

**GAPS IN RESEARCH NEEDED TO  
IMPROVE TREATMENT OF HEART,  
LUNG AND BLOOD DISEASES  
AMONG OLDER AMERICANS**

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# **PRACTICAL STUDIES NEEDED: WHAT HAPPENS IN THE REAL WORLD?**

- 1. WHAT DO TRADITIONAL CLINICAL TRIALS TELL US?  
CAUSE, EFFICACY “OPTIMAL IMPACT” OF THERAPY,  
LIMITED ADVERSE EVENT INFORMATION**
- 2. CLINICAL CARE ENVIRONMENT OFTEN DIFFERENT:  
MULTIPLE DISEASES, MULTIPLE DRUGS, LESS INTENSE RX**
- 3. WIDE VARIATION IN PT RESPONSE  
HEALTH CARE SYSTEM, PATIENT COMPLIANCE,  
ENVIRONMENT  
UNEXPECTED ADVERSE EVENTS**
- 4. PRACTICAL STUDIES NEEDED:  
SYSTEMATIC OBSERVATION TO MONITOR FOR BENEFIT AND  
HARM, RANDOMIZED CLINICAL TRIALS**
- 5. SYSTEM NEEDS TO BE AGILE (QUICK RESPONSE)**

# PREVENTION: HYPERTENSION CONTROL

## BACKGROUND:

1. MAJOR CAUSE OF CVD WORLDWIDE
2. EXTENSIVE CLINICAL TRIAL EVIDENCE
3. MAJOR BENEFITS ACHIEVED - BUT
4. MINORITY ACHIEVE OPTIMAL CONTROL
5. MULTIPLE CAUSES
  - PATIENTS
  - SYSTEM
  - ENVIRONMENT
6. PROGRESS LAGGING IN US SUBGROUPS
7. NEED: DATA FROM TRIALS AND ONGOING SURVEILLANCE FOR (DELIVERY, ADHERENCE, ETC.)

# PREVENTION: HYPERTENSION CONTROL

## STUDIES TO FILL DATA GAPS:

1. TRACKING OF SURVEILANCE DATA – MONITOR TRENDS  
NCHS Data Brief (App. 1 year delay)  
CLINICAL MONITORING
2. EVALUATE INTERVENTIONS FOR HTN TREATMENT IN  
MULTIPLE CLINICAL SETTINGS  
GOAL: ACHIEVE CONTROL RATES SEEN IN BEST HEALTH  
SYSTEMS
3. CLINICAL TRIAL: BP TREATMENT TO LOWER TARGETS IN  
HIGH RISK PATIENTS  
PROPOSED NIH SPRINT TRIAL

# PREVENTION: HEART FAILURE

## BACKGROUND:

1. PARTLY RESULT OF OUR PRIOR SUCCESS
2. MAJOR CAUSE OF MORBIDITY, MORTALITY
3. PREVENTION CRITICAL
4. MAJOR CAUSES OF CHF
  - HYPERTENSION
  - CORONARY ARTERY DISEASE - MI
5. DISPROPORTIONATE IMPACT: MINORITIES
6. NEED: TRIALS AND ONGOING SURVEILANCE FOR (PREVENTION, Rx DELIVERY, ADHERENCE, ETC.)

# PREVENTION: HEART FAILURE

## INTERVENTIONS:

### 1. PREVENTION:

INCREASE EFFORTS TO CONTROL KNOWN CHF RISK FACTORS

### 2. TREATMENT TRIAL: DIASTOLIC HEART FAILURE

CURRENT RECOMMENDATIONS – BP CONTROL  
VALUE OF ROUTINE HEART FAILURE TREATMENT  
UNCERTAIN

ONGOING NIH TRIAL: TOPCAT

TEST VALUE OF BETA BLOCKERS AND ACE INHIBITION IN  
DIASTOLIC HEART FAILURE,  
TEST ROLE OF MINERALOCORTICOID RECEPTOR ANTAGONISM

# **DIAGNOSIS: VASCULAR DISEASE IMAGING**

## **QUESTIONS THAT MUST BE ADDRESSED**

- **WHAT IS CLINICAL USEFULNESS OF NEW TEST?**
- **WHAT DOES THE TEST ADD?**
- **WHAT ARE ITS ADVANTAGES?**
- **WHAT ARE ITS COMPLICATIONS?**
- **WHAT ARE ITS COSTS?**
- **DOES IT REPLACE CURRENT ASSESSMENT?**
- **WHAT ARE CRITERIA FOR ACCEPTANCE?**
  
- **IS TECHNOLOGY DRIVING PRACTICE?**

# DIAGNOSIS: CT ANGIOGRAPHY

1. TRIAL(S) NEEDED TO LOOK AT ITS UTILITY IN DIAGNOSIS AND/OR PROGNOSIS
  - A. ADVANAGES FOR DISEASE ASSESSMENT?
  - B. IS TRADITIONAL ANGIOGRAPHY STILL NEEDED?
  - C. NEG: SUBSTANTIAL DOSE OF RADIATION
  - D. UTILITY FOR SCREENING UNCERTAIN  
NOT OPTIMAL FOR REPEATED EXAMS
  
3. TRIAL(S) NEEDED TO LOOK AT ITS UTILITY FOR PREVENTION AND/OR TREATMENT
  - A. WHAT IS THE OPTIMAL STUDY GROUP?  
PROBABLY INTEREDIATE RISK PATIENTS
  - B. CALCULATE BENEFITS/RISK OF NEW INFORMATION

\* SEE EXAMPLE OF NCI's LUNG CANCER SCREENING TRIAL

# TREATMENT: DRUG ELUTING STENTS

## AN OPPORTUNITY MISSED!

1. ADDRESSED MAJOR STENT PROBLEM
2. RAPID CLINICAL ADOPTION FORESEEN
3. INADEQUATE CLINICAL TRIAL RESULTS  
LONG TERM SAF/EFF DATA NEEDED
4. CONCERN ABOUT LATE EVENTS
5. COST PROJECTIONS OPTIMISTIC
6. CLINICAL QUESTIONS UNANSWERED  
LONG TERM COMPLICATIONS?  
APPROPRIATE FOR SEVERE DISEASE?
7. EVOLVING TECHNOLOGY- CHANGING RISK?
8. PROSPECTIVE TRIAL or REGISTRY NEEDED
9. RAISES NEED FOR AGILE RESPONSE

# TREATMENT: COPD

## INVESTIGATIONS

### 1. CONTINUOUS O2 SUPPLEMENTATION

NHLBI contracts for the Long-term Oxygen Treatment Trial (LOTT) in October 2006.

- A. CMS WILL COVER OXYGEN COSTS FOR MEDICARE PATIENTS
- B. OUTCOME MEASURES ARE MORTALITY AND QUALITY OF LIFE

### 2. VALUE OF PHYSICAL THERAPY

MEDICARE COVERS PULMONARY REHABILITATION IN THE CONTEXT OF LVRS

WOULD COVERAGE BE APPROPRIATE IN OTHER SITUATIONS?

- A. ALL WITH MODERATE-SEVERE COPD?
- B. FOLLOWING ACUTE EXACERBATION WITH HOSPITALIZATION?

# TREATMENT: BLOOD TRANSFUSIONS IN THE US

- **MORE THAN 5 MILLION PEOPLE ARE TRANSFUSED EVERY YEAR**
- **THE MAJOR CONDITIONS FOR WHICH ONE MAY RECEIVE BLOOD ARE MORE LIKELY TO OCCUR IN OLDER PERSONS:**
  - **SURGERY**
  - **ANEMIA (WHICH IS VERY COMMON IN CRITICALLY ILL PATIENTS)**
  - **CANCER**
  - **TRAUMA**
- **WHAT KIND OF BLOOD IS TRANSFUSED EVERY YEAR?**
  - **14 MILLION ALLOGENEIC RED BLOOD CELL TRANSFUSIONS**
  - **4 MILLION FRESH-FROZEN PLASMA TRANSFUSIONS**
  - **1.7 MILLION PLATELET TRANSFUSIONS**

# Optimizing Transfusion Therapies

- **PRACTICAL RESEARCH QUESTIONS OF INCLUDE:**
  - WHAT ARE THE IMMUNOMODULATORY, INFLAMMATORY, AND VASOREGULATORY PROPERTIES OF BLOOD PRODUCTS AS A FUNCTION OF STORAGE TIME?
  - WHAT ARE THE OPTIMAL TRANSFUSION TRIGGERS (E.G., AT WHAT HEMOGLOBIN LEVEL SHOULD ONE BE TRANSFUSED)?
  - HOW MANY BLOOD TRANSFUSIONS SHOULD BE GIVEN (E.G., WHAT TARGET HEMOGLOBIN LEVEL SHOULD BE REACHED)?
  - WHAT ARE THE CLINICAL OUTCOMES IN TRANSFUSION-RECIPIENTS COMPARED TO PATIENTS WHO DO NOT RECEIVE BLOOD?
  - WHAT IS THE COST EFFECTIVENESS OF VARIOUS PRACTICES?

# CONCLUSIONS:

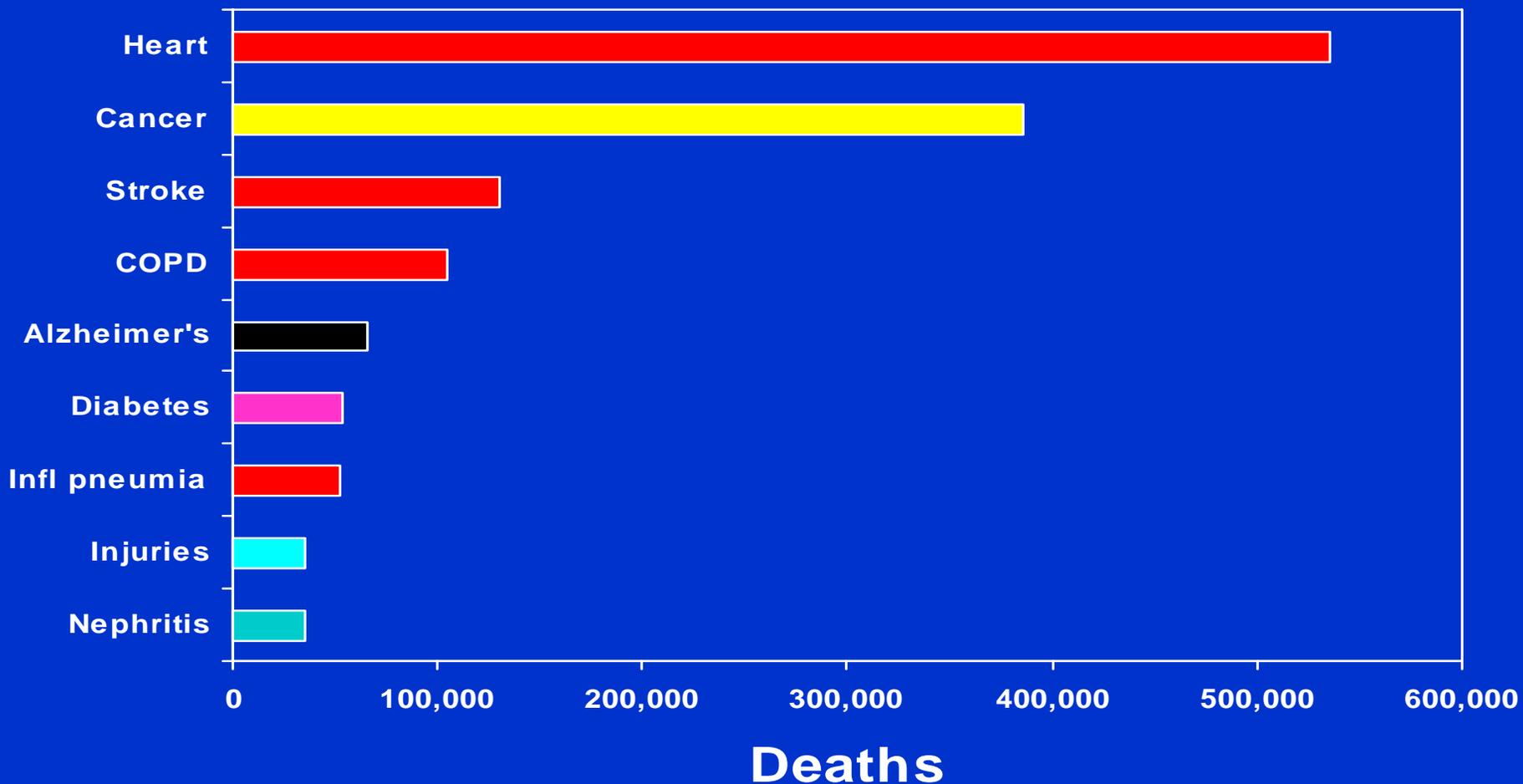
1. MAJOR PROGRESS IN SEVERAL CHRONIC DISEASES  
CVD IS BEST EXAMPLE – ALSO SHOWS COMPLEXITY
2. COST OF BENEFITS ACHIEVED VERY HIGH
3. BETTER UNDERSTANDING NEEDED TO OPTIMIZE  
PREVENTION
4. NEED BETTER WAYS TO APPLY and ASSESS CLINICAL  
TRIAL VALIDATED TREATMENTS IN “REAL WORLD”
5. NEED MORE RESEARCH IN CLINICAL ENVIRONMENT

# OPPORTUNITIES MISSED:

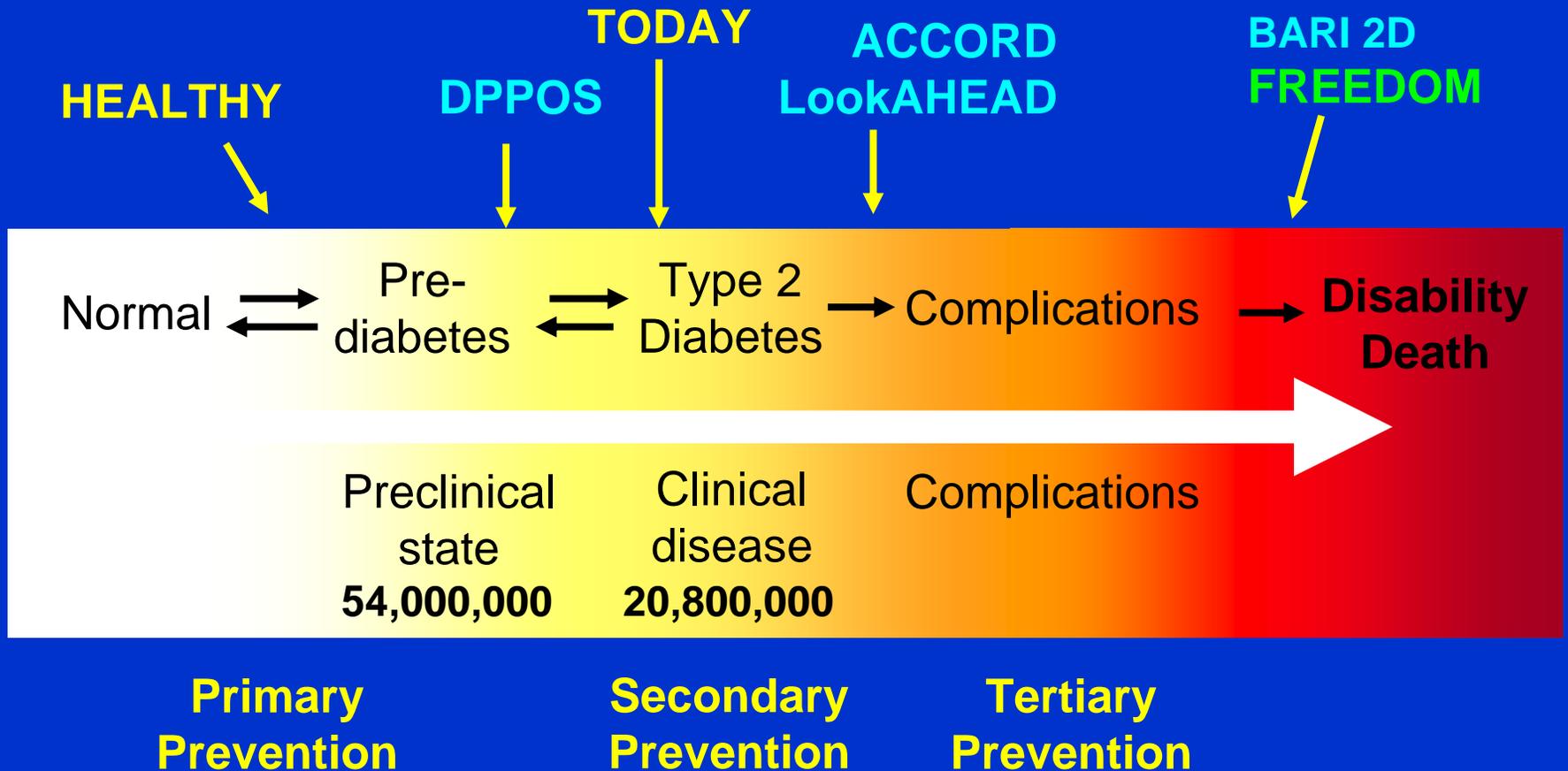
1. **DRUG ELUTING STENTS**
2. **TZD's and CVD RISK (i.e. rosiglitazone)**
3. **NSAID's and CVD (VIOX)**
4. **NON-INVASIVE IMAGING**
5. **COORDINATED PREVENTION PROGRAMS**

# LEADING CAUSES OF DEATH AGES 65+

## U.S., 2004



# Stages in the History of Type 2 Diabetes



# TREATMENT: COPD

## BACKGROUND

- 24 MILLION AFFECTED IN THE U.S.
- >120,000 DEATHS/YEAR (4<sup>TH</sup> LEADING CAUSE)
- ~900,000 DISABLED, WORKING AGE ADULTS
- TOTAL COST OF \$37 BILLION / YEAR