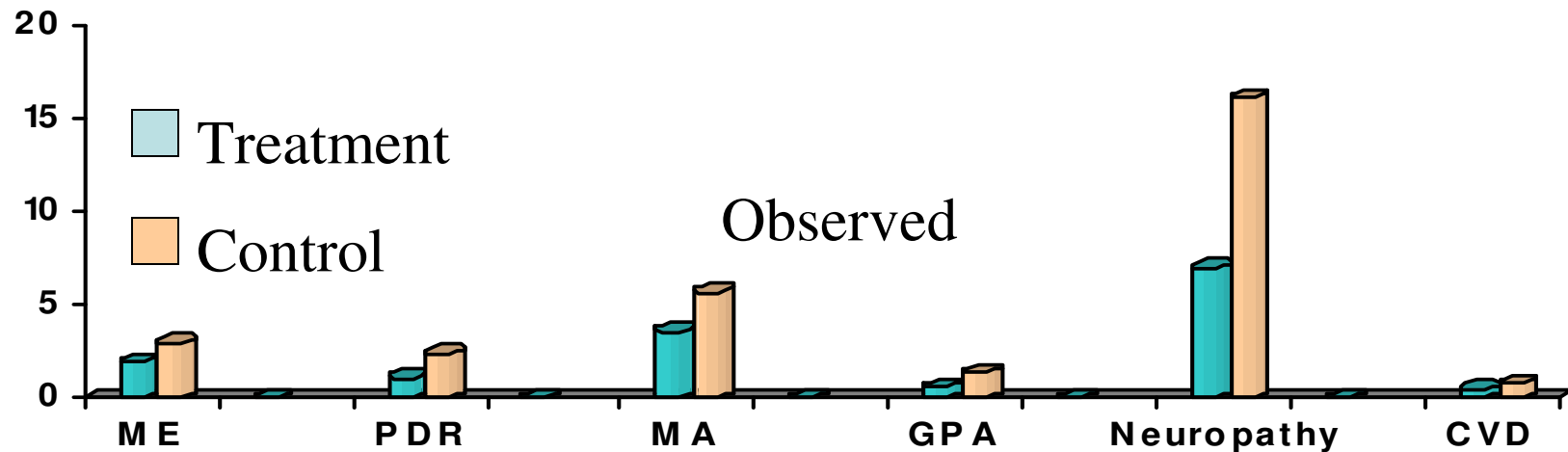
10 Year Incidence of Complications in UKPDS (Glycemic Control Trial): Observed vs. Predicted



10 Year Incidence of Complications in UKPDS (BP Control Trial): Observed vs. Predicted



Annual Incidence of Complication in DCCT: Observed vs. Predicted



Validation: Conclusions

- The model predicts similar incidence of major complications with what were observed in UKPDS and DCCT
- The predicted reductions of complications due to glycemic control and blood pressure control are the same with what were observed in UKPDS and DCCT