MO HEALTHNET OVERSIGHT COMMITTEE
AUGUST 5, 2008
MEETING HANDOUTS

This packet contains the following information:

1. Enrollment by Eligibility Category

2. On Line MO HealthNet Application for Families

3. MO HealthNet Managed Care Contract Rebid Status Presentation given by Dr. Ian McCaslin

4. Projected Timeline for Administrative Services Organization Contract

5. Biography of guest speaker John W. Newcomer, MD, Washington University, St. Louis, Missouri

6. Children and Use of Psychotropic Medications Presentation given by Dr. John Newcomer

7. *Severe Mental Illness and Risk of Cardiovascular Disease*, co-authored by Dr. John Newcomer

8. Primary Care Provider Network Presentation given by Debbie Kolb

9. Personal Health Records Presentation given by Dr. Ian McCaslin

10. *Tectonic Shifts in the Health Information Economy*, New England Journal of Medicine, 358;16 April 17, 2008, downloaded from www.nejm.org

11. Healthcare Information Technology Report Update Presentation given by Debbie Kolb

12. Four-Year Plan to Reach Reimbursement Parity Presentation given by Marga Hoelscher

Participation

	Participants as of March 2008	Participants as of June 2008	Percentage of June 2008 Participants	Income Eligibility Maximums (Shown as a Percentage of Federal Poverty Level)
Children	484,750	485,522	58.4%	300%
Persons with Disabilities	147,208	148,754	17.8%	85%
Custodial Parents	94,392	92,894	11.2%	TANF level (approximately 21%)
Seniors	76,808	76,425	9.2%	85%
Pregnant Women	28,301	28,344	3.4%	185%
Total	831,459	831,939		

Source: Missouri Department of Social Services, Family Support Division/MO HealthNet Division, Monthly Management Report

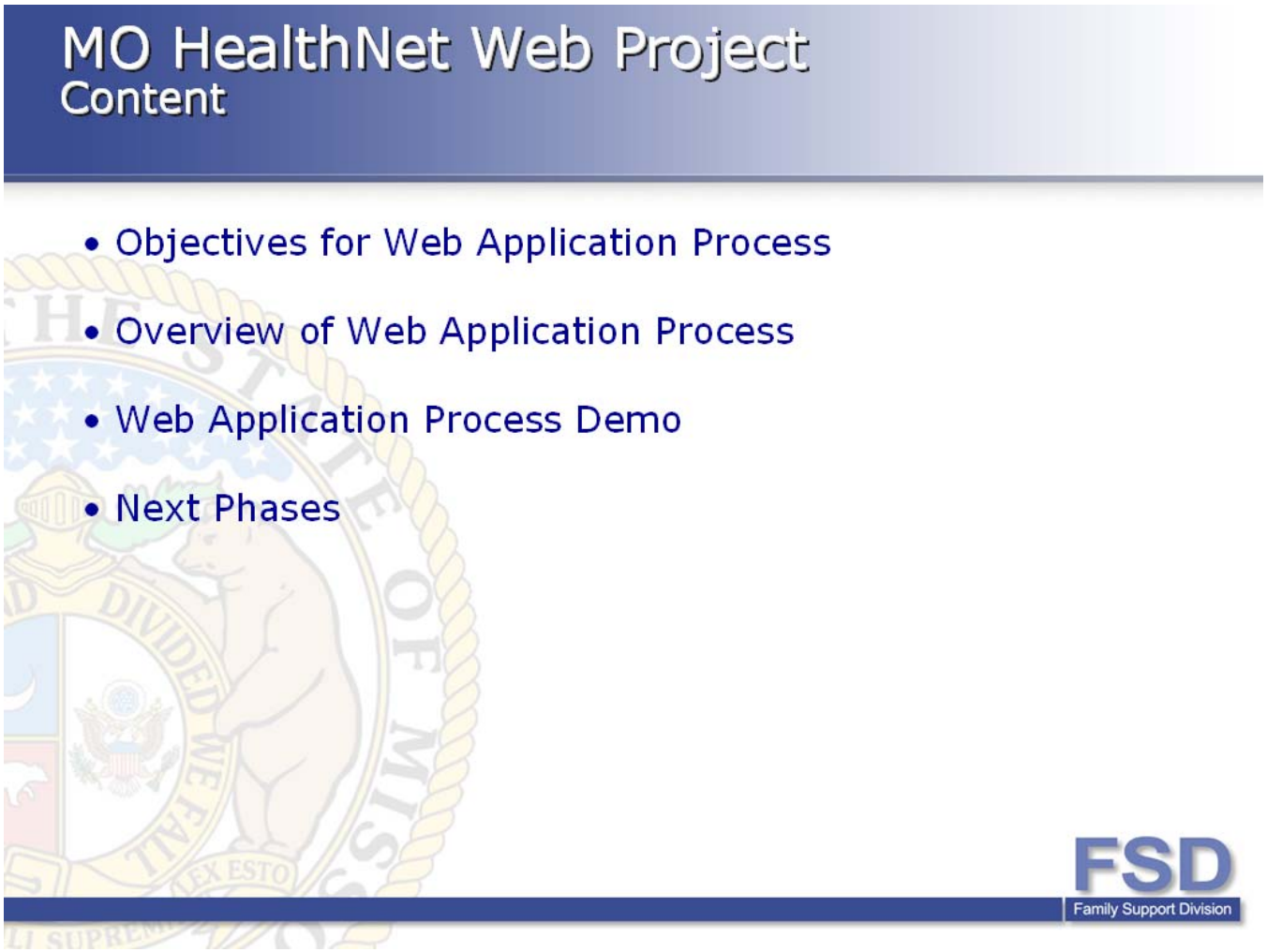
MO HealthNet Web Project

Apply For MO HealthNet Benefits

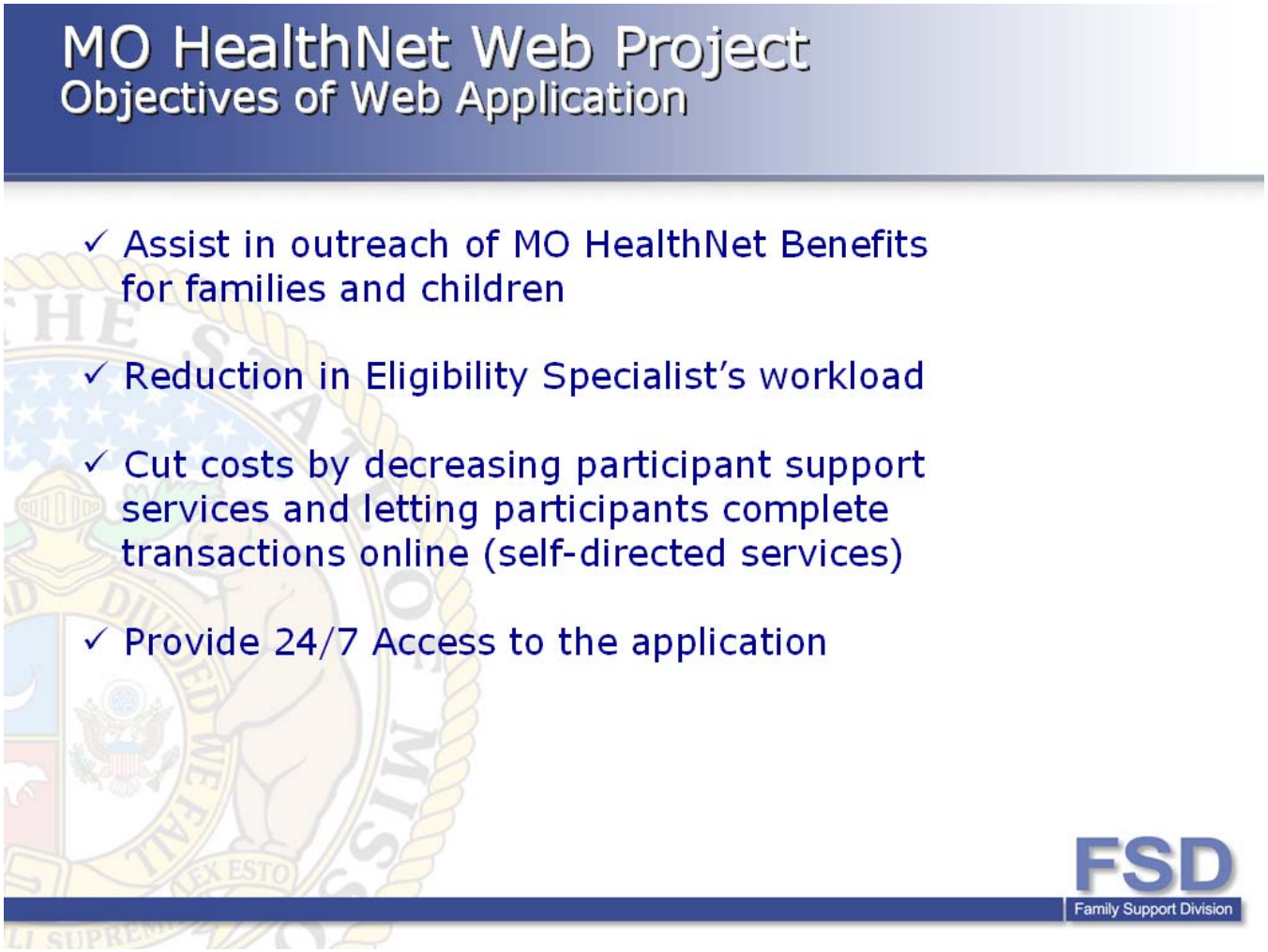
08.05.2008

FSD
Family Support Division

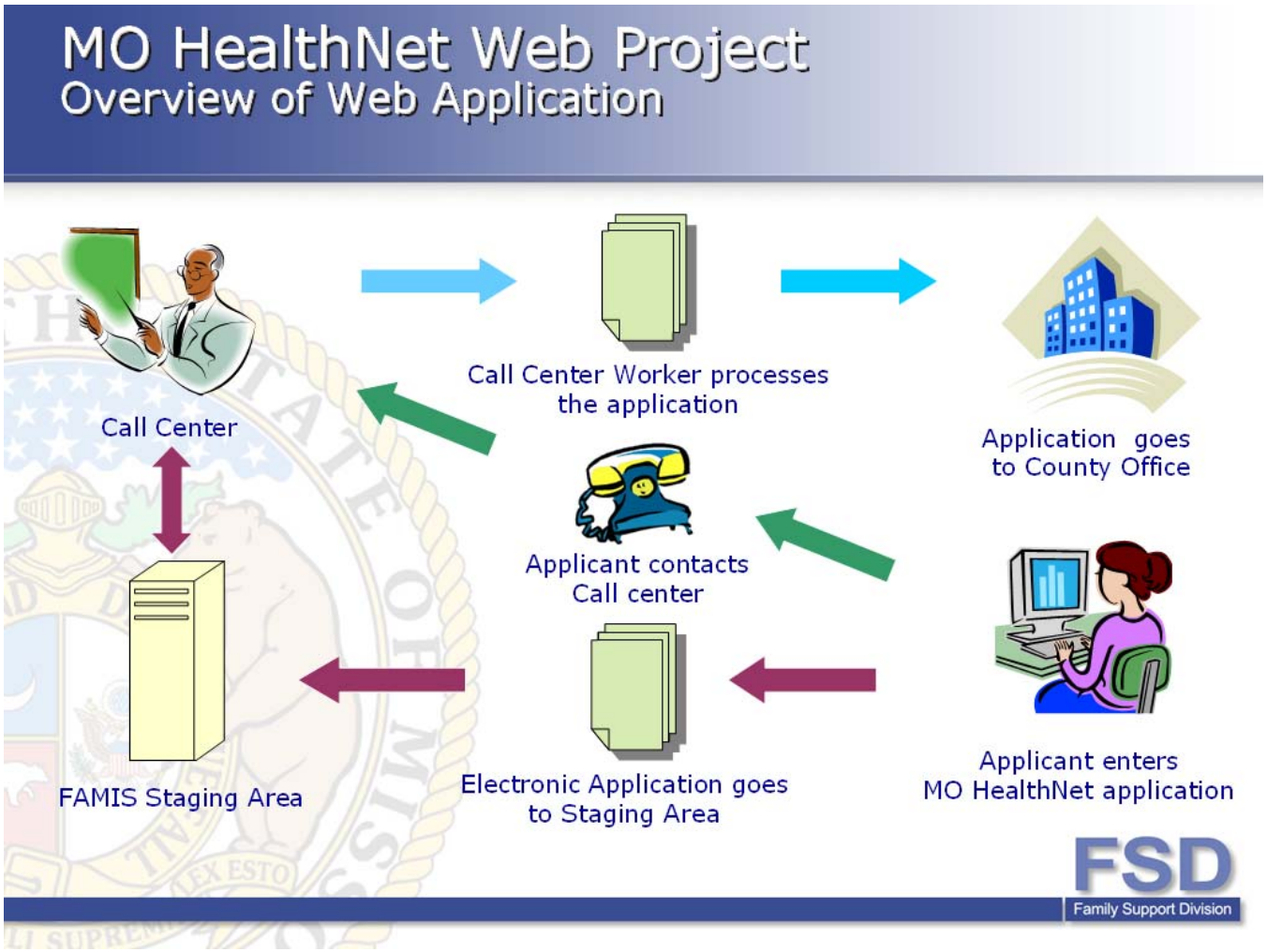
Web Application Process Contents



Web Application Process Objectives

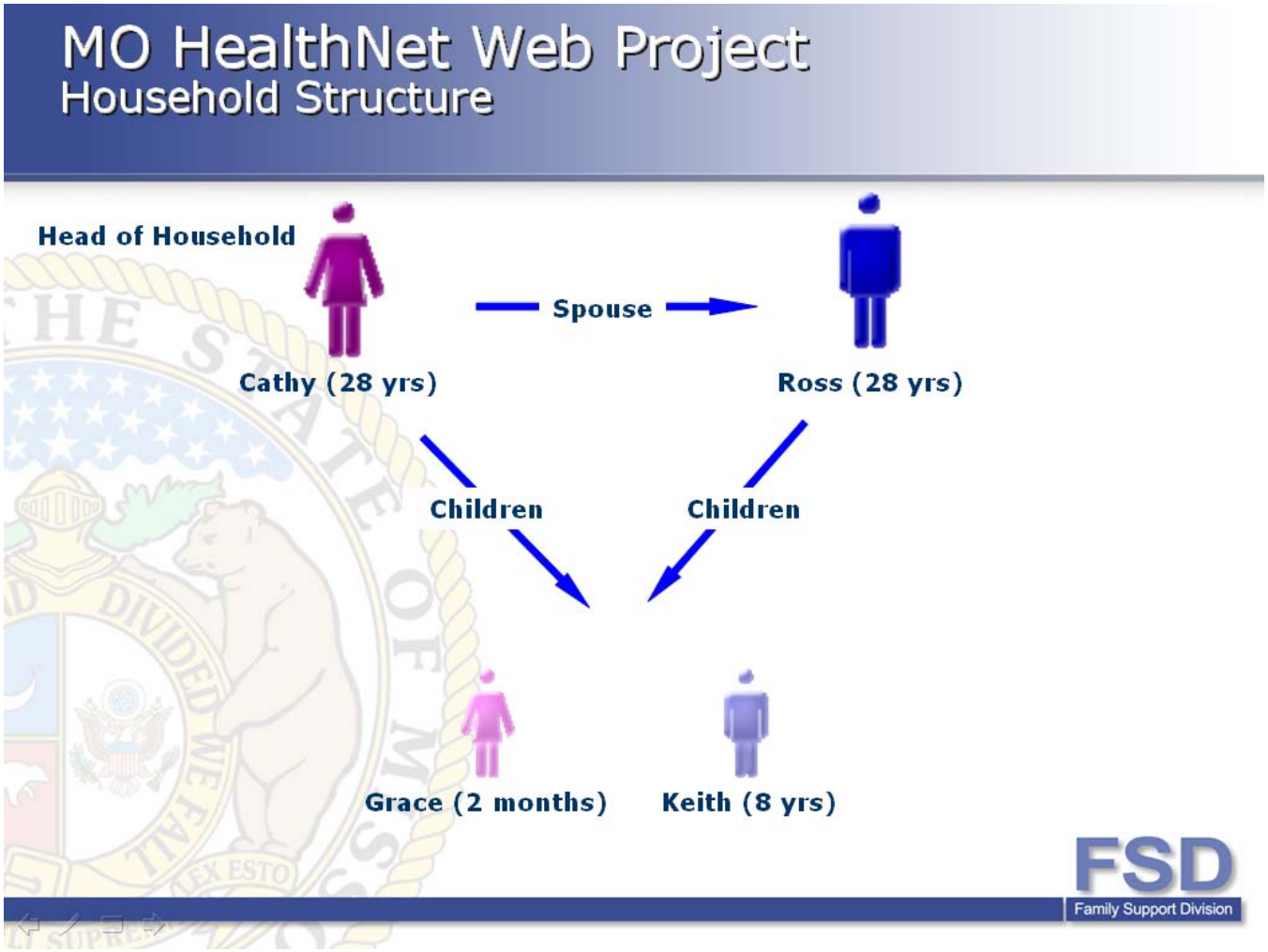


Overview of Web Application Process

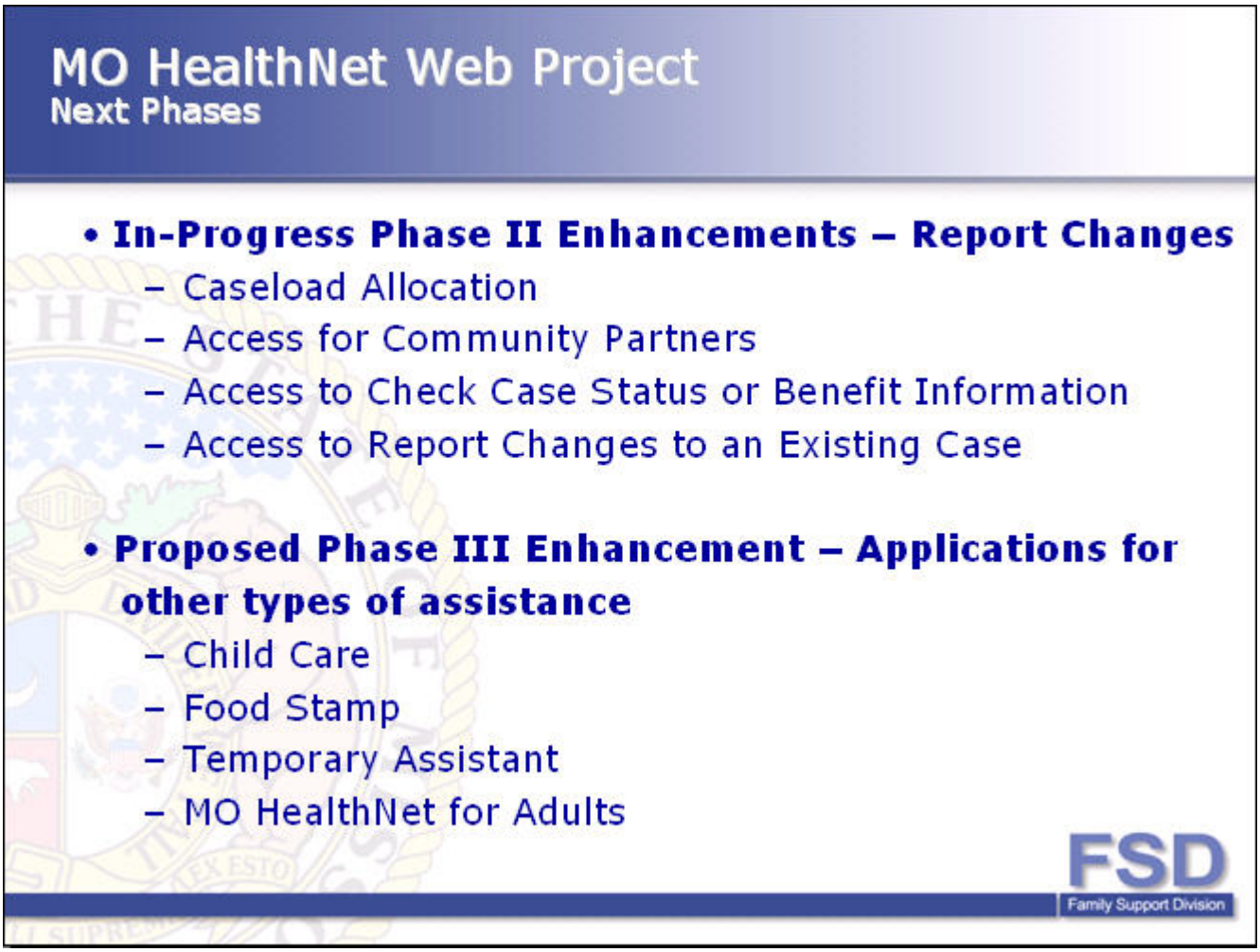


- Applicant enters a MO HealthNet web application.
- Once the application is submitted. It goes to FAMIS Staging Area where the call center will have access to view the electronic application.
- Once the application reaches the call center, the applicant can call the call center to find out the application status.
- The call center will process the application and assign DCN and SCN.
- Once the application is processed from the call center, it goes to County Office to determine eligibility.

Demo Household Structure



Next Phases


MO HealthNet Web Project
Next Phases
• In-Progress Phase II Enhancements – Report Changes
– Caseload Allocation
– Access for Community Partners
– Access to Check Case Status or Benefit Information
– Access to Report Changes to an Existing Case
• Proposed Phase III Enhancement – Applications for other types of assistance
– Child Care
– Food Stamp
– Temporary Assistant
– MO HealthNet for Adults
FSD
Family Support Division

Login Page

Note:

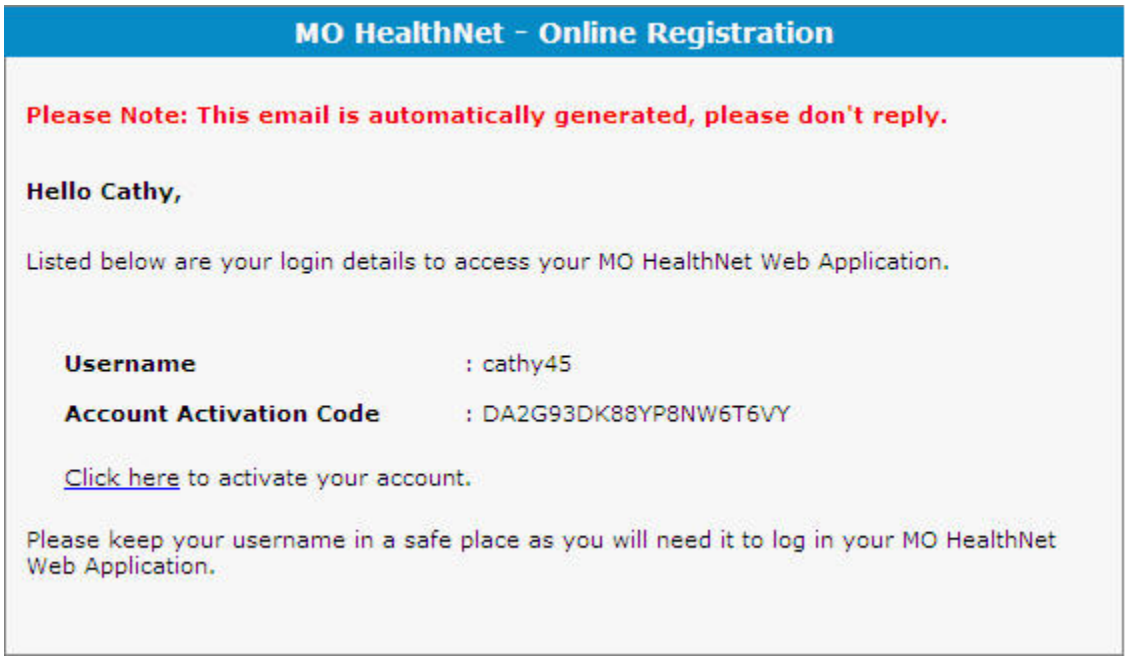
- The applicant logs in with a user name and password to get their application.
- If the applicant doesn't have a username they click on "New User Registration" and get a new user name and password.
- If the applicant forgets their password, they can click on "Forget Password" and create a new password.

New User Registration

Note:

- The applicant enters their information here to create a username and password.
- If the applicant doesn't have an E-mail Address they don't need to enter it.
- If the applicant has an E-mail Address they will be sent an activation code to their E-mail to activate their account when they log in again.

Automated E-mail when Registration is completed



MO HealthNet - Online Registration

Please Note: This email is automatically generated, please don't reply.

Hello Cathy,

Listed below are your login details to access your MO HealthNet Web Application.

Username : cathy45

Account Activation Code : DA2G93DK88YP8NW6T6VY

Click here to activate your account.

Please keep your username in a safe place as you will need it to log in your MO HealthNet Web Application.

Note:

- The applicant will receive this mail (if they had entered an e-mail address while registering) once they register.

User Account Activation

Fields marked with (*) are required.

Need Help? Reset.

User Account Activation

Please enter your password to activate account.

Username:	cathy45
***Password:**	•••••••
***Activation Code:**	DA2G93DK88YP8NW6T6VY

Activate Account Cancel

Applicant Detail (Cathy Owen)

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- Applicant Details
- Add Member
- Benefit Request
- Citizenship & SSN
- Net Worth
- Pregnancy
- Absent Parent
- Household Summary
- Employment
- Other Income
- Income Summary
- Child Care Expenses
- Court Ordered Expenses
- Expense Summary
- Insurance
- Lost Insurance
- Medical Condition
- Third-Party Resources
- Insurance Summary
- Submit Application

Application Status Key

- Page is completed
- On completed page
- Page is required
- On required page
- Page is incomplete
- On incomplete page
- Page is not required

- FAQs
- Change Profile
- Sign Off

0% Complete

Welcome Cathy

MoHealthNet

Fields marked with (*) are required to complete the application.

Print. Help? Reset.

Information About You

Enter information about you:

* **First Name:** Cathy
Middle Name:
* **Last Name:** Owen
Suffix : - Select Suffix -
* **Gender:** ○ Male ◉ Female
* **What is your date of birth?** August 24 1980

Where were you born?

City: Jeffson City
State : Missouri
Country: United States

Mailing Address

Enter your Mailing Address:

* **Address** *(House No, Street, P.O.Box or Rural)*:
820 Jackson Street
* **City:** Jefferson CIty
* **State:** Missouri
* **Zip Code:** 65109
* **County:** Cole

☐ **I am homeless and I don't have a mailing address.**

Contact Numbers

Enter your Contact Numbers:

What is your Home Phone Number?	573	316	5415
What is your Work Phone Number?			
What is your Message Phone Number?			

Race and Ethnicity

Select your Race & Ethnicity:

Are you Hispanic? ○ Yes ◉ No

Please select your race / ethnicity:

☐ American Indian / Alaskan
☐ Asian
☐ Black / African American
☐ Native Hawaiian / Pacific Islander
☑ White

Unpaid Medical Bills

* **Do you have any unpaid bills for medical services received in the past 3 months?**

○ Yes ◉ No

Away From Home

* **Are you Away from Home** *(Not living at the above address)*?

○ Yes ◉ No

Save & Exit Next >

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Household Members (Ross Owen)

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- Applicant Details
- Add Member
- Benefit Request
- Citizenship & SSN
- Net Worth
- Pregnancy
- Absent Parent
- Household Summary
- Employment
- Other Income
- Income Summary
- Child Care Expenses
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- Sign Off

5% Complete

Welcome Cathy

MoHealthNet

Fields marked with (*) are required to complete the application.

Print. Help? Reset.

Family Members

You have provided information for the following members:

Cathy

Household Information

Enter information about all Children, Parents/Guardians and Stepparents who live in your home:

* **First Name:** Ross
Middle Name:
* **Last Name:** Owen
Suffix: - Select Suffix -
* **Gender:** (•) Male ( ) Female
* **What is Ross 's date of birth?** September 23 1980

Where was Ross born?

City: Jefferson City
State : Missouri
Country: United States

Relationship

* Select the relationship with **Cathy Owen** :

Ross is Spouse **of Cathy Owen**

Race and Ethnicity

Select **Ross** 's Race and Ethnicity:

Is Ross Hispanic? ( ) Yes (•) No

Please select Ross 's race / ethnicity:

- [ ] American Indian / Alaskan
- [ ] Asian
- [ ] Black / African American
- [ ] Native Hawaiian / Pacific Islander
- [x] White

Unpaid Medical Bills

* **Does Ross have any unpaid bills for medical services in the past 3 months?**

( ) Yes (•) No

Away From Home

* **Is Ross Away from Home (Not living at the Cathy Owen 's residence address)?**

( ) Yes (•) No

Would you like to add another household member? Yes +

Save & Exit

< Previous Next >

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Household Members (Keith Owen)

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- Applicant Details
- Add Member
- Benefit Request
- Citizenship & SSN
- Net Worth
- Pregnancy
- Absent Parent
- Household Summary
- Employment
- Other Income
- Income Summary
- Child Care Expenses
- Court Ordered Expenses
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- Third-Party Resources
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- Submit Application

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- FAQs
- Change Profile
- Sign Off

5% Complete

Welcome Cathy

MoHealthNet

Fields marked with (*) are required to complete the application.

Print. Help? Reset.

Family Members

You have provided information for the following members:

Cathy Ross

Household Information

Enter information about all Children, Parents/Guardians and Stepparents who live in your home:

* **First Name:** Keith
Middle Name:
* **Last Name:** Owen
Suffix: - Select Suffix -
* **Gender:** (•) Male ( ) Female
* **What is Keith 's date of birth?** May 23 2000

Where was Keith born?

City: Jefferson City
State : Missouri
Country: United States

Relationship

* Select the relationship with **Cathy Owen** :

Keith is Son **of Cathy Owen**

Race and Ethnicity

Select **Keith** 's Race and Ethnicity:

Is Keith Hispanic? ( ) Yes (•) No

Please select Keith 's race / ethnicity:

- [ ] American Indian / Alaskan
- [ ] Asian
- [ ] Black / African American
- [ ] Native Hawaiian / Pacific Islander
- [x] White

Unpaid Medical Bills

* **Does Keith have any unpaid bills for medical services in the past 3 months?**

( ) Yes (•) No

Away From Home

* **Is Keith Away from Home (Not living at the Cathy Owen 's residence address)?**

( ) Yes (•) No

Would you like to add another household member? Yes +

Save & Exit

< Previous Next >

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Household Members (Grace Owen)

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- Applicant Details
- Add Member
- Benefit Request
- Citizenship & SSN
- Net Worth
- Pregnancy
- Absent Parent
- Household Summary
- Employment
- Other Income
- Income Summary
- Child Care Expenses
- Court Ordered Expenses
- Expense Summary
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- Medical Condition
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- Insurance Summary
- Submit Application

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- FAQs
- Change Profile
- Sign Off

5% Complete

Welcome Cathy

MoHealthNet

Fields marked with (*) are required to complete the application.

Print. Help? Reset.

Family Members

You have provided information for the following members:

Cathy Ross Keith

Household Information

Enter information about all Children, Parents/Guardians and Stepparents who live in your home:

* **First Name:** Grace
Middle Name:
* **Last Name:** Owen
Suffix: - Select Suffix -
* **Gender:** ○ Male ◉ Female
* **What is Grace 's date of birth?** June 9 2008

Where was Grace born?

City: Jefferson City
State : Missouri
Country: United States

Relationship

* Select the relationship with **Cathy Owen** :

Grace is Daughter **of Cathy Owen**

Race and Ethnicity

Select **Grace** 's Race and Ethnicity:

Is Grace Hispanic? ○ Yes ◉ No

Please select Grace 's race / ethnicity:

☐ American Indian / Alaskan ☐ Asian ☐ Black / African American
☐ Native Hawaiian / Pacific Islander ☑ White

Unpaid Medical Bills

* **Does Grace have any unpaid bills for medical services in the past 3 months?**

○ Yes ◉ No

Away From Home

* **Is Grace Away from Home (Not living at the Cathy Owen 's residence address)?**

○ Yes ◉ No

Would you like to add another household member? Yes +

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Benefit Request

Note:

- In this page, only the applicants who want get benefits are selected.

Citizenship and SSN

Note:

- The user needs to enter if the household member is a Citizen or not.
- Entering the Social Security Number (SSN) is not mandatory.

Net-Worth

Note:

- The User needs to enter the range of the Household Net-Worth
- The User also needs to enter the type of Assets they own

Pregnancy

Note:

- In the Pregnancy section only the female member of the house will be listed.
- This page will only be scheduled in the application if there is a female in the household above 10 years.
- If the applicant is pregnant and you select them then a box will dynamically pop up to ask a few more questions about the pregnancy.

Absent Parent Question

Note:

- In this page, only the children (below 19 years) of the house are listed.
- This Page will only be scheduled if there are children in the house who are equal to or less than 19 years.

Household Summary

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- Applicant Details
- Add Member
- Benefit Request
- Citizenship & SSN
- Net Worth
- Pregnancy
- Absent Parent
- Household Summary
- Employment
- Other Income
- Income Summary
- Child Care Expenses
- Court Ordered Expenses
- Expense Summary
- Insurance
- Lost Insurance
- Medical Condition
- Third-Party Resources
- Insurance Summary
- Submit Application

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- Page is completed
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- FAQs
- Change Profile
- Sign Off

30% Complete

Welcome Cathy

MoHealthNet

Fields marked with (*) are required to complete the application.

Print. Help? Reset.

Household Summary

Please review the Household Summary:

Name	Gender	DOB	Relationship To Applicant	Action
Cathy Owen	Female	8/24/1980	Self	Update
Ross Owen	Male	9/23/1980	Spouse	Update / Delete
Keith Owen	Male	5/23/2000	Son	Update / Delete
Grace Owen	Female	6/9/2008	Daughter	Update / Delete

Would like to add another household member? Yes +

Benefit Request Summary

The following members are applying for MO HealthNet Benefits:

Name	Applied for Benefits	Action
Cathy Owen	Yes	Change the request
Ross Owen	Yes	Change the request
Keith Owen	Yes	Change the request
Grace Owen	Yes	Change the request

SSN & Citizenship Summary

Please review the SSN & Citizenship Summary of your household:

Name	SSN	Citizenship	Action
Cathy Owen	154-65-4654	US Citizen	Update
Ross Owen	465-16-5465	US Citizen	Update
Keith Owen	654-16-4654	US Citizen	Update
Grace Owen	461-46-5454	US Citizen	Update

Net Worth Summary

Please review the Net Worth Summary of your household:

Amount	Net Worth Types	Action
$0.00 - $50,000.00	Automobile	Update

Pregnancy Summary

Please review the Pregnancy Summary of your household:

Name	Expected/Actual Due Date	Unborn Children	Action
Cathy Owen	12/29/2008	1	Update / Delete

Absent Parent Information

No Absent Parent information found.

Would like to add another absent parent? - Select member to add - Yes +

Save & Exit

< Previous Next >

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Employment Question

Note:

- This is the Employment Page.
- In this page if any of the household members have Employment or Self-Employment, their name are selected under the category.

Employment Detail (Ross Owen)

Note:

- In this page if a member has Employment the details are captured.
- The details captured are the following:
  - Employer
  - Income and Frequency of Income

Other Income Question

Note:

- Other Income is the money that the household gets other than from work.

Other Income Types

Note:

- If the type of Other Income is not listed here, the user can select “Other”.

Other Income Details

Note:

- In this page, the details of the Other Income need to be entered.
- The additional question asked will be the following:
  - Source Name
  - Frequency in which the applicant gets paid
  - Income

Income Summary

Note:

- This is the Income Summary Page.
- In this page, all the information taken up to this point after Household Summary is listed.
- This page is given so that the applicant can read the information and review it. The applicant can edit or delete or add information if they want to.

Child Care Question

Note:

- This page will only be scheduled if there are children in the house.

Child Care Details (Grace Owen)

Note:

- If a child is selected, then the details for the child care needs to be entered.
- The question asked will be the following:
  - Who takes care of the child
  - How often are they paid
  - The amount paid

Court Ordered Questions

Note:

- If any of the household members are paying court ordered expense, their name is selected otherwise “No One” is selected.

Expense Summary

Note:

- This is the Expense Summary Page.
- This page is given so that the applicant can read the information and review it.
- The applicant can edit or delete or add information if they want to.

Insurance Question

Note:

- If the household has Health Insurance or Employer Sponsored Insurance then select “Yes” otherwise select “No”

Employer Sponsored Health Insurance

Note:

- If the household has Employer Sponsored Health Insurance they need to enter the details for their Employer Sponsored Health Insurance.

Lost Insurance

Note:

- This page will scheduled only if there are child(s) in the house.
- If a name is selected then a box dynamically pops up.
- The applicant needs to enter additional information if there is a lost insurance.

Medical Condition

Note:

- This page will only be scheduled if there are children in the house.

Third Party Insurance

Insurance Summary

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- Applicant Details
- Add Member
- Benefit Request
- Citizenship & SSN
- Net Worth
- Pregnancy
- Absent Parent
- Household Summary
- Employment
- Other Income
- Income Summary
- Child Care Expenses
- Court Ordered Expenses
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- Submit Application

Application Status Key

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FAQs
Change Profile
Sign Off

96% Complete

Welcome Cathy

MoHealthNet

Fields marked with (*) are required to complete the application.

Print. Help? Reset.

Health Insurance Summary

There is currently no Health Insurance information available.

Would you like to add another Health Insurance policy information? Yes +

Employer Sponsored Health Insurance Summary

Please review your Employer Sponsored Health Insurance summary.

Group Name	Monthly Premium	Members who can be covered in the Policy	Action
Target	$120.00	Cathy Ross Keith Grace	Update / Delete

Would you like to add another Employer Sponsored Health Insurance information? Yes +

Lost Insurance Summary

There is no Lost Insurance information available.

Would you like to add Lost Insurance Details for any other children? Yes +

Child Medical Condition Summary

None of the children in the household have a medical condition that if left untreated would result in death or serious physical injury.

Would you like to edit the information about the medical condition of any child/children? Yes +

Third Party Resources Summary

Please review the summary of your third party resources.

Is Third Party Responsible?	Third Party Name	Action
No	-	Update

Save & Exit

< Previous Next >

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Submit

Note:

- If the applicant is filling this application through a Community Partner, then they have to select the Community Partner Name

Thank You

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Home / Children / Family / Health Care / Youth / Local Offices

- Application History
- Create New Application
- FAQs
- Change Profile
- Sign Off

Welcome Cathy

MoHealthNet

Thank You

Dear Cathy:

Thank you for using the MO HealthNet online application system. Your application has been sent to the MO HealthNet Service Center for review. You will be notified by mail when we have completed our review. For pregnant women, applications are processed within 15 days. All other MO HealthNet applications are processed within 30 days. An eligibility specialist may contact you if additional information is needed to process your application.

The information below may be needed prior to approving your MO HealthNet application.

- Income verification for the past 30 days (i.e. paycheck stubs, letter from employer, federal income tax return, award letter, etc.);
- Proof of U.S. citizenship, or if not a U.S. citizen, immigration documents showing name, immigration status, registration number and date of entry of those persons applying for MO HealthNet who are not U.S. citizens;
- Medical statement confirming pregnancy and expected date of delivery (if applying for MO HealthNet as a pregnant woman).

We will contact you if we need additional information. If you do not have the above documents, an eligibility specialist may be able to help you.

If you have questions or want to check on the status of your application, you may call the MO HealthNet Service Center toll free at 1-888-275-5908 or you may call your local Family Support Division office. Your application number is 4300001054.

Sincerely,
MO HealthNet Service Center

Summary Application

If you would like to print or save a copy of your application for your files, click the Print Application button. If you decide to print or save, keep in mind that your application has your private, personal information in it.

Print Application

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Automated E-mail Generated after Application is Submitted

MO HealthNet Web

****Please Note: This email is automatically generated, please don't reply.****

Dear Cathy:

Thank you for using the MO HealthNet online application system. Your MO HealthNet application has been sent to the MO HealthNet Service Center for review. You will be notified by mail when we have completed our review. For pregnant women, applications are processed within 15 days. All other MO HealthNet applications are processed within 30 days. An eligibility specialist may contact you if additional information is needed to process your application.

The following information may be needed prior to approving your application:

- Income verification for the past 30 days (i.e. paycheck stubs, letter from employer, federal income tax return, award letter, etc.);
- Proof of U.S. citizenship, or if not a U.S. citizen, immigration documents showing name, immigration status, registration number and date of entry of those persons applying for MO HealthNet who are not U.S. citizens;
- Medical statement confirming pregnancy and expected date of delivery (if applying for MO HealthNet as a pregnant woman).

We will contact you if we need additional information. If you do not have the above documents, an eligibility specialist may be able to help you.

If you have questions or want to check on the status of your application, you may call the MO HealthNet Service Center toll free at 1-888-275-5908 or you may call your local Family Support Division office. Your application number is 4300001054.

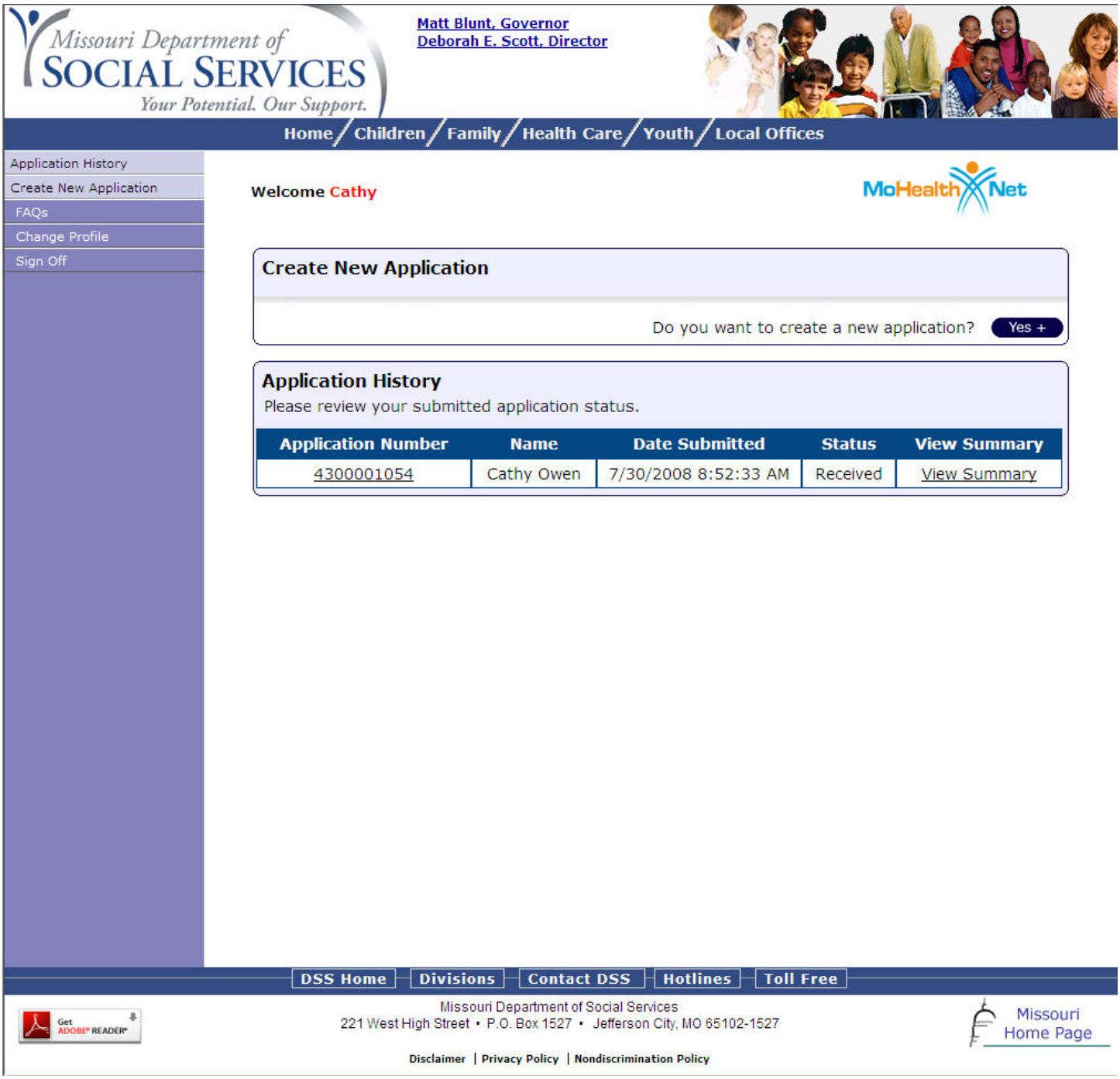
Sincerely

MO HealthNet Service Center

Note:

- If the applicant is filling this application through a Community Partner, then they have to select the Community Partner Name

Application History



Note:

- If the applicant log in again after submitting an application, they will see this screen.
- In this screen the applicant will be able to see the status of their application
- The applicant will also be able to create a new application.

Change Profile

Note:

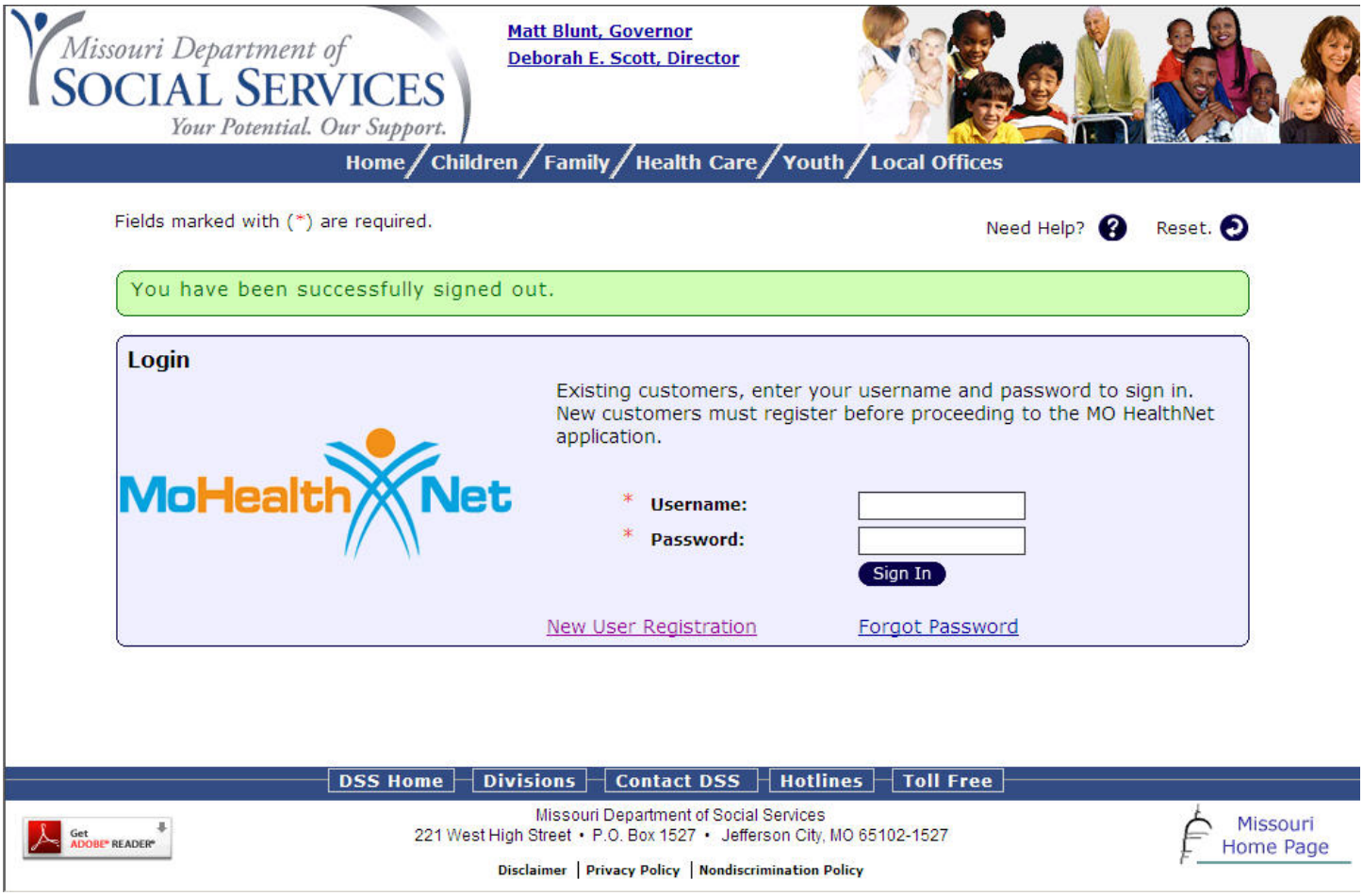
- If the applicant needs to change their profile they can click on the link on the "Change Profile" link on the left navigation bar

Updating Profile

Note:

- In this screen the applicant is changing their Personal Information, Secret Question and Password

Log Out



Note:

- This is the screen which an applicant can see when they log out.

MO HealthNet Managed Care Contract Rebid Status

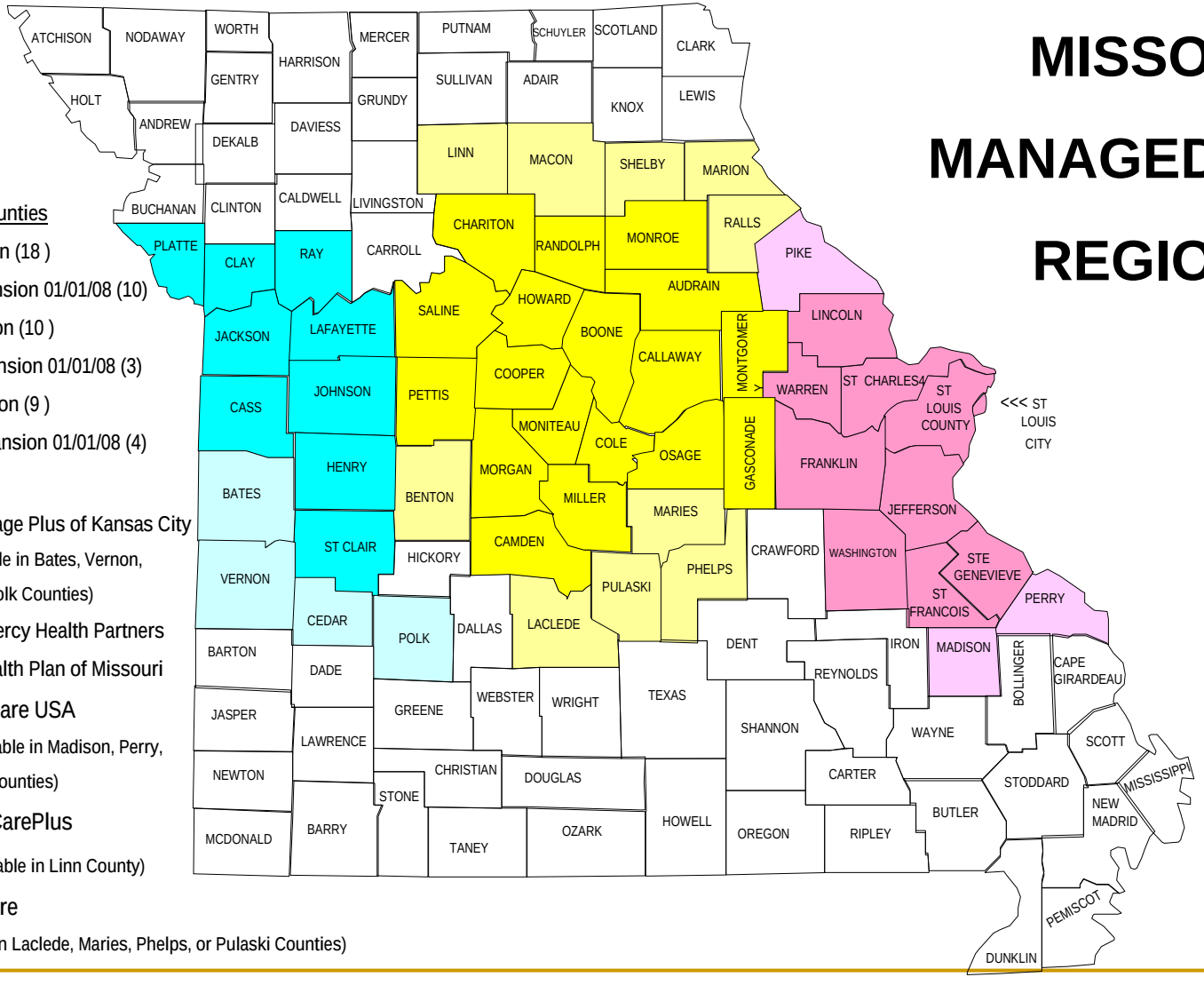
MO HealthNet Oversight Committee

August 5, 2008

MO HealthNet Managed Care Eligibility Groups

- **In General:**
  - **Adolescents, children, and infants; Pregnant women; Refugees**
  - **Children in foster care, in custody, and adoption subsidy**
  - **State Children's Health Insurance Program children (SCHIP)**
- **Reside in specified Missouri counties**

MISSOURI MANAGED CARE REGIONS



Number of Counties

- Central Region (18)
- Central Expansion 01/01/08 (10)
- Eastern Region (10)
- Eastern Expansion 01/01/08 (3)
- Western Region (9)
- Western Expansion 01/01/08 (4)

Health Plans

- Blue-Advantage Plus of Kansas City
  (not available in Bates, Vernon, Cedar, or Polk Counties)
- Children's Mercy Health Partners
- Harmony Health Plan of Missouri
- HealthCare USA
  (not available in Madison, Perry, or Polk Counties)
- Mercy CarePlus
  (not available in Linn County)
- Missouri Care
  (not available in Laclede, Maries, Phelps, or Pulaski Counties)

MCO Enrollment – 383,517*

- **Eastern Region – 189,472***
  - *Harmony Health Plan of Missouri*
  - *HealthCare USA*
  - *Mercy CarePlus*
- **Central Region – 73,194***
  - *HealthCare USA*
  - *Mercy CarePlus*
  - *Missouri Care*
- **Western Region – 120,851***
  - *Blue-Advantage Plus of Kansas City*
  - *Children's Mercy Family Health Partners*
  - *HealthCare USA*
  - *Mercy CarePlus*

*source: state managed care provider inquiry (MPRI) screens, current to 08/01/08

Stakeholder Input

- On site meetings with each current Plan
- Meetings with:
  - Advocacy organizations
  - Provider groups
  - General public
- Rate-setting process – actuarial analysis
- Review of best practices from other states

Contract Enhancement - Considerations

- **Ensure each participant is placed into a health care home**
- **Strengthen care coordination measures**
  - **Behavioral and physical health linkage**
  - **Chronic conditions**
- **Pursue national accreditation standards, e.g. National Committee for Quality Assurance (NCQA)**
- **Enhanced network adequacy compliance measures**

Contract Enhancement - Considerations

- Ombudsman program communication
- Improved rural provider and participant outreach and education
- Improved transfer of encounter data
- Specific program elements of discussion
  - Pharmacy
  - Behavioral health
  - Dental

CONTRACT REBID DRAFT TIMELINE

- **Jul – Aug 2008** **Health Plan Site visits**
- **Oct 1, 2008** **RFP to Office of Administration**
- **Dec 8, 2008** **RFP Released**
- **January 6, 2009** **Pre-Proposal Conference**
- **February 13, 2009** **Bids Due**
- **March 20, 2009** **Contracts awarded**
- **April 6-10, 2009** **On-Site Readiness Review**
- **Jul 15, 2009** **Open Enrollment Begins**
- **Sep15, 2009** **Open Enrollment Ends**
- **Oct 1, 2009** **New Contract begins**

PROJECTED TIMELINES:
Administrative Services Organization Contracts in Northwest and Southwest Missouri

Northwest Missouri Administrative Services Organization RFP:

Proposal Return Date:	August 7, 2008
Award Date (approximately 30 days):	August-September, 2008
Implementation Date:	90 days from date of award

Southwest Missouri Administrative Services Organization RFP:

Proposal Issue Date:	Late September, 2008
Pre-Proposal Conference:	2 weeks after Issue Date
Proposal Return Date:	November, 2008
Award Date (approximately 30 days):	December, 2008
Implementation Date:	90 days from date of award

Biography

John W. Newcomer, MD

John W. Newcomer, MD, is the Gregory B. Couch Professor of Psychiatry, Psychology and Medicine at Washington University School of Medicine in St. Louis. He is also the Medical Director for the Center for Clinical Studies at Washington University. Dr. Newcomer is a Principal Investigator on research grants funded through the National Institutes of Health (NIH), and also serves as the Chairman of the Drug Utilization Review (Medicaid) Board for the State of Missouri.

Dr. Newcomer received his undergraduate degree at Brown University (magna cum laude) and his medical degree at Wayne State University School of Medicine. He completed his residency and a research fellowship in Psychiatry at Stanford University School of Medicine, prior to joining the faculty at Washington University. Dr. Newcomer has received a number of honors and awards, including a 1999 Exemplary Psychiatrist Award from the National Alliance for the Mentally Ill (NAMI), an Independent Scientist Award from the National Institute of Mental Health (NIMH), and a 2002 Gerald L. Klerman Award for Outstanding Clinical Research from the National Alliance for Research on Schizophrenia and Depression (NARSAD). Funded continuously by the NIH for 15 years, Dr. Newcomer has also served as a reviewer for the NIH as well as other funding agencies, including the Department of Veteran's Affairs and the National Science Foundation.

Dr. Newcomer serves on the editorial board for, *Journal of Clinical Psychiatry, Journal of Psychotic Disorders, Clinical Schizophrenia & Related Psychoses* and *Obesity*, and he is a reviewer for numerous journals, including the *New England Journal of Medicine, Diabetes Care, American Journal of Physiology, American Journal of Psychiatry, Archives of General Psychiatry*, and the *Journal of Neuroscience*. He has contributed numerous articles to leading scientific journals, including *Archives of General Psychiatry, The Journal of Clinical Endocrinology & Metabolism, The Journal of Neuroscience, The Journal of the American Medical Association* and *Neuropsychopharmacology.*

Identifying Key Sources of Modifiable Risk for Morbidity and Mortality in the MO HealthNet Population of Adults and Children with Mental Illness

John W. Newcomer, MD

Gregory B. Couch Professor of Psychiatry, Psychology, and Medicine

Medical Director, Center for Clinical Studies

Washington
WASHINGTON·UNIVERSITY·IN·ST·LOUIS

Disclosure

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Janssen
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Wyeth Research
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Forest
Organon
VIVUS
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Tikvah
Dainippon Sumitomo
Legal consultant
Compact Clinicals

} Grant Support and/or Consultant

No significant financial conflict of interest in compliance with Washington University Conflict of Interest Policy

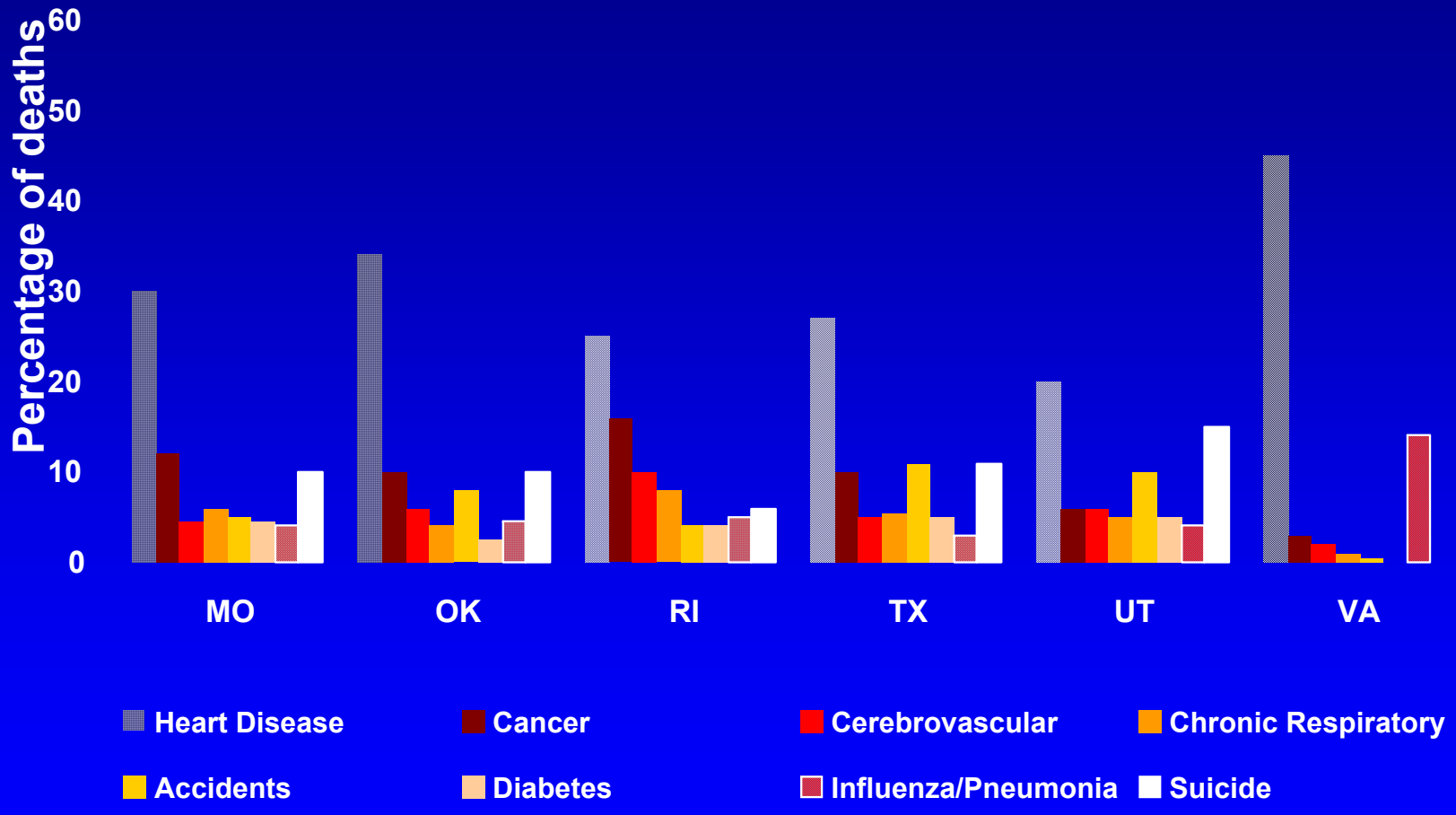
Mortality Associated with Major Mental Disorders: Mean Years of Potential Life Lost

Year	AZ	MO	OK	RI	TX	UT
1997		26.3	25.1		28.5	
1998		27.3	25.1		28.8	29.3
1999	32.2	26.8	26.3		29.3	26.9
2000	31.8	27.9		24.9		

Compared with the general population, persons with major mental illness lose 25–30 years of normal life expectancy

Colton CW, Manderscheid RW. *Prev Chronic Dis.* Available at: http://www.cdc.gov/pcd/issues/2006/apr/05_0180.htm.

Cardiovascular Disease Is Primary Cause of Death in Persons with Mental Illness*

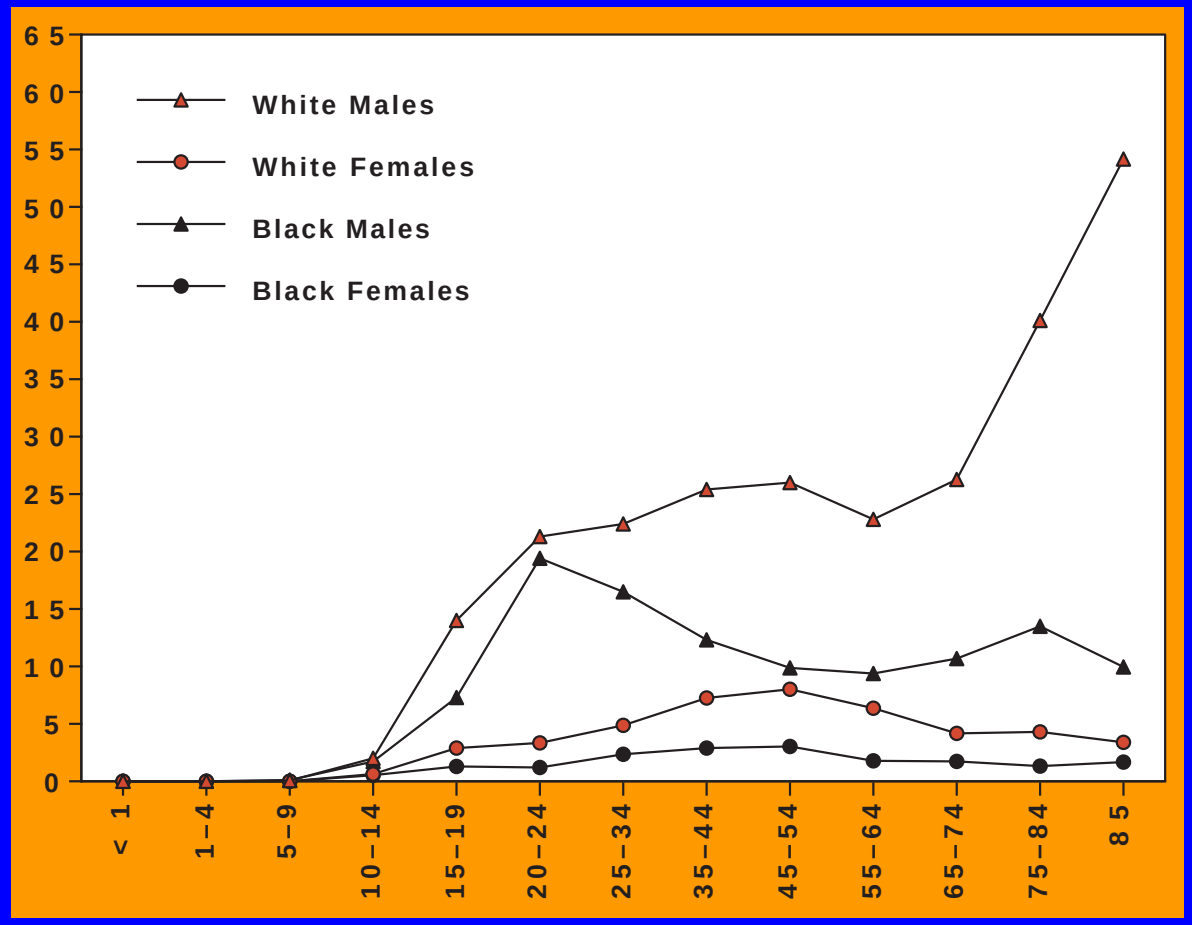


*Average data from 1996-2000.

Colton CW, Manderscheid RW. Prev Chronic Dis [serial online] 2006 Apr [date cited].
Available at URL: http://www.cdc.gov/pcd/issues/2006/apr/05_0180.htm

Suicide Rates By Gender And Race Per 100,000 Living Population

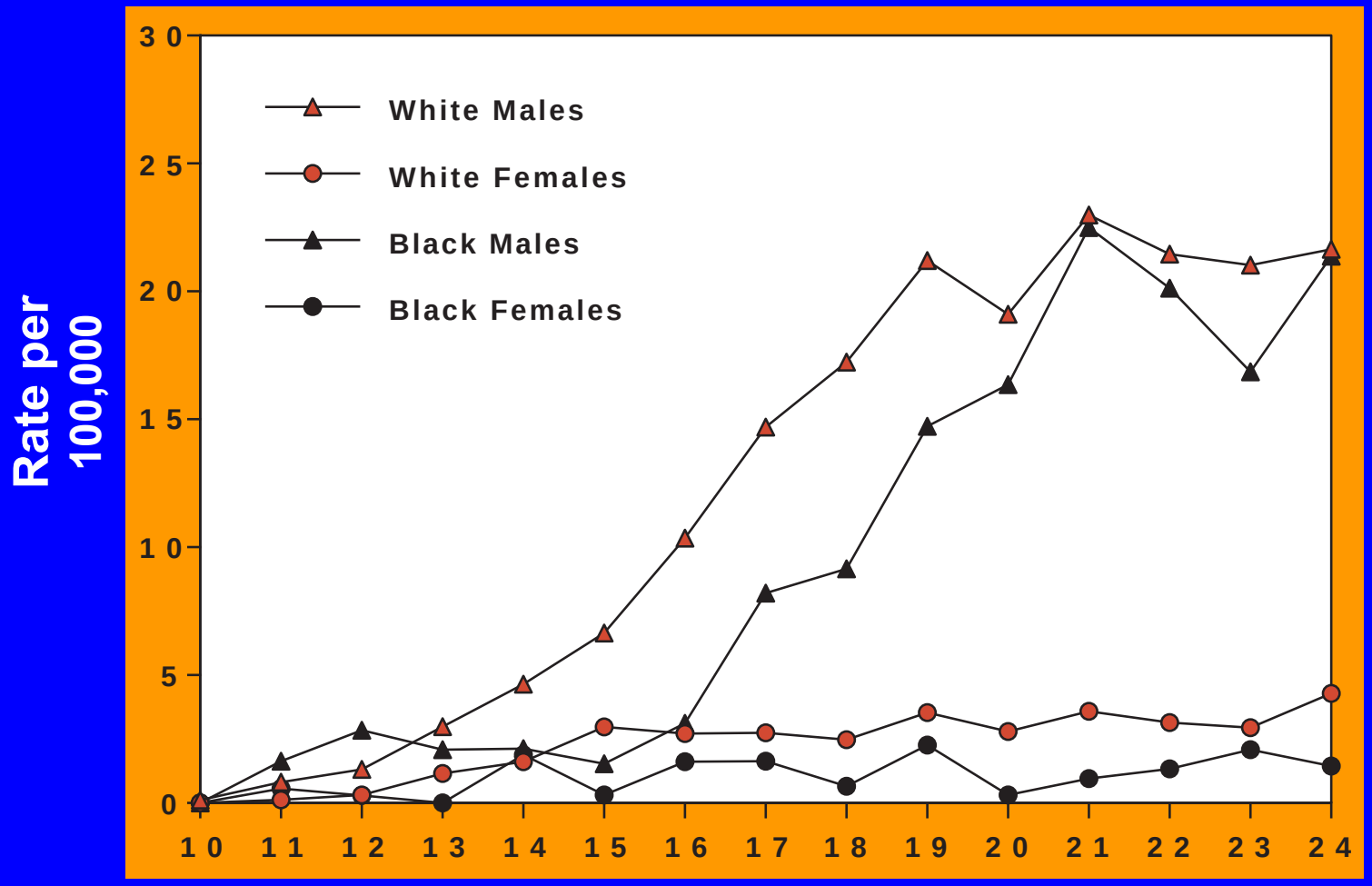
—UNITED STATES, ALL AGES, 2001—



CDC 2003 (WISQARS)

Suicide Rates During Adolescence

— UNITED STATES, AGES 10–24, 2001 —



CDC 2003 (WISQARS)

Leading Causes Of Death In 15- To 19-year-olds

— U N I T E D S T A T E S, 2001 —

CAUSE	# OF DEATHS	
Accidents	6646	
Homicide	1899	
Suicide	1611	
Cancer	732	1599
Heart Disease	347	
Congenital Anomalies	255	
Chronic Lower Respiratory Disease	74	
Stroke	68	
Influenza and Pneumonia	66	
Blood Poisoning	57	

Anderson & Smith 2003

Teen Suicide Rates In Countries With Effective Reporting

— MALES AGE 15–19 —

	COUNTRY*	YEARS	RATE**
1	Russian Federation	1997–1998	34.5
2	New Zealand	1997–1998	33.2
3	Kazakhstan	1998–1999	30.7
4	Estonia	1998–1999	28.8
5	Lithuania	1998–1999	28.5
6	Finland	1997–1998	24.2
7	Latvia	1998–1999	22.1
8	Belarus	1998–1999	21.4
9	Canada	1996–1997	19.1
10	Austria	1999–2000	18.6
11	Ukraine	1999–2000	18.6
12	Croatia	1998–1999	17.7
13	Australia	1997–1998	17.5
14	Ireland	1996–1997	16.0
15	Switzerland	1995–1996	15.2
16	**USA**	**1997–1998**	**14.9**
17	Belgium	1994–1995	14.6
18	Poland	1995–1996	14.4
19	Norway	1996–1997	14.0
20	Hungary	1999–2000	12.2
21	Bulgaria	1997–1998	11.9
22	Czech Republic	1998–1999	11.5
23	Germany	1998–1999	9.5
24	Sweden	1995–1996	9.4
25	Denmark	1995–1996	8.7
26	France	1997–1998	7.6
27	Japan	1996–1997	6.8
28	Romania	1998–1999	6.6
29	United Kingdom	1998–1999	6.3
30	Netherlands	1998–1999	5.9
31	Italy	1996–1997	5.2
32	Spain	1997–1998	4.9
33	China *(selected urban and rural)*	1997–1998	3.9
34	Greece	1997–1998	2.3

Pelkunen & Marttunen 2003; *available from WHO 3/5/2003; **2-year average per 100,000 population

American Foundation for Suicide Prevention

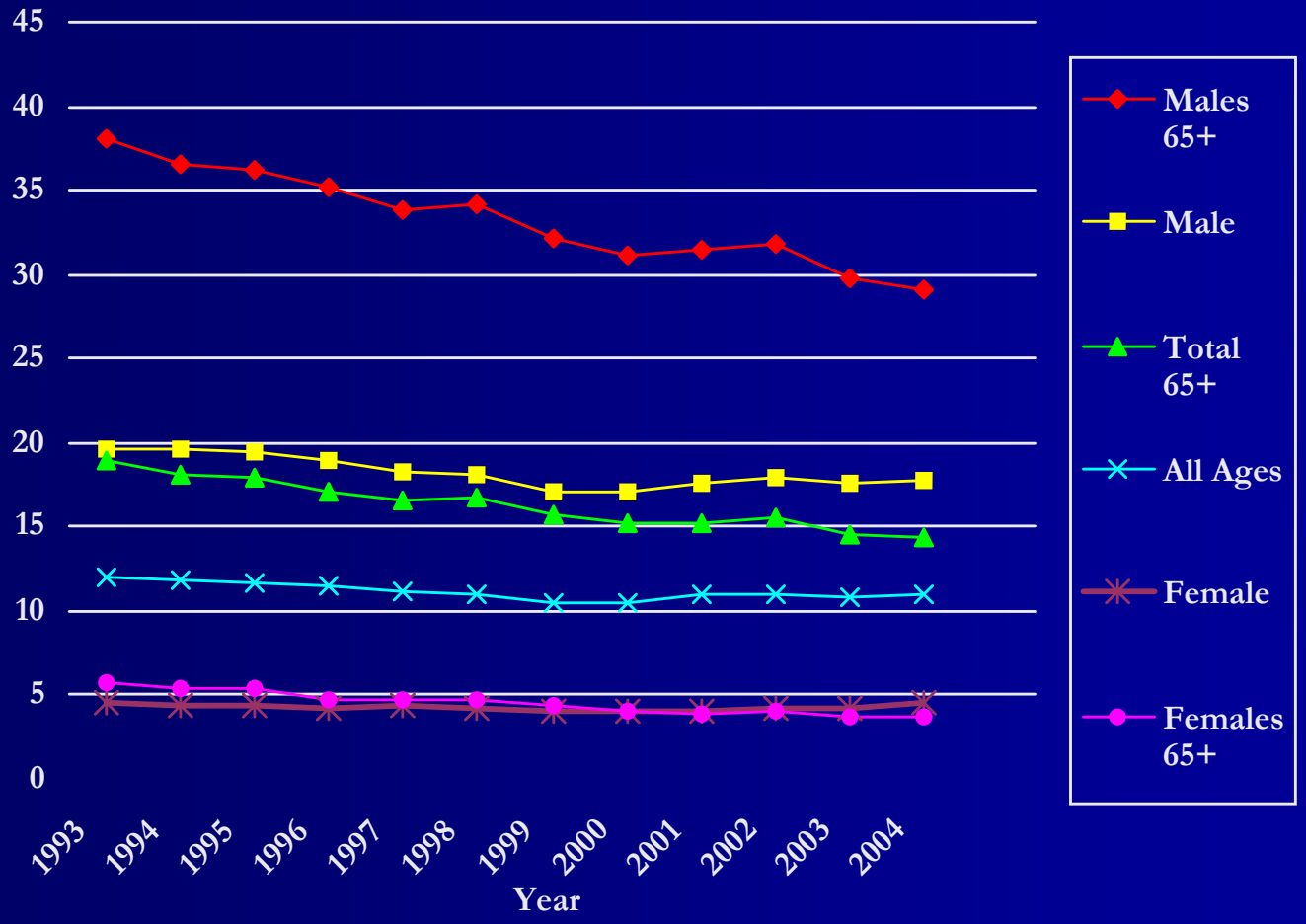
Facts

- Approximately 32,000 people in the United States die by suicide each year. About every 16.6 minutes someone in this country intentionally ends his/her life.

- Although the suicide rate fell slightly from 1992-1999, it was steady for 5 consecutive years despite all of our new treatments. It rose by 955 deaths in 2004, leading to debate about a potential relationship to reductions in new prescriptions due to the black box warning.

American Foundation for Suicide Prevention

U.S. Suicide Rates of All Ages and Those 65+, by Gender



Centers for Disease Control, WISQARS.
http://www.cdc.gov/ncipc/wisqars/

American Foundation for Suicide Prevention

Suicide Is Not Predictable in Individuals

- In a study of 4,800 hospitalized vets, it was not possible to identify who would die by suicide — too many false-negatives, false-positives.
- Individuals of all races, creeds, incomes and educational levels die by suicide. There is no typical suicide victim.

Pokorny, Arch. Gen. Psychiatry 1983,
Pokorny Life Threat Beh 1993

There are several risk factors for suicide:

- Psychiatric disorders
- Past suicide attempts
- Symptom risk factors
- Genetic risk factors
- Sociodemographic risk factors
- Environmental risk factors

American Foundation for Suicide Prevention

Death by Suicide and Psychiatric Diagnosis

- Psychological autopsy studies done in various countries over almost 50 years report the same outcomes:
  - At least 90% of people who die by suicide are suffering from one or more psychiatric disorders:
    - Major Depressive Disorder
    - Bipolar Disorder, Depressive phase
    - Alcohol or Substance Abuse*
    - Schizophrenia
    - Personality Disorders such as Borderline and Antisocial
    - PTSD is noticeably absent

*Primary diagnoses in youth suicides.

Robins, E. (1981). *The final months: A study of the lives of 134 persons who committed suicide.* New York: Oxford University Press.

American Foundation for Suicide Prevention

Other Medical History Data

- Major Medical Illness-especially recent
- Chronic physical pain
- History of trauma, abuse or being bullied
- Drinking/Drug use
- Being a smoker
- Family history of death by suicide

American Foundation for Suicide Prevention

Sociodemographic Risk Factors*

- Male
- Being over 65
- White
- Separated, widowed or divorced
- Isolation, living alone
- Being unemployed or retired
- Occupation**: dentists, physicians (especially women physicians), psychiatrists, nurses, and social workers

*Qin et al, Am J Psychiatry, 2003

**Stack, Social Science Quarterly, 2001

American Foundation *for* Suicide Prevention

Environmental Risk Factors

- Easy access to lethal means
- Local clusters of suicide that have a “contagious influence”

Gould, M.S., & Davidson, L. (1988). Suicide contagion among adolescents. In A.R. Siffman, & R.A. Feldman (Eds.), *Advances in Adolescent Mental Health* (pp. 29-59). Greenwhich, CT: JAI Press.

Antidepressants: Suicide Risk

American Foundation for Suicide Prevention

- FDA review of adverse events in drug trials showed an increased risk of suicide behavior after starting antidepressant in people up to age 24 but a protective effect for older adults.
- Led to black box warning.

FDA Statement on Recommendations of the Psychopharmacologic Drugs and Pediatric Advisory Committees, September 16, 2004.*

The Food and Drug Administration (FDA) generally supports the recommendations that were recently made to the agency by the Psychopharmacologic Drugs and Pediatric Advisory Committees regarding reports of an increased risk of suicidality (suicidal thoughts and actions) associated with the use of certain antidepressants in pediatric patients. FDA has begun working expeditiously to adopt new labeling to enhance the warnings associated with the use of antidepressants and to bolster the information provided to patients when these drugs are dispensed.

In summary, the members of the advisory committees:

- endorsed FDA's approach to classifying and analyzing the suicidal events and behaviors observed in controlled clinical trials and expressed their view that the new analyses increased their confidence in the results
- concluded that the finding of an increased risk of suicidality in pediatric patients applied to all the drugs studied (Prozac, Zoloft, Remeron, Paxil, Effexor, Celexa Wellbutrin, Luvox and Serzone) in controlled clinical trials
- recommended that any warning related to an increased risk of suicidality in pediatric patients should be applied to all antidepressant drugs, including those that have not been studied in controlled clinical trials in pediatric patients, since the available data are not adequate to exclude any single medication from an increased risk
- reached a split decision (15-yes, 8-no) regarding recommending a "black-box" warning related to an increased risk for suicidality in pediatric patients for all antidepressant drugs
- endorsed a patient information sheet ("Medication Guide") for this class of drugs to be provided to the patient or their caregiver with every prescription
- recommended that the products not be contraindicated in this country because the Committees thought access to these therapies was important for those who could benefit
- recommended that the results of controlled pediatric trials of depression be included in the labeling for antidepressant drugs.

*From the Food and Drug Administration, www.fda.gov/bbs/topics/news/2004/new01116.html.

Newman (2007) A Black-Box Warning for Antidepressants in Children? NEJM (351)1595-1598.

Summary of FDA Findings

- Event Data
  - Risk ratios for pooled analyses were significant (range from 1.7 to 2.2)
  - Signals seen predominantly in MDD patients
  - Remain inconsistencies in risk:
    - Across trials within programs
    - Across programs
  - Nevertheless, a reasonably consistent signal:
    - Evidence for suicidality risk in 7 of 9 programs
    - No events in Wellbutrin and Serzone programs
  - Risk difference overall about 2 to 3%
  - **No completed suicides in any of 24 trials**

How Should These Findings Be Interpreted?

- May be increased risk for suicidality during short-term treatment with all drugs in the antidepressant class
- Signal most compelling in MDD population, but may not be limited to this population
- Many possible explanations for variation in signal within and across programs

FDA Adult Analysis of Risk

- Following up from their analysis of pediatric data, the FDA analyzed suicidality data from randomized controlled efficacy trials of newer antidepressant for adult psychiatric conditions.
- N=100,000
- 372 trials
  - Mood Disorders (N=187)
  - Other Psychiatric Disorders (N=108)
  - Other Behavioral Disorders (N=43)
  - Other Disorders (N=34)
- Trial duration mean 10 weeks (range 4-84)

FDA Adult Analysis of Risk

- Overall, no significant risk in adults
- When combined with pediatric findings, results demonstrated an age-effect
  - Risk of suicidality was apparent in those up to 25 years in the antidepressant group;
  - No effect was found for adults 25-64 (no difference between placebo and drug);
  - While an expected or protective effect was found in those 65 years and older.
  - For psychiatric disorder subgroup
    - Sertraline significant for protective effect OR .25 (.07-.90) p=.03
    - Paroxetine significant for risk OR 2.76 (1.16-6.60) p =.02

Meta-analyses & large database studies

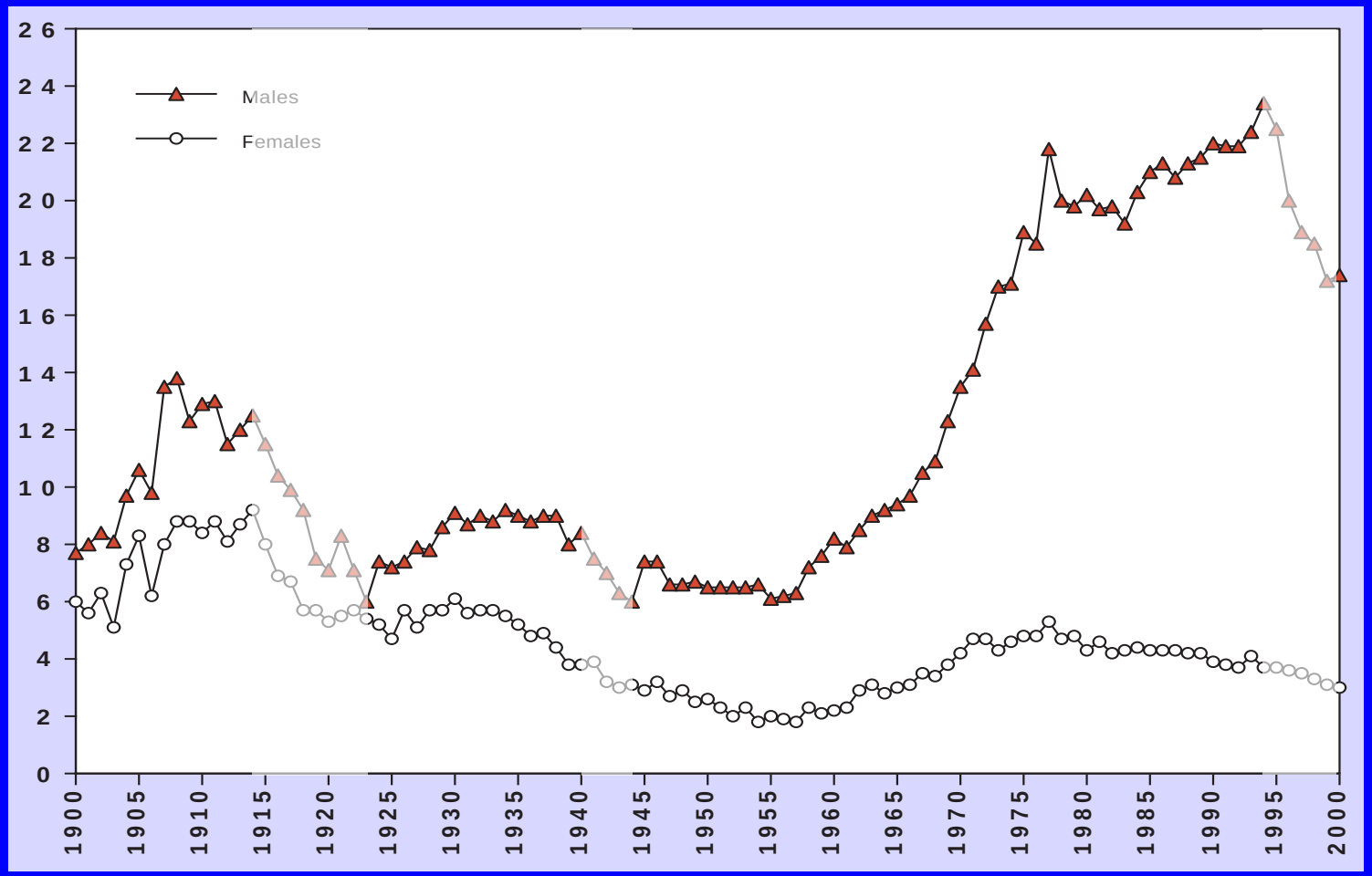
- No evidence of association between antidepressants and risk of suicidality/suicide
  - Beasley et al. (1991)
  - Khan et al (2003)
  - Gunnell et al 2005
  - FDA meta-analysis
  - Jick et al. (2004)
  - Valuck et al. (2004) (adolescents)

Meta-analyses & large database studies

- Some evidence of association between antidepressants and risk of suicidality/suicide
  - Fergusson et al (2005) increased risk of attempt
  - Martinez et al (2005) increased risk of self-harm but not suicide in under 18 year olds

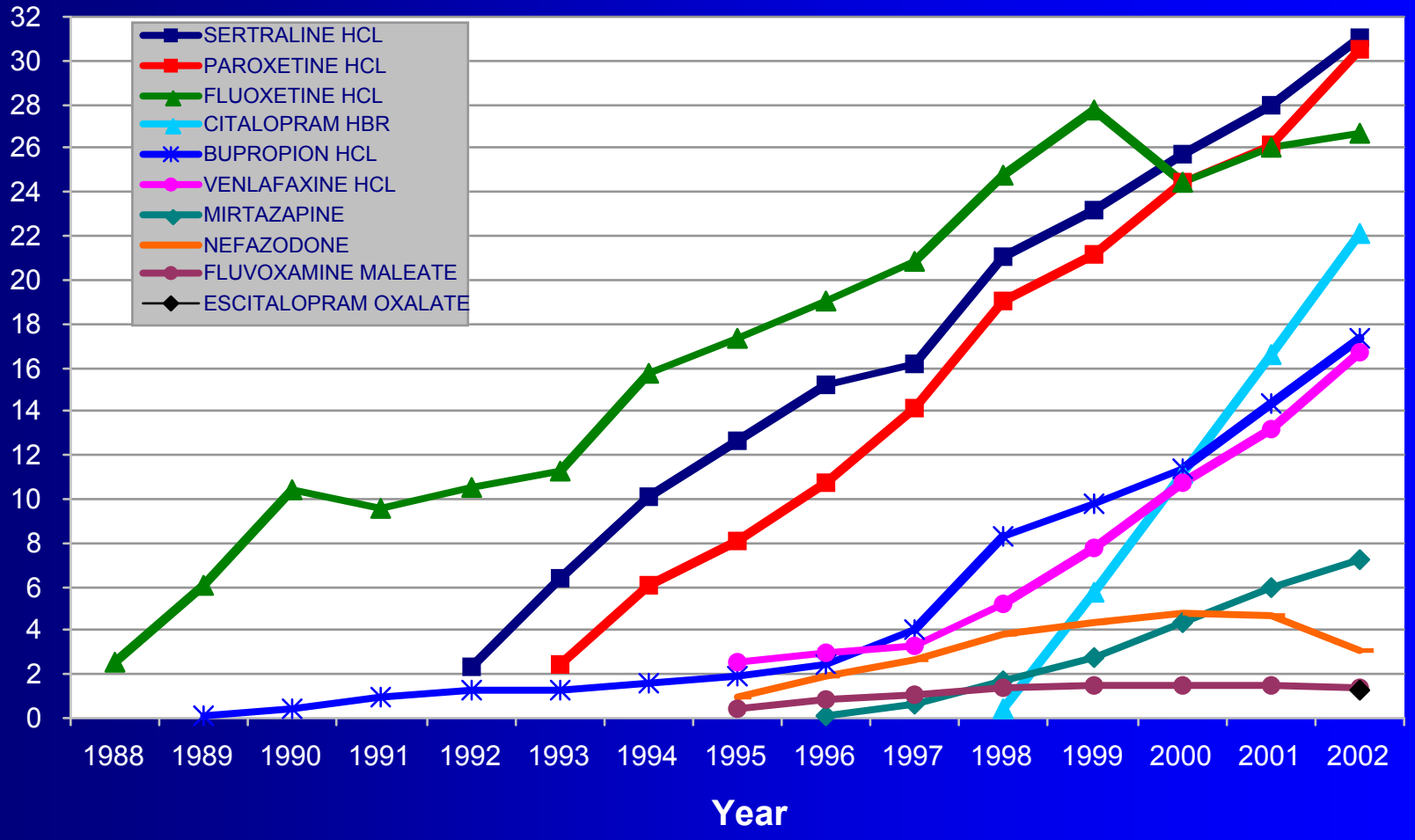
20th-century - Changes In Youth Suicide Rates

— UNITED STATES, AGES 15–24 —



Anderson 2002, CDC Wonder 2003, USDHEW 1956, Vital Statistics U.S. 1954–1978

Total U.S. Prescriptions Dispensed* Annually for Selected Antidepressants, All Ages, 1988-2002

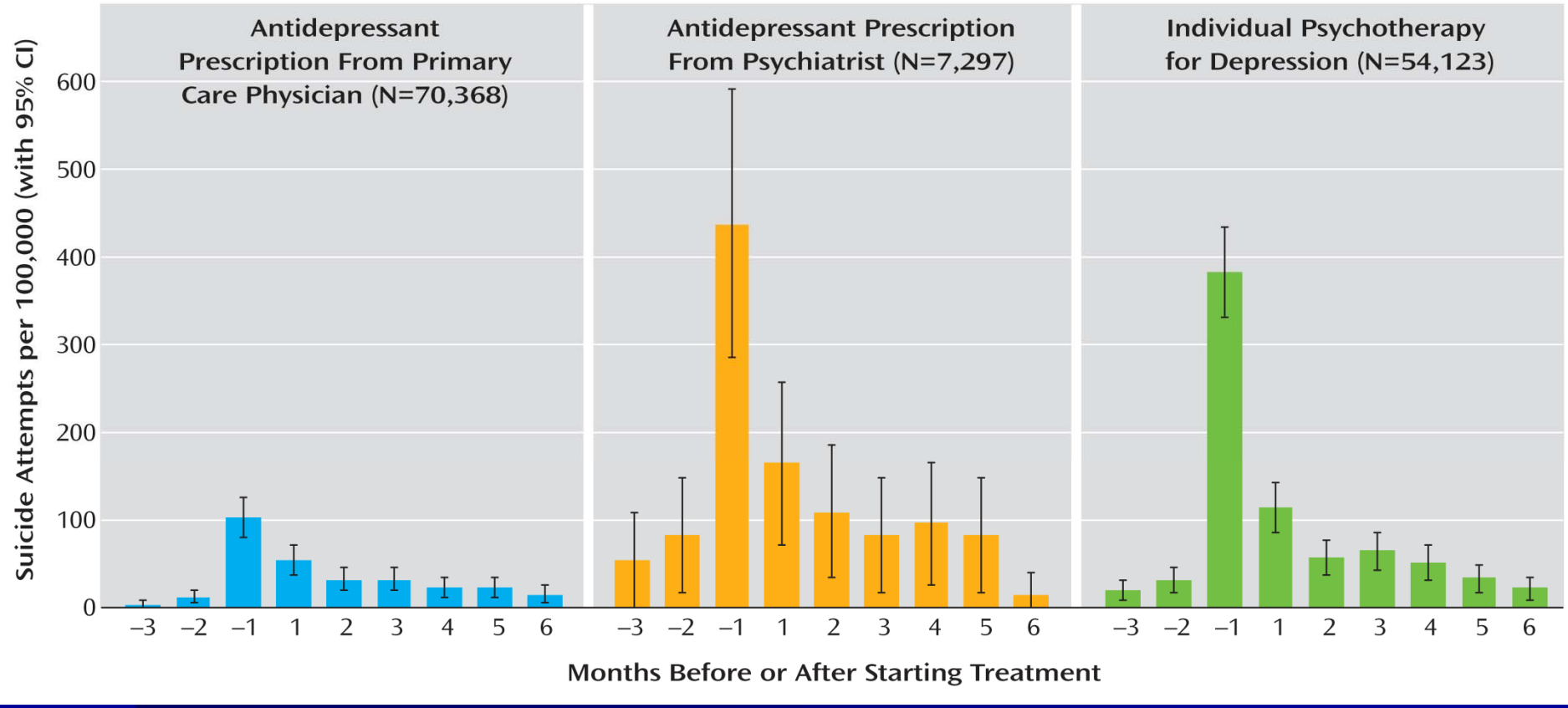


* Source: IMS Health, National Prescription Audit Plus™, Year 1988 to 2002, Data Extracted January 2004.

Evidence That SSRIs May Prevent Suicide

- Studies show suicide rate steadily increased *prior to SSRI*s and has fallen steadily since their introduction
  - Across age groups
  - In many countries
- Areas of the US with the biggest increases in SSRI prescriptions are associated with the biggest declines in youth suicide rates (Olfson et al 2003).

Risk of suicide attempt or possible suicide attempt before and after starting treatment among adolescents and adults



Simon et al (2007) *Am J Psychiatry* 164:1029-1034.

Evidence Suggests That it is Untreated Depression Kills

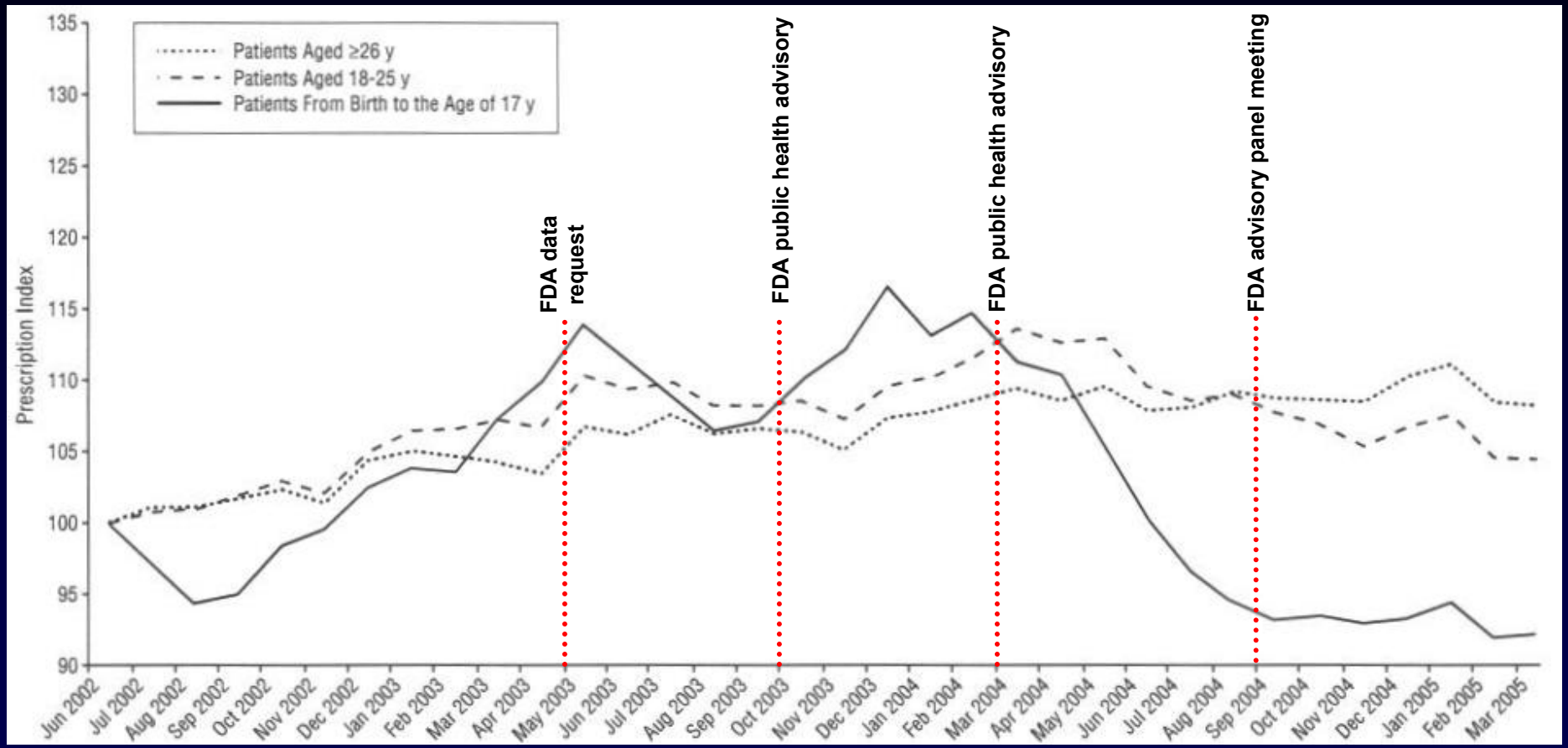
- Autopsy studies show suicide associated with no treatment or non-compliance in children and adolescents
  - Of 49 completed suicides, 24% had been prescribed an antidepressant and NONE had any SSRIs in system at time of death (Utah Youth Suicide Study Gray et al, 2003)
  - 66 suicides under 18, no Paxil found and only 3 had any antidepressant
  - One of 36 had an antidepressant (sertraline & bupropion) in a sample of <18 year olds (Leon et al 2006)

Across country, antidepressants associated with LOWER suicide rates

- National country-level suicide rate data (1996-1998) were broken down by age, sex, income, and race.
- Within individual classes of antidepressants, SSRIs and atypicals were associated with **lower** suicide rates (both within and between counties).
- Positive association between TCA prescriptions and suicide rate between counties, but not within counties.

Gibbons et al (2005)

Antidepressant total prescriptions by age



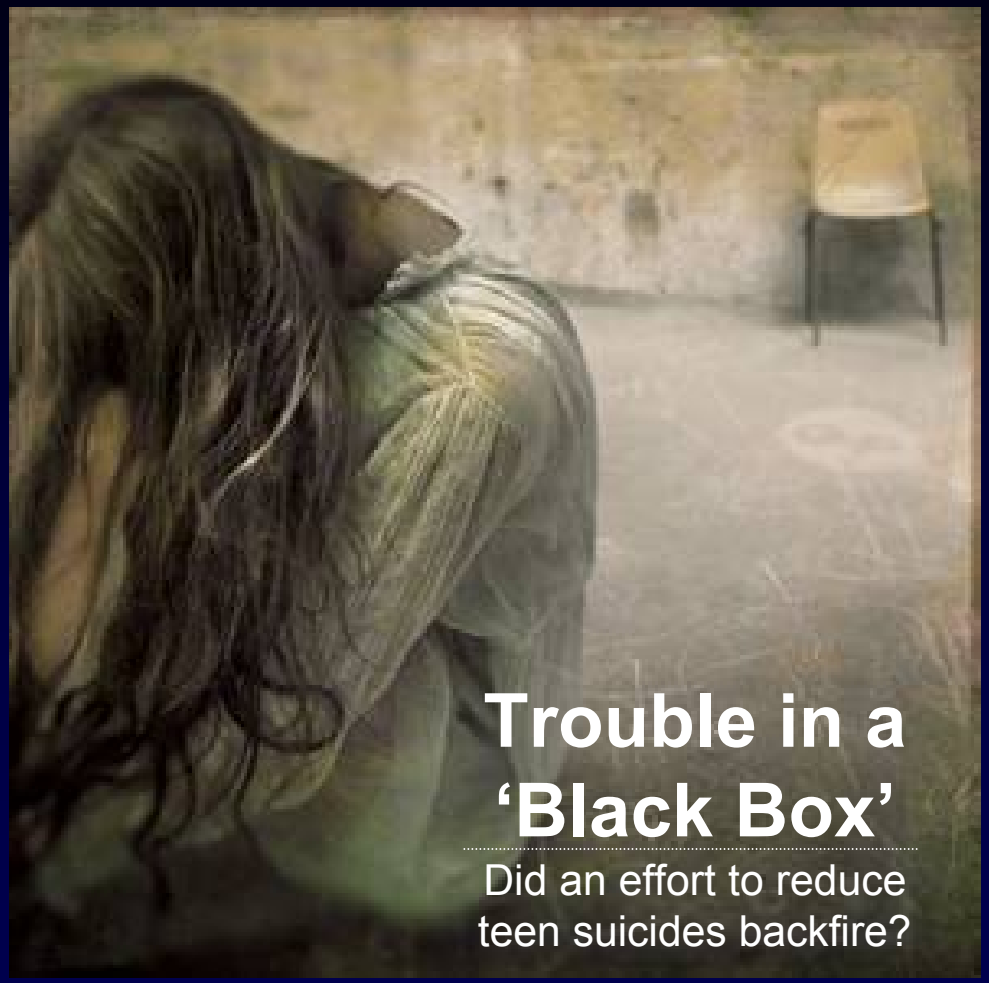
Prescription volume indexed to normalize the difference in prescription volume between the age groups. June 2002=100 and subsequent data points are relative to this baseline value.

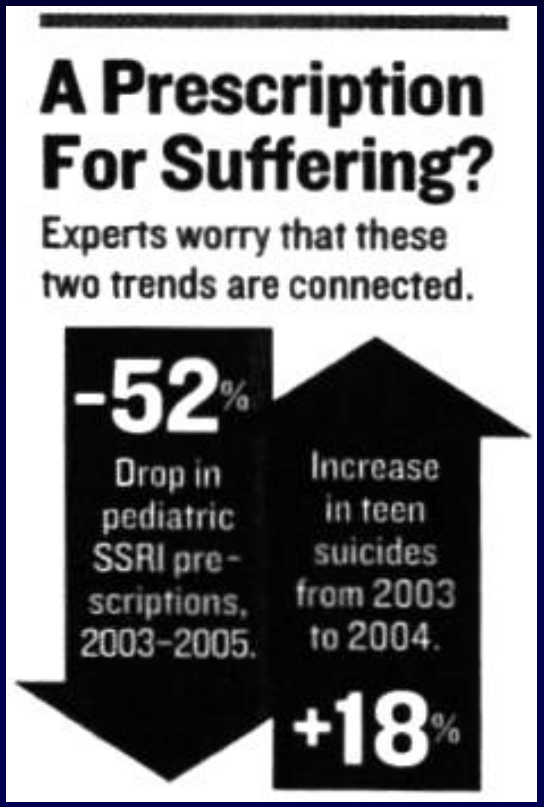
Nemeroff et al (2007) *Archives of General Psychiatry* 64:466-472.

Suicide Increase……?

- Gibbons et al 2007
  - Netherlands: Since warnings, 22% drop in prescriptions and 49% increase in youth suicide
- CDC: 15% increase in youth completed suicide 2003 to 2004

Newsweek July 16, 2007





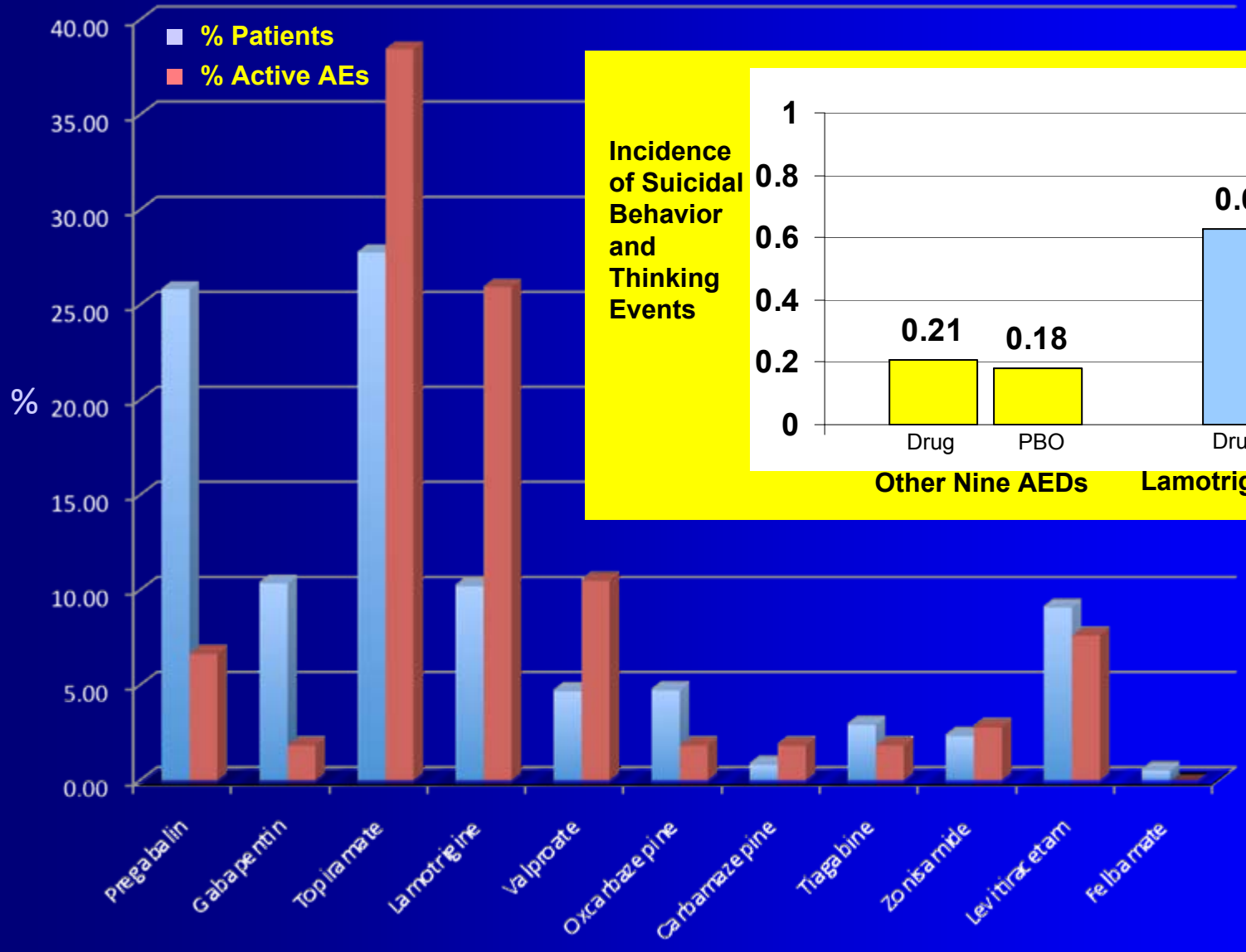
By Tony Dokoupil

Potentially suicide related adverse events (PSRAEs) with antiepilieptic agents: a pharmacological class effect?

Compound	Mechanism of Action	Drug	Placebo	%N in FDA	%Events in FDA
Pregabalin	$\alpha_2\delta$ ligand	7/7201	2/3125	23.5%	6.3%
Gabapentin	$\alpha_2\delta$ ligand	2/2903	1/2029	11.2%	2.1%
Topiramate	Na^+ channel blocker; enhance GABA-A; inhibit AMPA/kainate	40/7742	8/3971	26.7%	33.8%
Lamotrigine	Na^+ channel blocker; N/P Ca^{2+} channel blocker	27/2865	11/2070	11.2%	26.8%
Valproate	Na^+ channel blocker; T Ca^{2+} channel blocker; GABA-T inhibitor	11/1327	9/992	5.3%	14.1%
Oxcarbazapine	Na^+ channel blocker	2/1342	1/827	4.9%	2.1%
Carbamazepine	Na^+ channel blocker	2/252	3/250	1.1%	3.5%
Tiagabine	GAT-1 blocker	2/835	0/608	3.3%	1.4%
Zonisamide	Na^+ channel blocker; T Ca^{2+} channel blocker	3/672	1/438	2.5%	2.8%
Levitiracetam	SVA-2 ligand	8/2554	2/1549	9.3%	7.0%
Felbamate	Na^+ channel blocker; enhance GABA-A; inhibit NMDA recptr	0/170	0/170	0.8%	0.0%

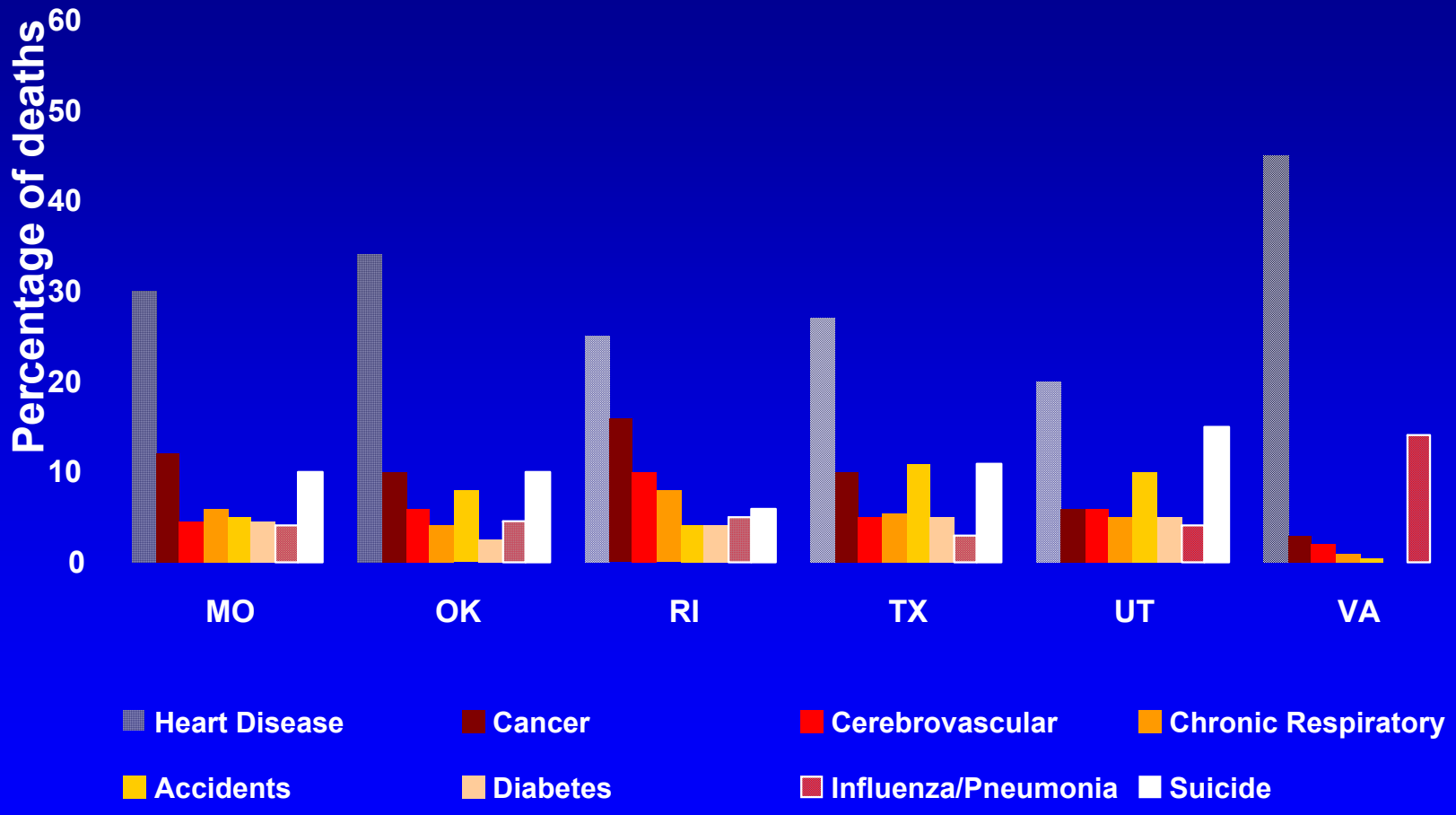
Data source: FDA Statistical Review and Evaluation, 23 May 2008, Table 7

PSRAE incidence is not uniform across active groups



Incidence of Suicidal Behavior and Thinking Events

Cardiovascular Disease Is Primary Cause of Death in Persons with Mental Illness*



*Average data from 1996-2000.

Colton CW, Manderscheid RW. Prev Chronic Dis [serial online] 2006 Apr [date cited].
Available at URL: http://www.cdc.gov/pcd/issues/2006/apr/05_0180.htm

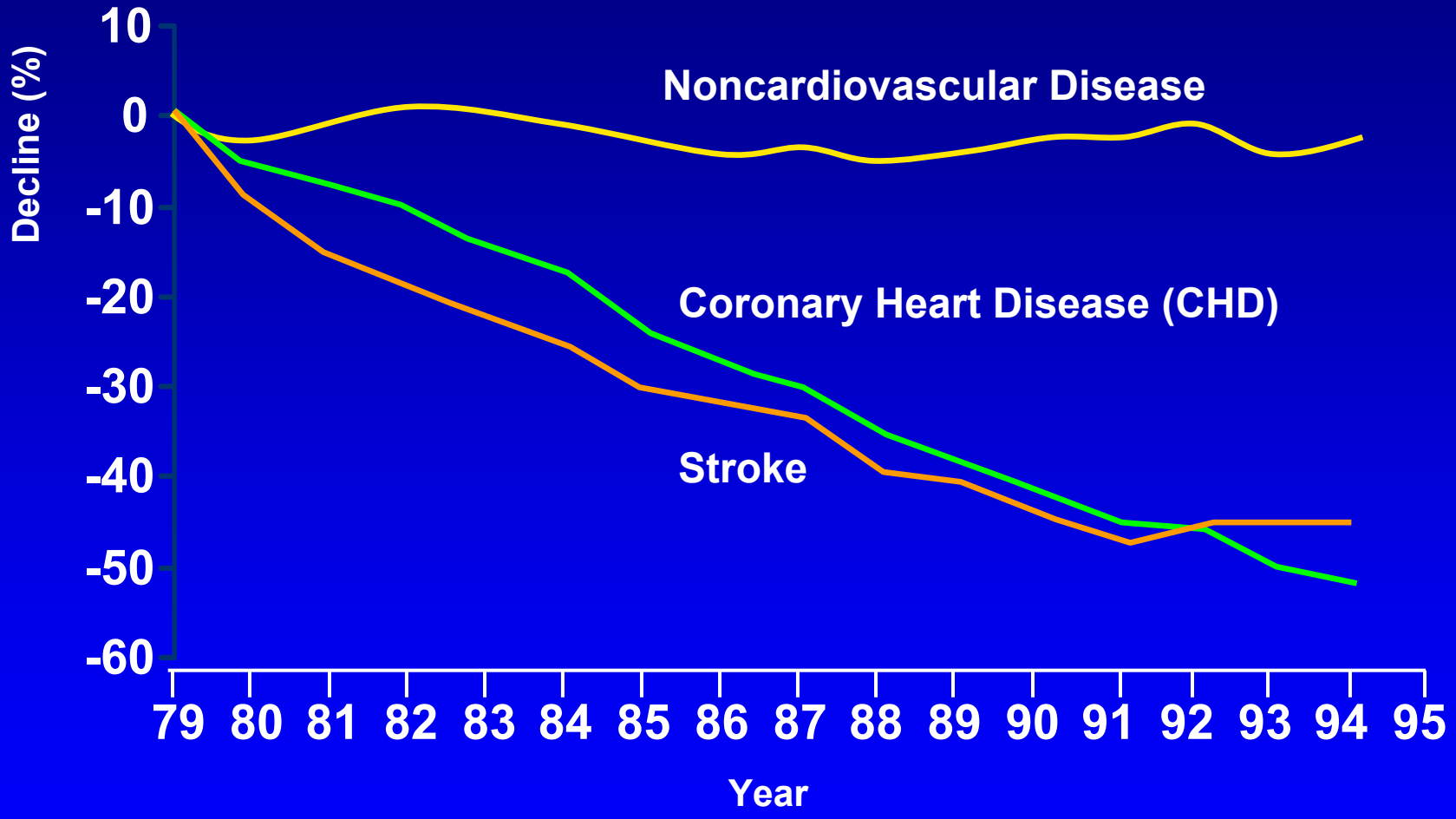
Total Years of Potential Life Lost (YPLL) by Primary Cause for Public Mental Health Patients with Schizophrenia/Schizoaffective in MO, OK, RI, TX and UT Combined (1997-2001)

Primary Cause of Death	Total YPLL (Person-years lost)	# Deaths
Heart Disease	14,871.2	612
Cancer	5,389.9	241
Suicide	4,726.1	115
Accidents, including vehicles	3,467.0	98
Chronic Respiratory	2,700.9	113
Diabetes	1,419.6	61
Pneumonia/Influenza	1,254.2	67
Cerebrovascular	1,195.9	58
All Causes of Death*	47,812.2	1,829

*Note: Includes deaths from causes not listed

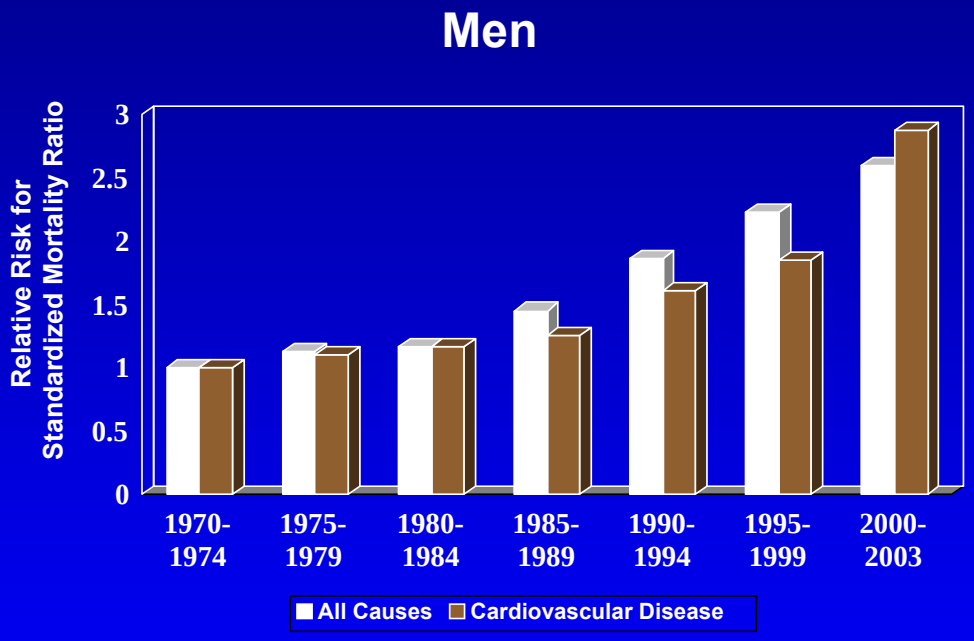
Unpublished results courtesy of CW Colton

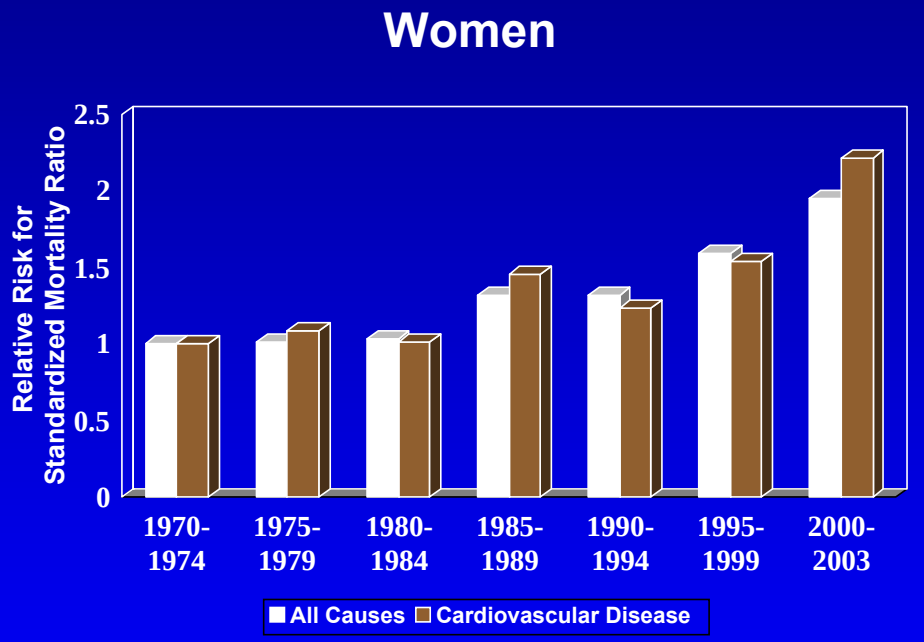
Change in US General Population Age-Adjusted Mortality (1979-1995)



Morbidity and Mortality Weekly Report. 1999; 48(30):649-656.

Mortality Risk From All Causes and From Cardiovascular Disease Increased Among Patients With Schizophrenia Between 1970-2003





Test for time trends of excess relative risks for SMRs were statistically significant ($P<0.001$) for all cause mortality and mortality due to cardiovascular disease.

Ösby U et al. BMJ. 2000;321:483-484, and unpublished data courtesy of Urban Osby.

Reasons for Increased CVD Mortality in Major Mental Disorders

- ↑ Modifiable health risk factors
  - ↑ Lipid abnormalities (TC, LDL-C, TG, HDL)
  - ↑ Diabetes
  - ↑ Hypertension
  - ↑ Metabolic syndrome
  - ↑ Physical inactivity
  - ↑ Smoking
- ↓ Access to and/or utilization of medical care
- ↓ Adherence with therapies
- ↓ Economic capabilities

Newcomer J Hennekens CH. *JAMA* 2007; 298(15):1794-1796

Cardiovascular Disease (CVD) Risk Factors

Modifiable Risk Factors	Estimated Prevalence and Relative Risk (RR)	
	Schizophrenia	Bipolar Disorder
Obesity [1-5]	45-55%, 1.5-2 × RR	21-49%,1-2 × RR
Smoking [4-8]	50-80%, 2-3 × RR	54-68%, 2-3 × RR
Diabetes [2, 8-11]	10-15%, 2 × RR	8-17%, 2 × RR
Hypertension [2-4, 7-9, 11]	19-58%, 2-3 × RR	35-39%, 2 × RR
Dyslipidemia [2, 4, 11-13]	25%, ≤5 × RR	23%, ≤5 × RR

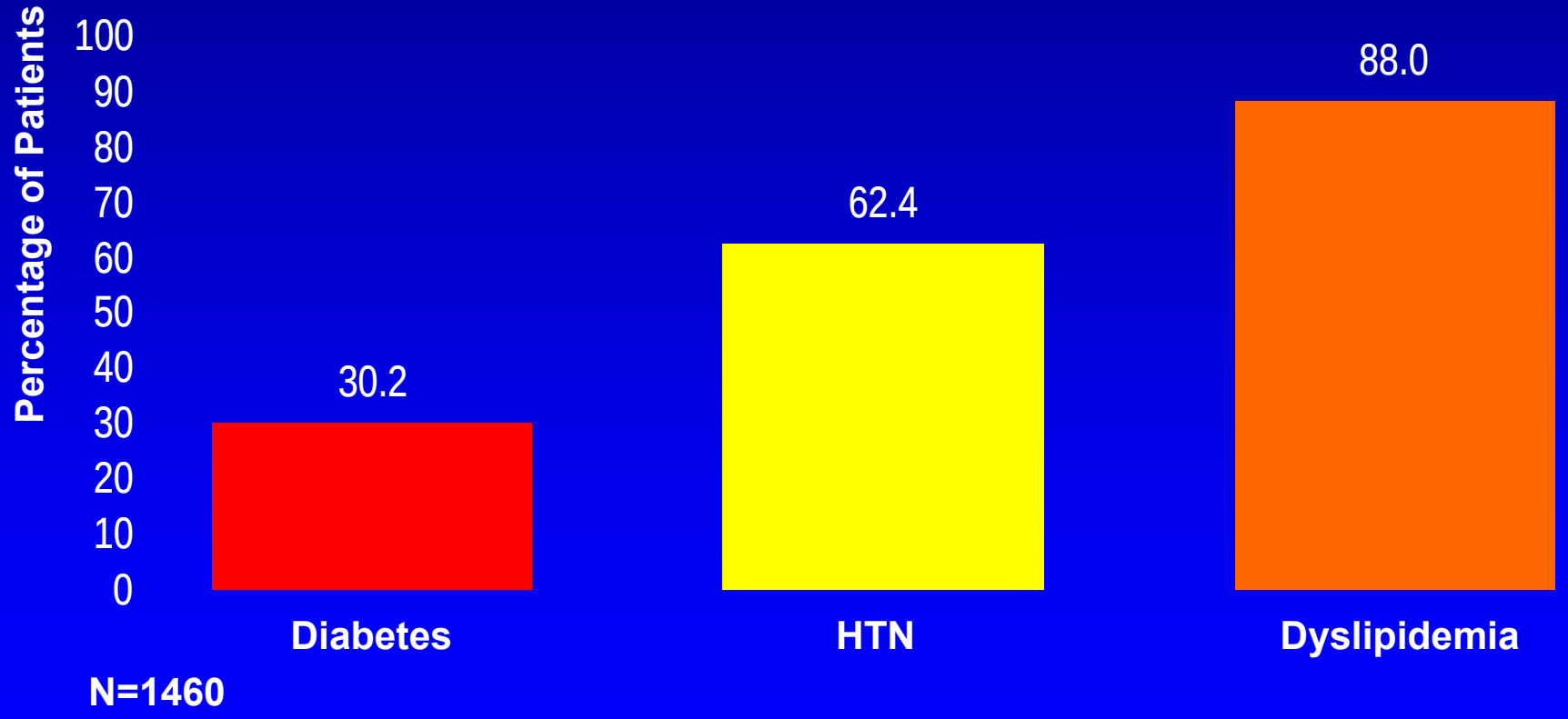
[1]Allison DB et al. (1999), J Clin Psychiatry 60(4):215-220; [2]Fagiolini A et al. (2005), Bipolar Disord 7(5):424-430; [3]McElroy SL et al. (2002), J Clin Psychiatry 63(3):207-213; [4]Hennekens CH et al. (2005), Am Heart J 150(6):1115-1121; [5]Davidson S et al. (2001), Aust N Z J Psychiatry 35(2):196-202; [6]Ucok A et al. (2004), Psychiatry Clin Neurosci 58(4):434-437; [7]Herran A et al. (2000), Schizophr Res 41(2):373-381; [8]Goff DC et al. (2005), Schizophr Res 80(1):45-53; [9]Dixon L et al. (1999), J Nerv Ment Dis 187(8):496-502; [10]Cassidy F et al. (1999), Am J Psychiatry 156(9):1417-1420; [11]Kilbourne AM (2004), Bipolar Disord 6(5):368-373; [12]Allebeck P (1999), Schizophr Bull 15(1):81-89; [13]Koro CE et al. (2002), Arch Gen Psychiatry 59(11):1021-1026

Reasons for Increased CVD Mortality in Major Mental Disorders

- Primary and secondary prevention limitations for mentally ill versus general population
  - Less likely to be screened or treated for dyslipidemia, hyperglycemia, hypertension
  - Less likely to receive angioplasty or CABG
  - Less likely to receive drug therapies of proven benefit (thrombolytics, aspirin, beta-blockers, ACE inhibitors) post-myocardial infarction
  - More likely to have premature mortality post-myocardial infarction

Newcomer J Hennekens CH. *JAMA* 2007; 298(15):1794-1796
Druss BG et al. Arch Gen Psychiatry. 2001;58:565-572.

Prevention Opportunities Missed: Low Rates of Treatment for Metabolic Disorders In Schizophrenia in CATIE



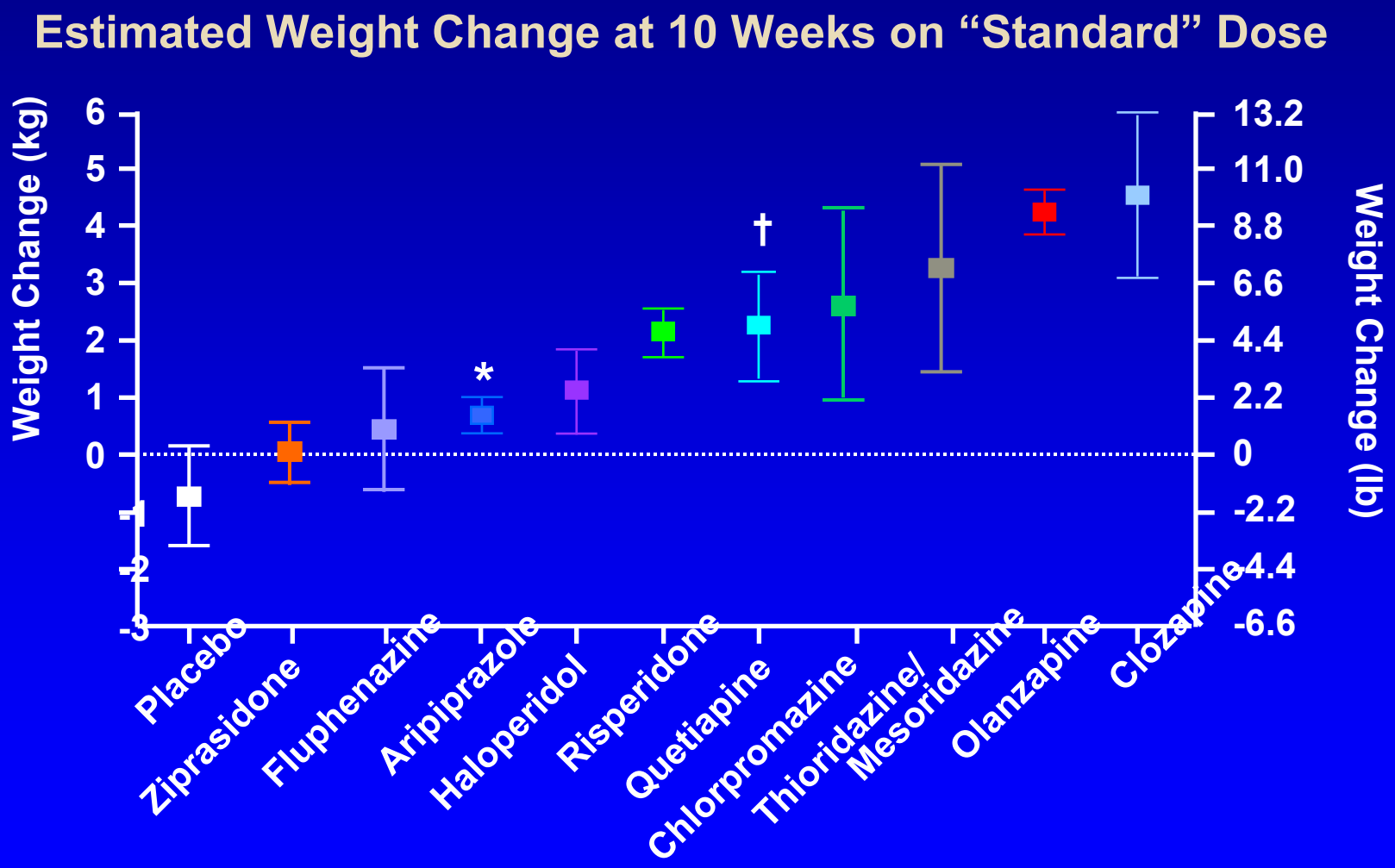
Nasrallah H et al. *Schizophrenia Research* 2006; 86:15–22

Modifiable Risk Factors Affected by Psychotropics

- Overweight/Obesity
- Insulin resistance
- Diabetes/hyperglycemia
- Dyslipidemia

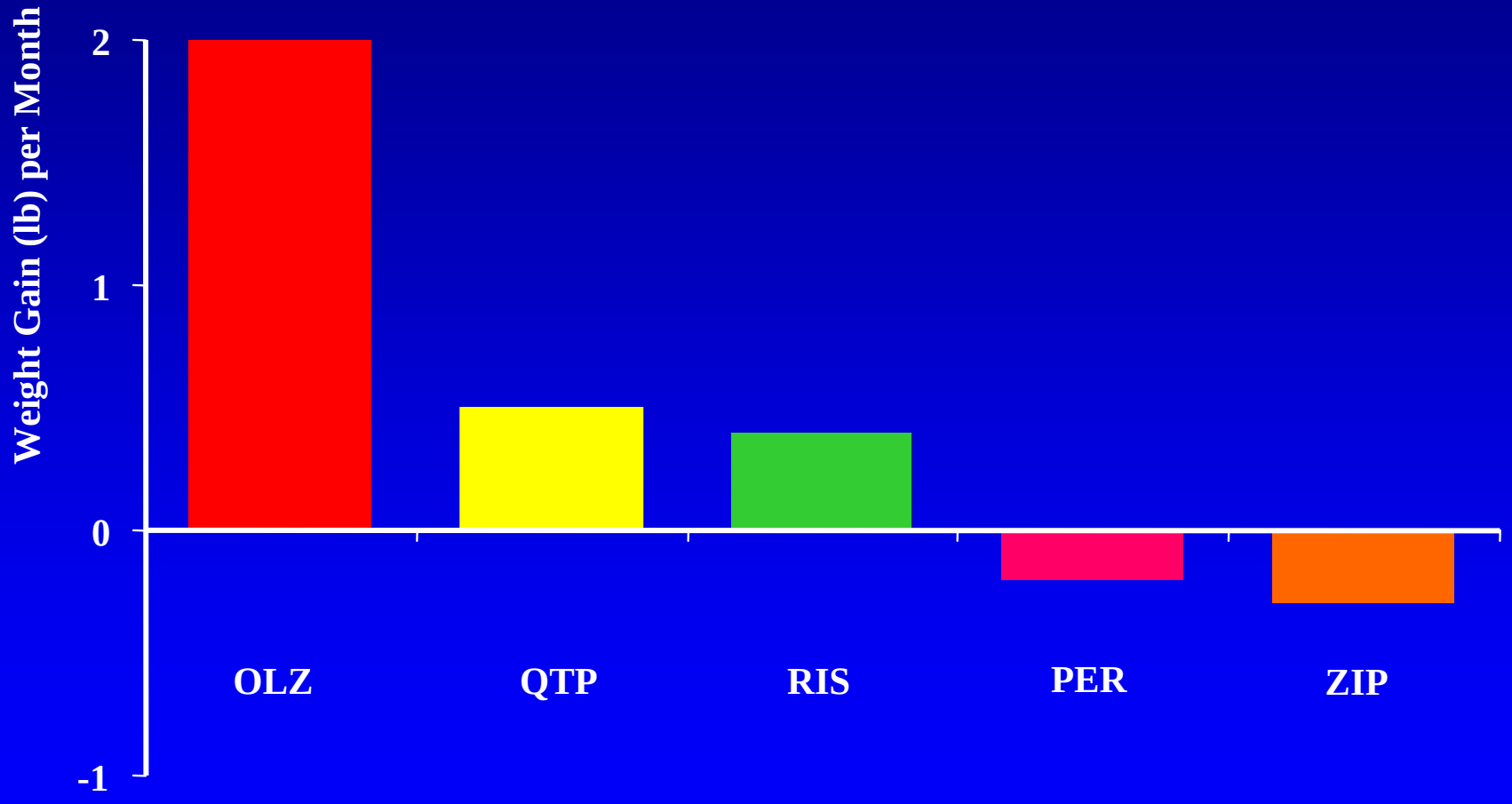
Newcomer JW. *CNS Drugs*. 2005;19(Supp 1):1-93.

Mean Change in Weight With Antipsychotics



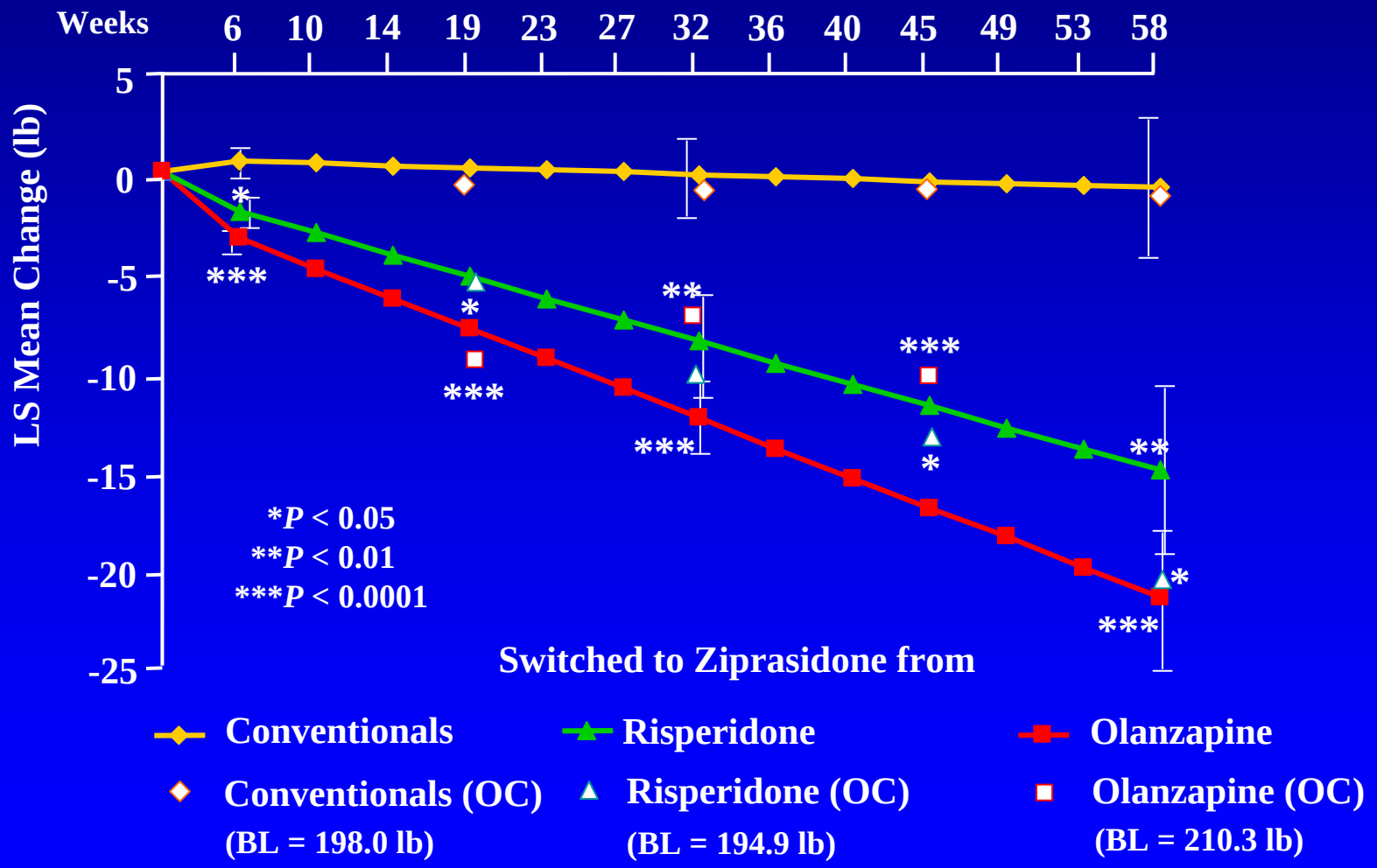
*4–6 week pooled data (Marder SR et al. *Schizophr Res*. 2003;1;61:123-36; †6-week data adapted from Allison DB, Mentore JL, Heo M, et al. *Am J Psychiatry*. 1999;156:1686-1696; Jones AM et al. ACNP; 1999.

CATIE Phase 1 Trial Results: Weight Gain per Month of Treatment



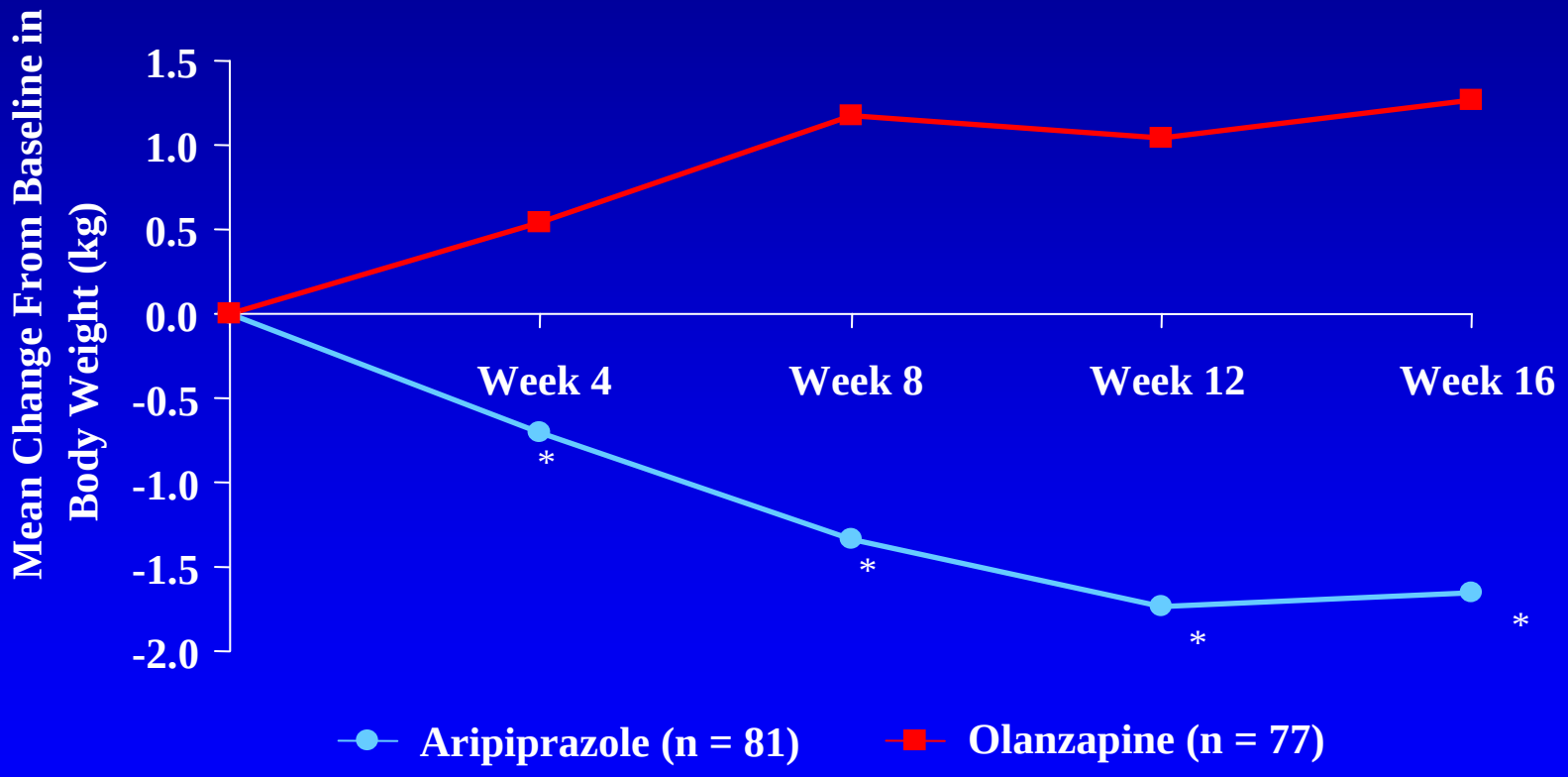
Lieberman JA, et al. *N Eng J Med*. 2005;353:1209-1223.

Change in Weight From Baseline 58 Weeks After Switch to Low Weight Gain Agent



Weiden P, et al. *Neuropsychopharmacology*. 2007.

Randomized Switch to Aripiprazole in Overweight Olanzapine-treated Patients: Weight Change Over 16 Weeks



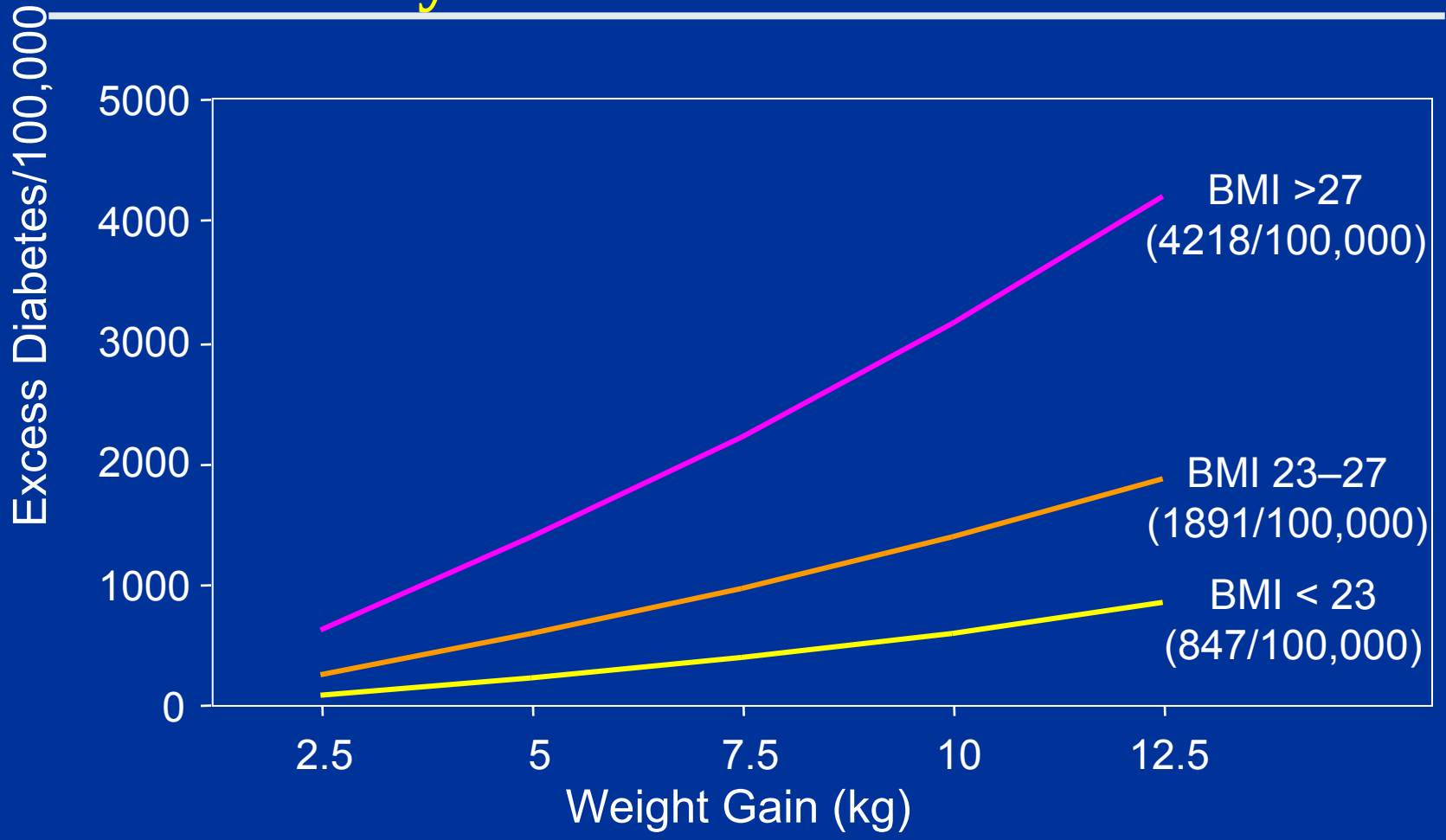
*$P < 0.001$ vs. olanzapine

Last observation carried forward

Overweight patients with schizophrenia or schizoaffective disorder previously treated with olanzapine.

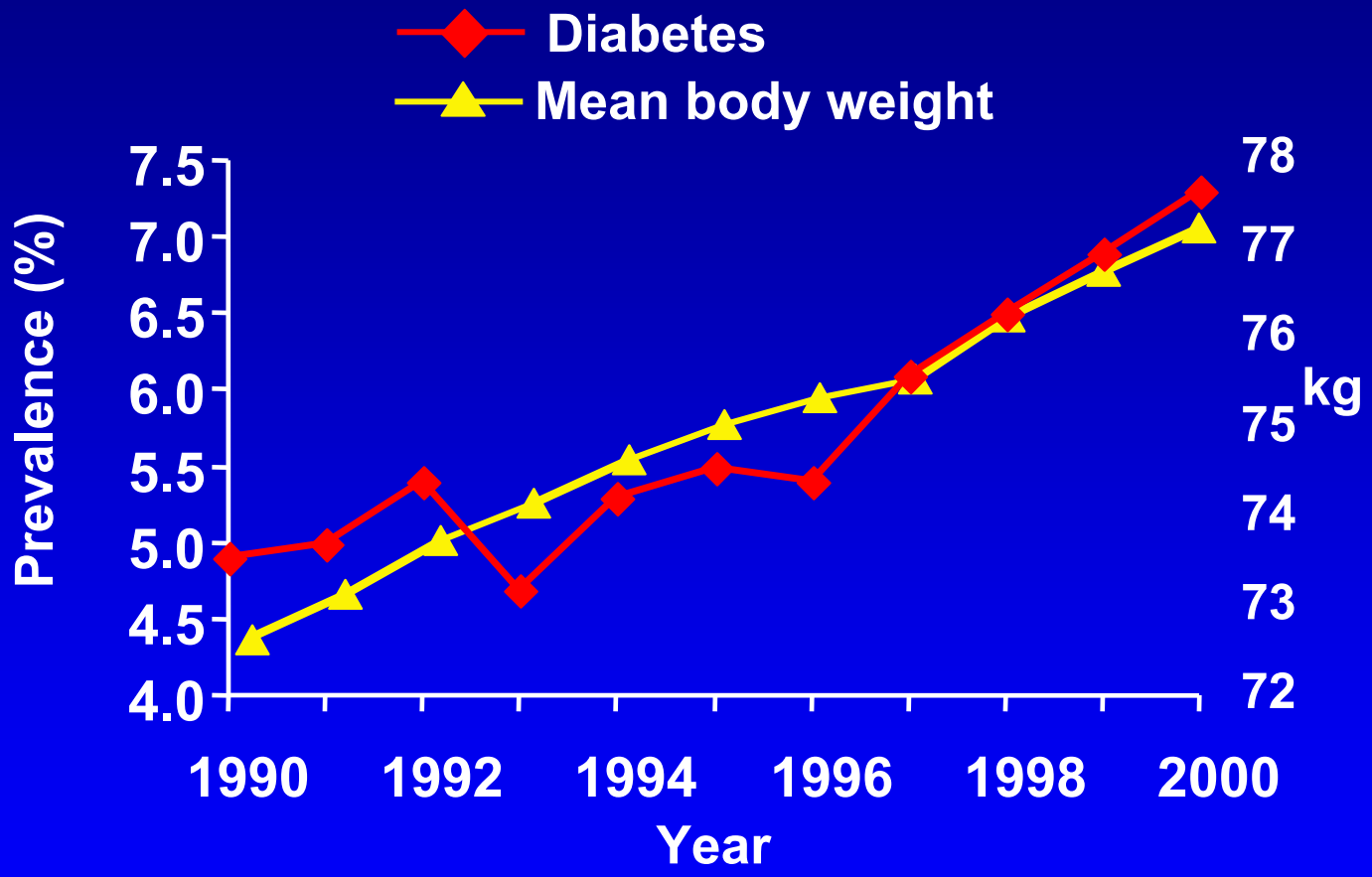
Newcomer J, et al. J Clin Psychiatry, in press.

Excess Cases of Diabetes* Per 100,000 Per 10 Years with Weight Gain by Baseline BMI Status



*Framingham criteria based on 1948 Framingham distribution.
Fontaine et al (2001).

Diabetes and obesity in the US



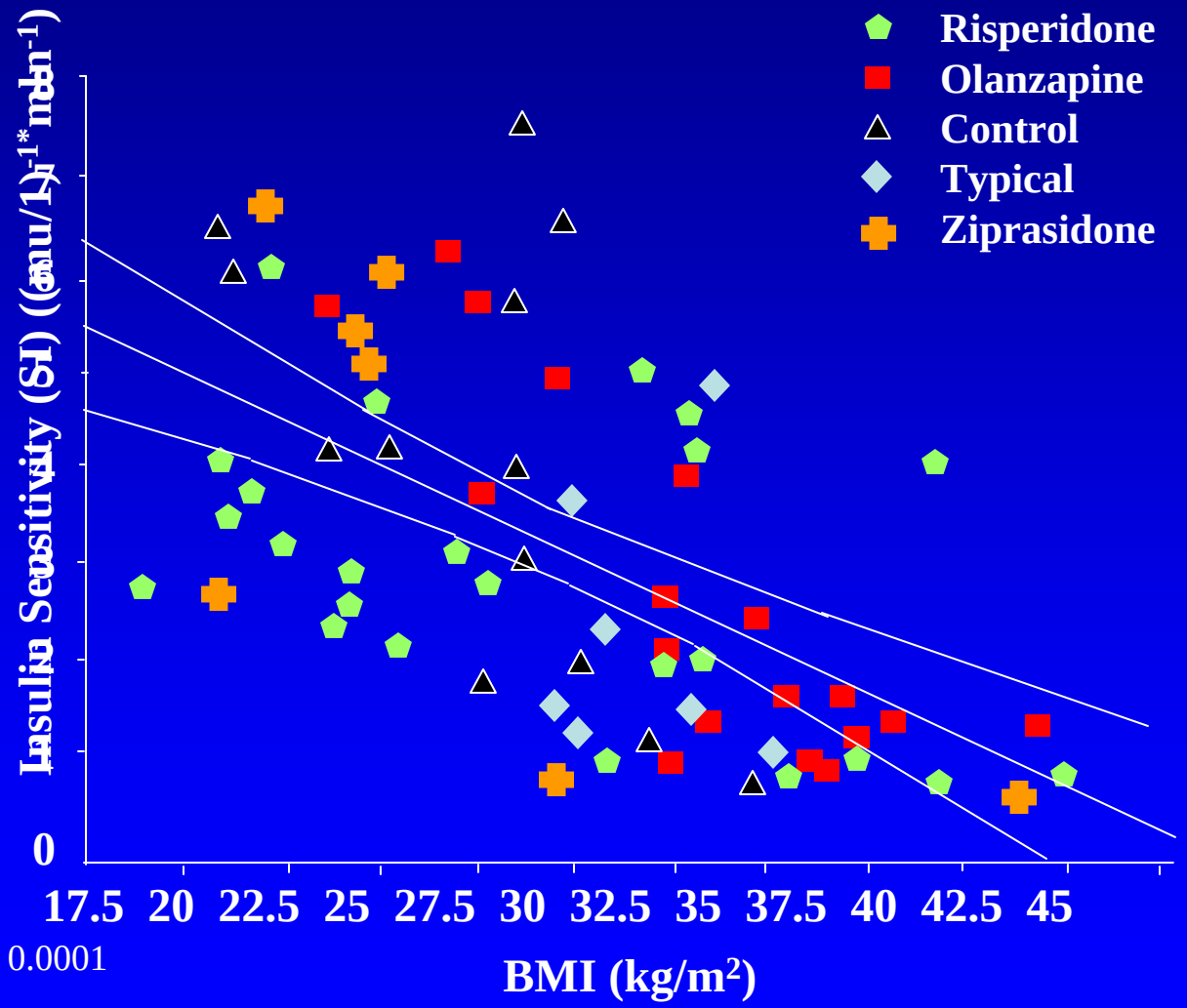
Mokdad et al. *Diabetes Care*. 2000;23:1278.
Mokdad et al. *JAMA*. 1999;282:1519.
Mokdad et al. *JAMA*. 2001;286:1195.

Modifiable Risk Factors Affected by Psychotropics

- Overweight/Obesity
- Insulin resistance
- Diabetes/hyperglycemia
- Dyslipidemia

Newcomer JW. *CNS Drugs* 2005;19(Supp 1):1-93.

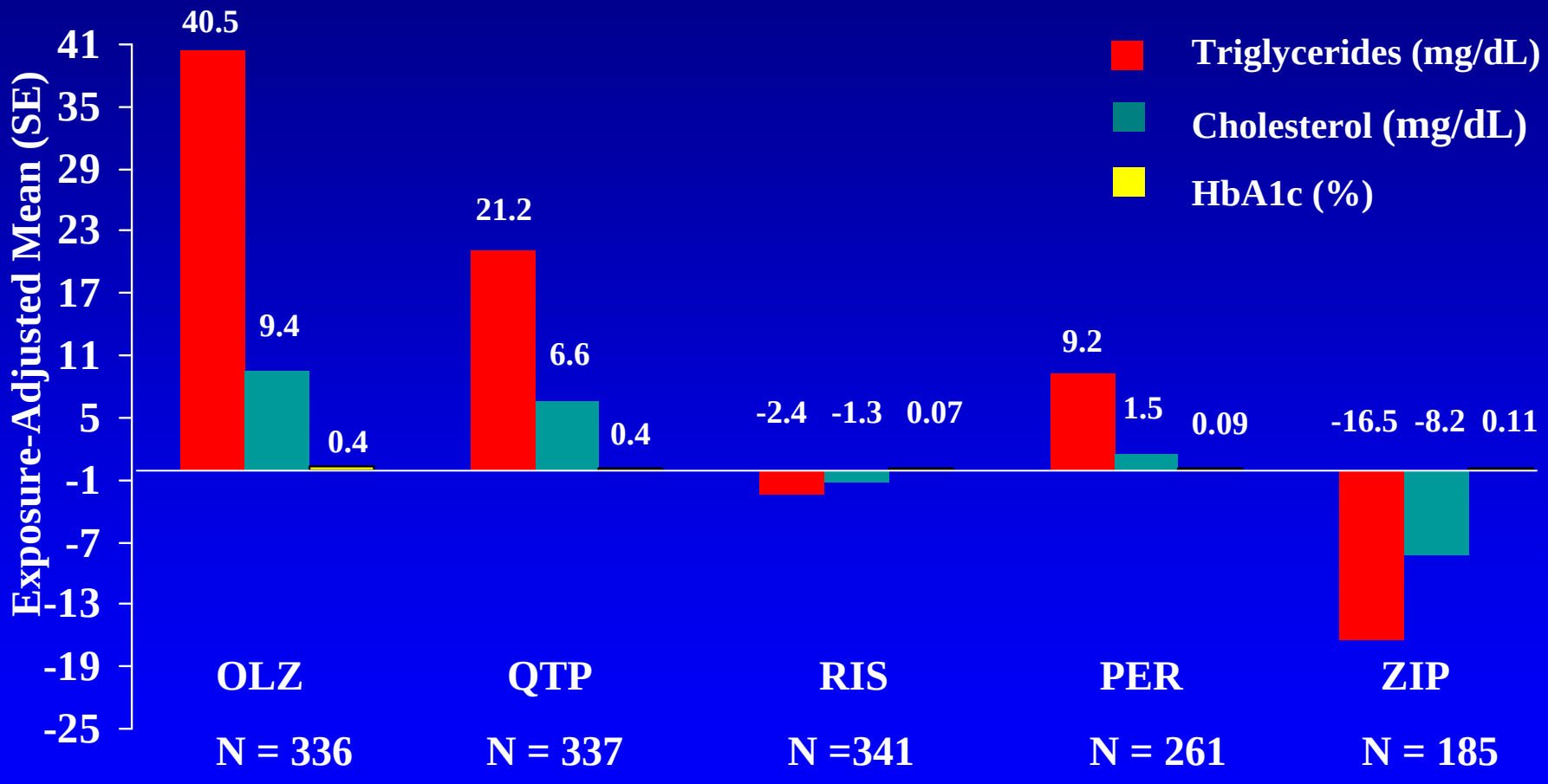
Antipsychotic-related Adiposity Predicts Insulin Sensitivity



F(1,62) = 35.11, $P < 0.0001$

Haupt, et al. *Neuropsychopharmacology*. (Advance online publication). 21 March 2007.

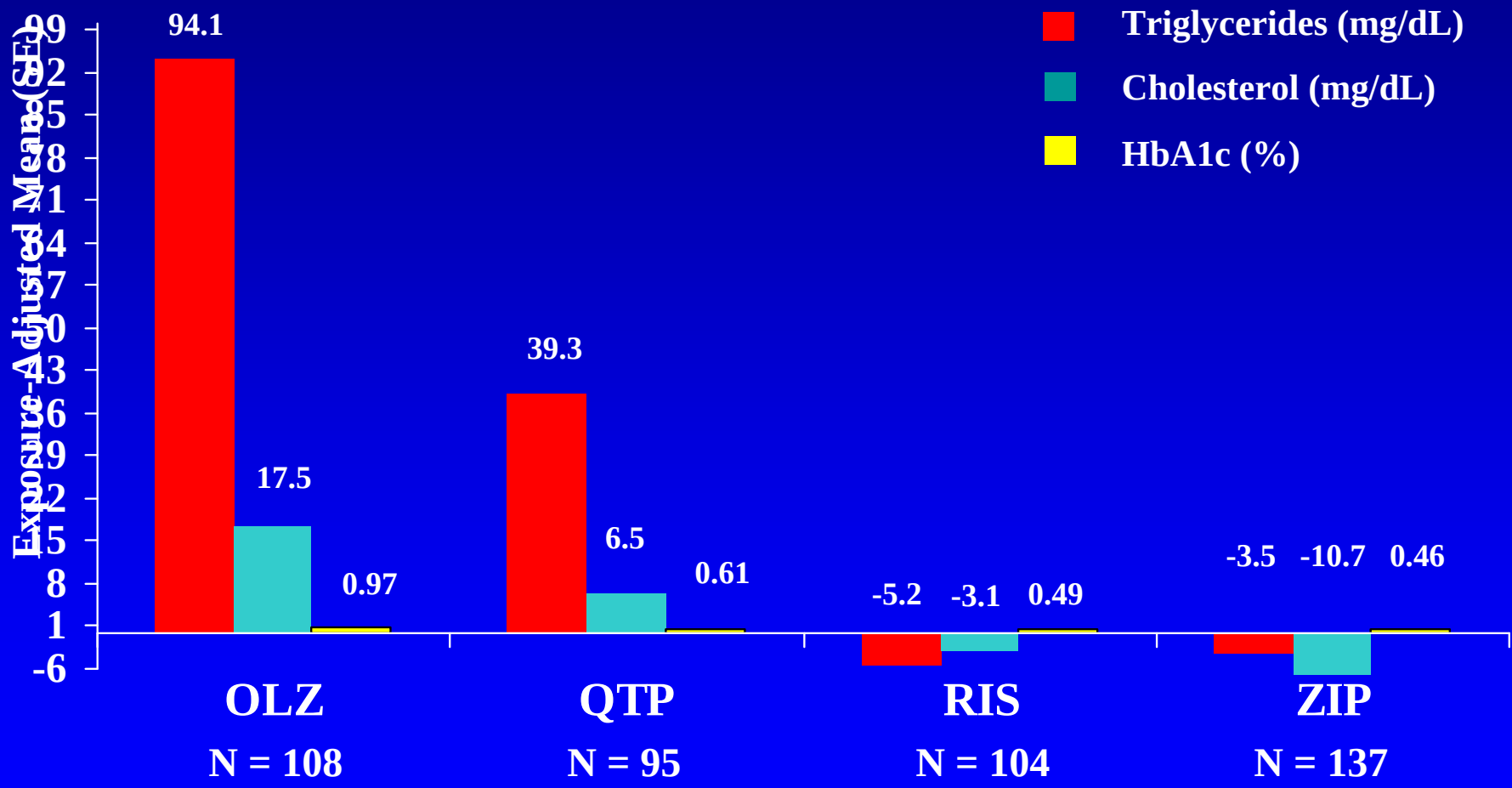
Changes in Weight, Lipids, and Glucose Measures: CATIE Phase 1 Randomized Patients



Exp-Adj Mean=Exposure-adjusted mean (least-squares mean from an ANCOVA adjusting for whether the patient had an exacerbation in the preceding 3 months and for duration of exposure to the study drug in phase 1)

Lieberman JA et al. *N Engl J Med*. 2005;353:1209-1223.

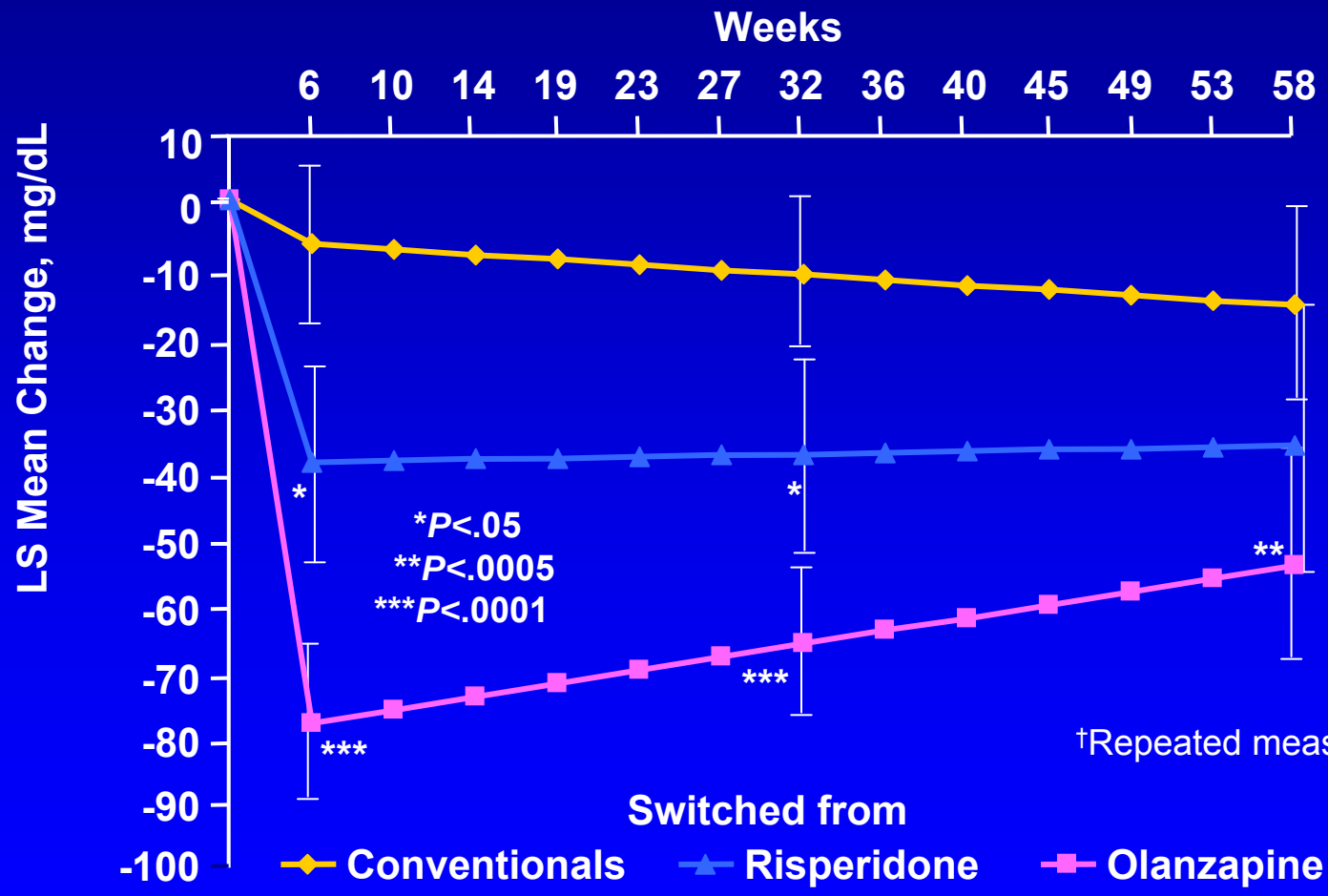
Changes in Weight, Lipids, and Glucose in the CATIE Tolerability Phase (2T)



Exp-Adj Mean=Exposure-adjusted mean (ANCOVA least squares mean adjusting for whether the patient had an exacerbation in the preceding 3 months and duration of exposure to phase 1)

Stroup TS. et al. *Am J Psychiatry.* 2006;163:611-622.

Change in Triglycerides from Baseline over 58 Weeks after Switch to Ziprasidone†



Weiden P, et al. *Neuropsychopharmacology.* 2007.

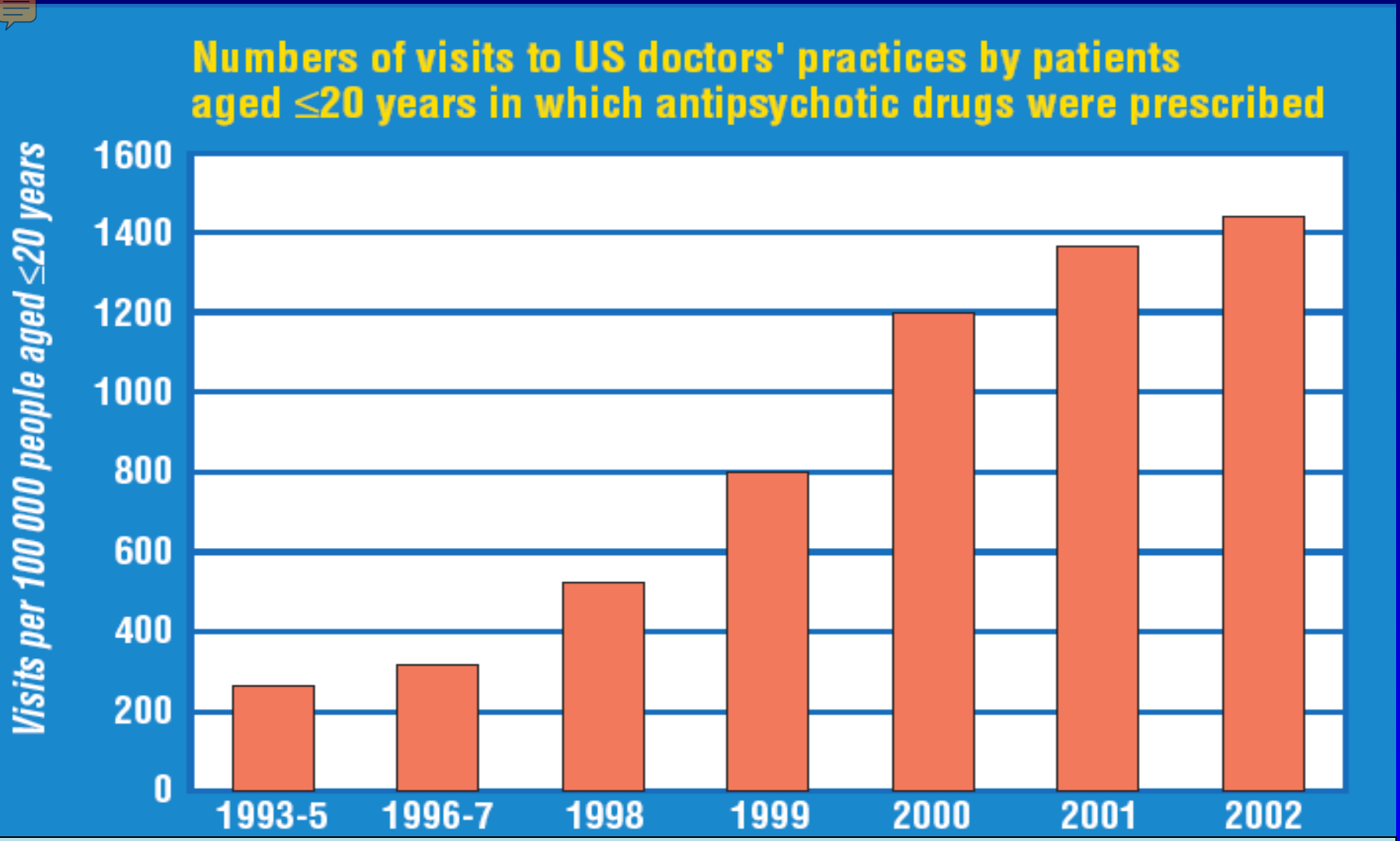


Figure. National trends in office-based visits by children and adolescents that included antipsychotic treatment, 1993-2002. Annualized visit rates per 100,000 population aged 0 to 20 years were calculated using National Ambulatory Medical Care Survey and US Census Bureau Data. (Source: Olfson M,Blanco C, Liu L, Moreno C, Laje G. National trends in the outpatient treatment of children and adolescents with antipsychotic drugs. *Arch Gen Psych*. 2006;63:681.)

Metabolic Effects of Antipsychotics in Children (MEAC): Methods

- 5-year, NIMH funded study
- Target sample size 240 subjects

Preliminary results from first 47 completed subjects

Ages 7-18

- Multiple eligible childhood onset psychiatric diagnoses

Antipsychotic naïve sample

- "Real-world" with SSRIs and stimulants (50%) permitted

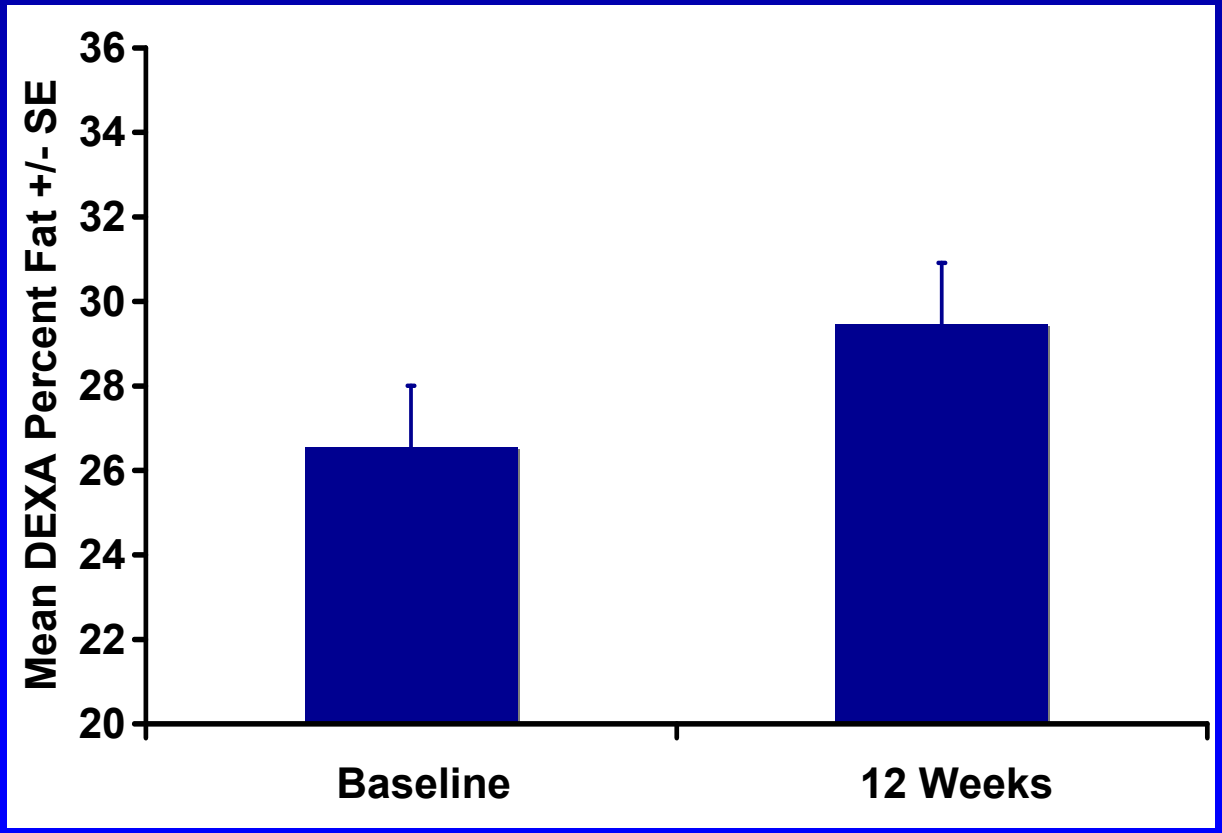
Target symptoms aggression/irritability

- ≥ 18 on Aberrant Behavior Checklist (ABC) irritability subscale

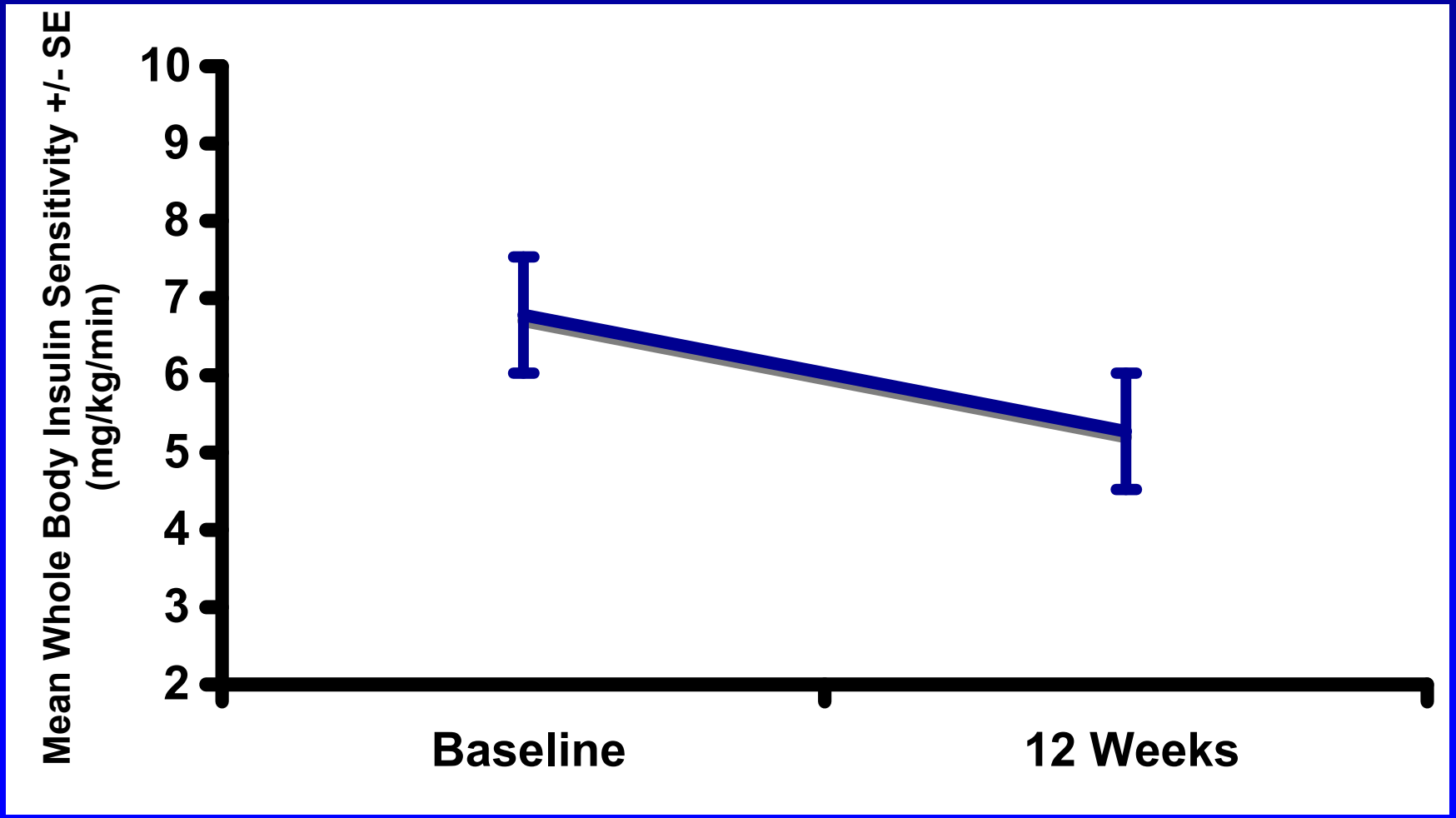
12 weeks of open-label randomized treatment

- risperidone (n=80)
- olanzapine (n=80)
- aripiprazole (n=80)

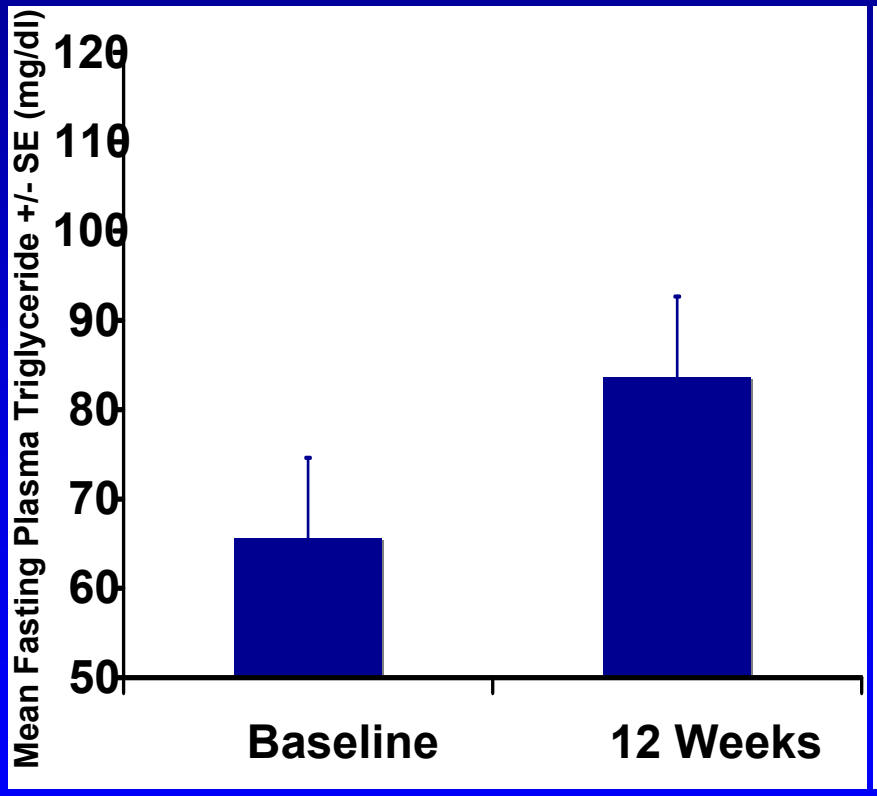
DEXA Percent Fat Change During 12 Weeks of Treatment

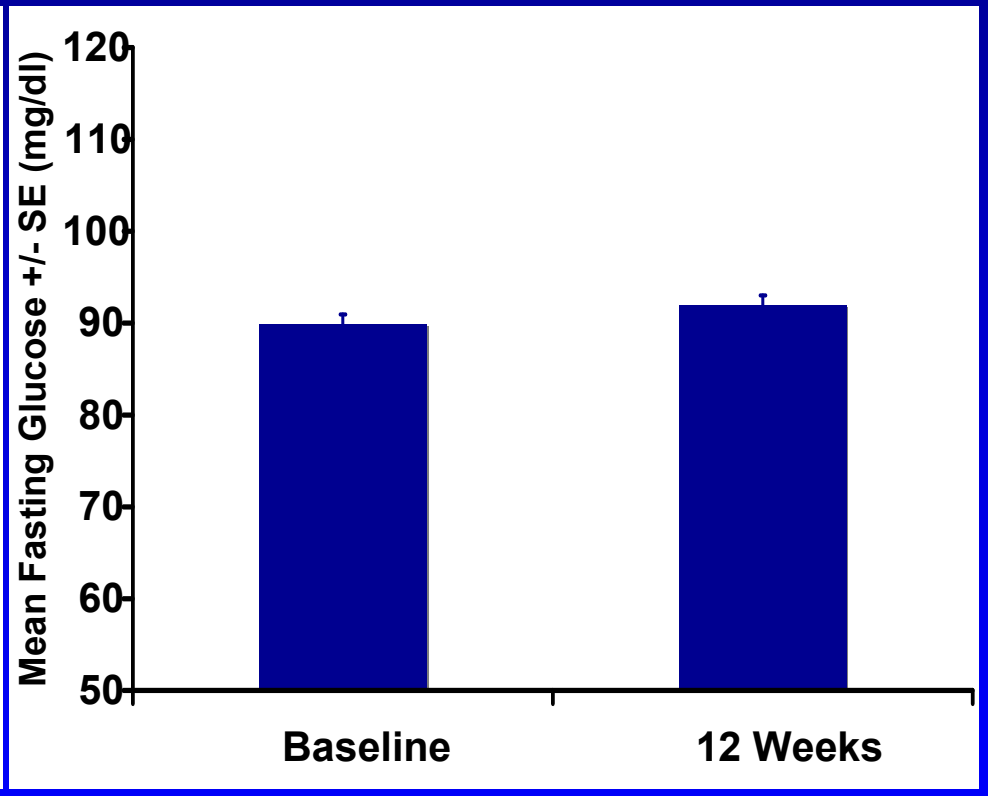


Euglycemic Clamp-Derived Whole Body Insulin Sensitivity: Change During 12 Weeks of Treatment

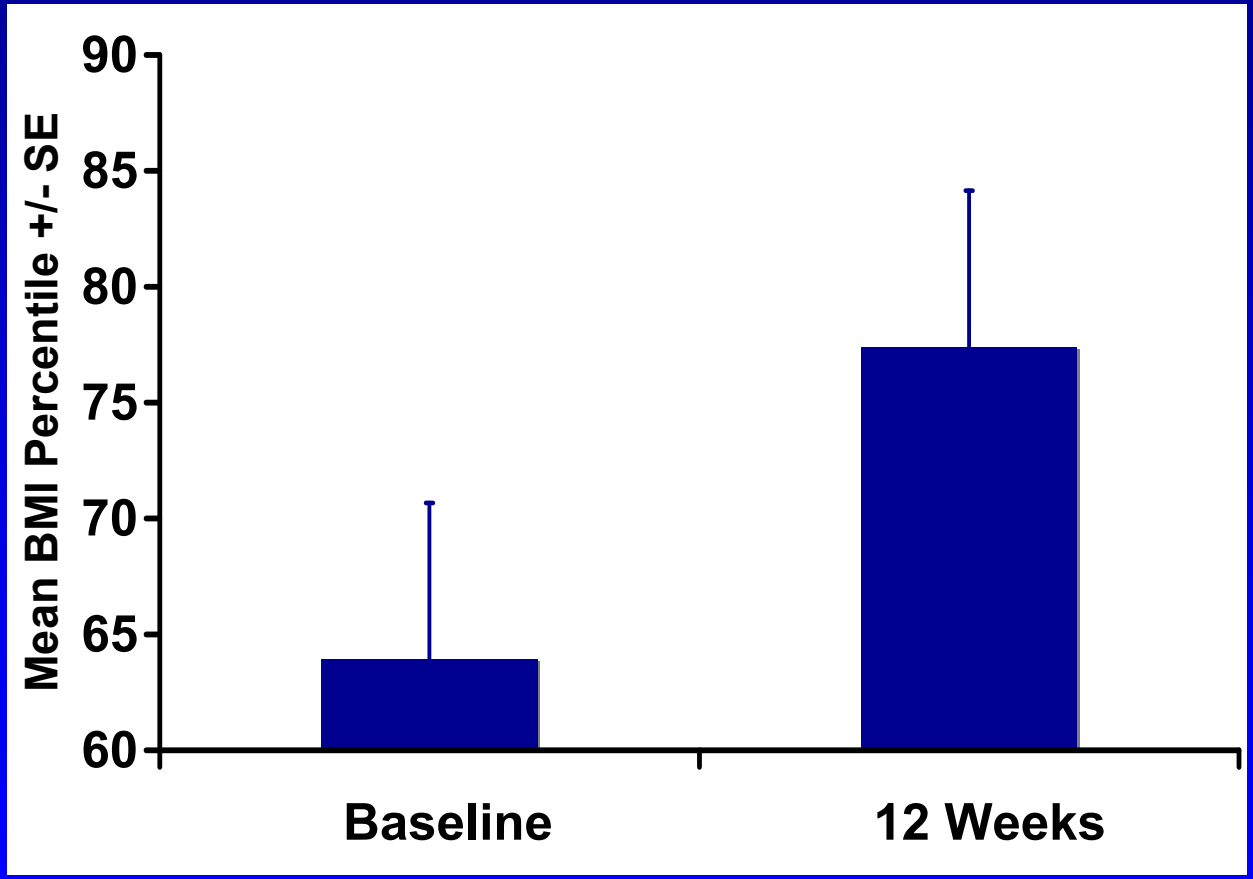


Fasting Triglyceride vs. Glucose Change During 12 Weeks of Treatment





Body Mass Index (BMI) Percentile Change During 12 Weeks of Treatment



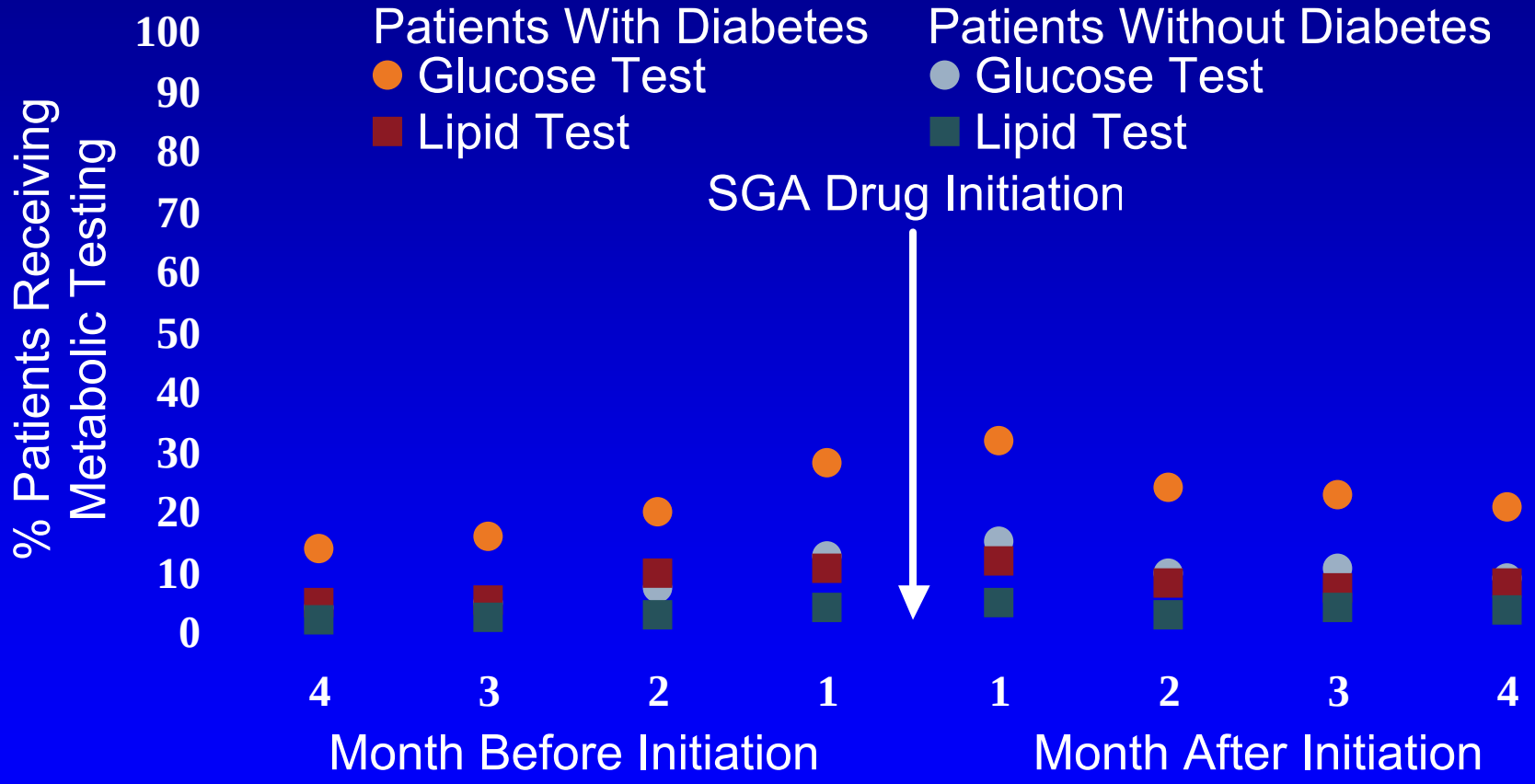
ADA Consensus on Antipsychotic Drugs and Obesity and Diabetes: Monitoring Protocol*

	Start	4 wks	8 wks	12 wks	Qtr.	12 mos.	5 yrs.
Personal/family Hx	X					X	
Weight (BMI)	X	X	X	X	X		
Waist circumference	X					X	
Blood pressure	X			X		X	
Fasting glucose	X			X		X	
Fasting lipid profile	X			X		X	X

***More frequent assessments may be warranted based on clinical status**

***Diabetes Care.* 27:596-601, 2004**

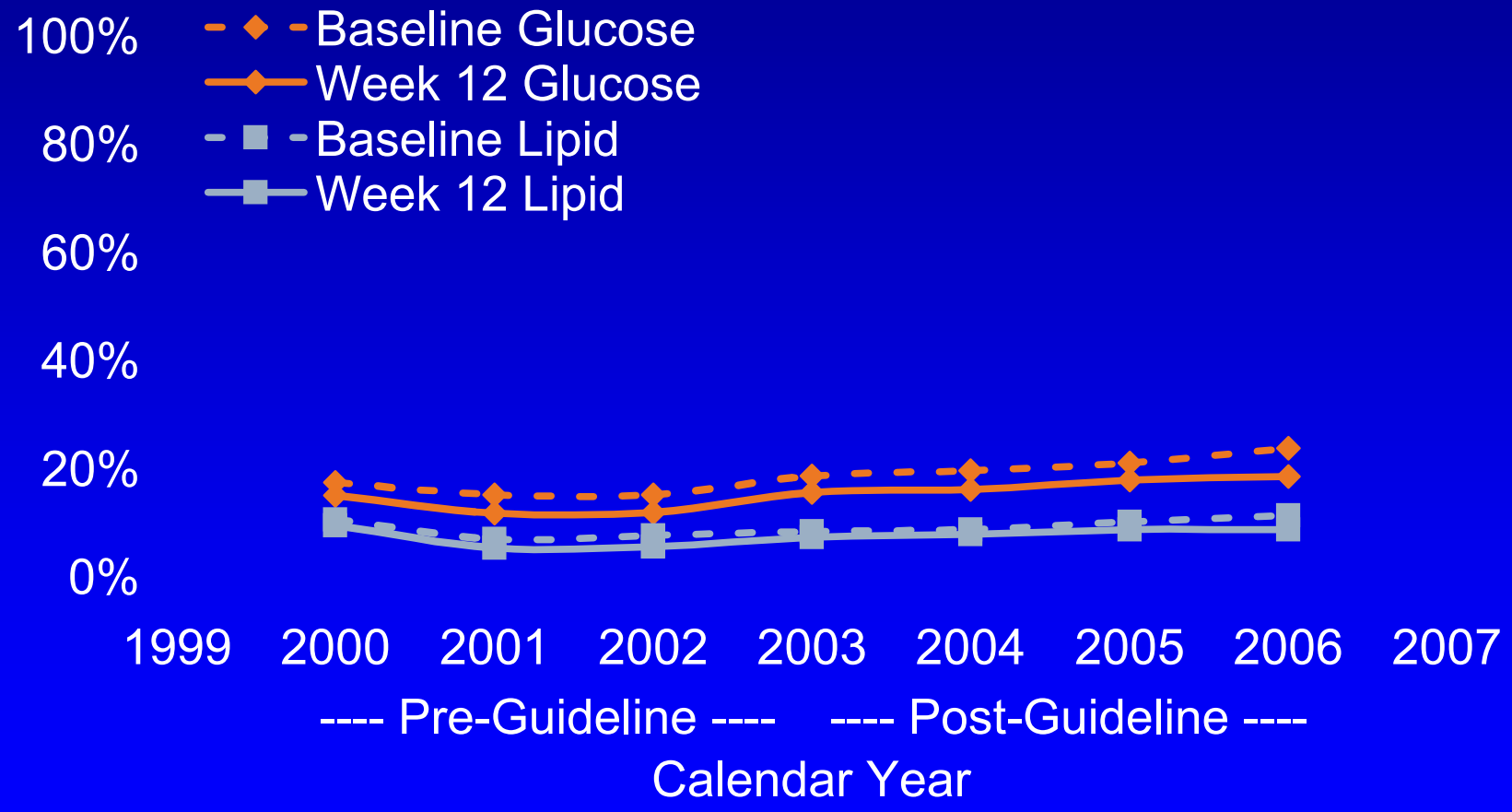
Glucose Testing Frequency Relative to Atypical Antipsychotic Index Date



Across group comparison: $p < .001$

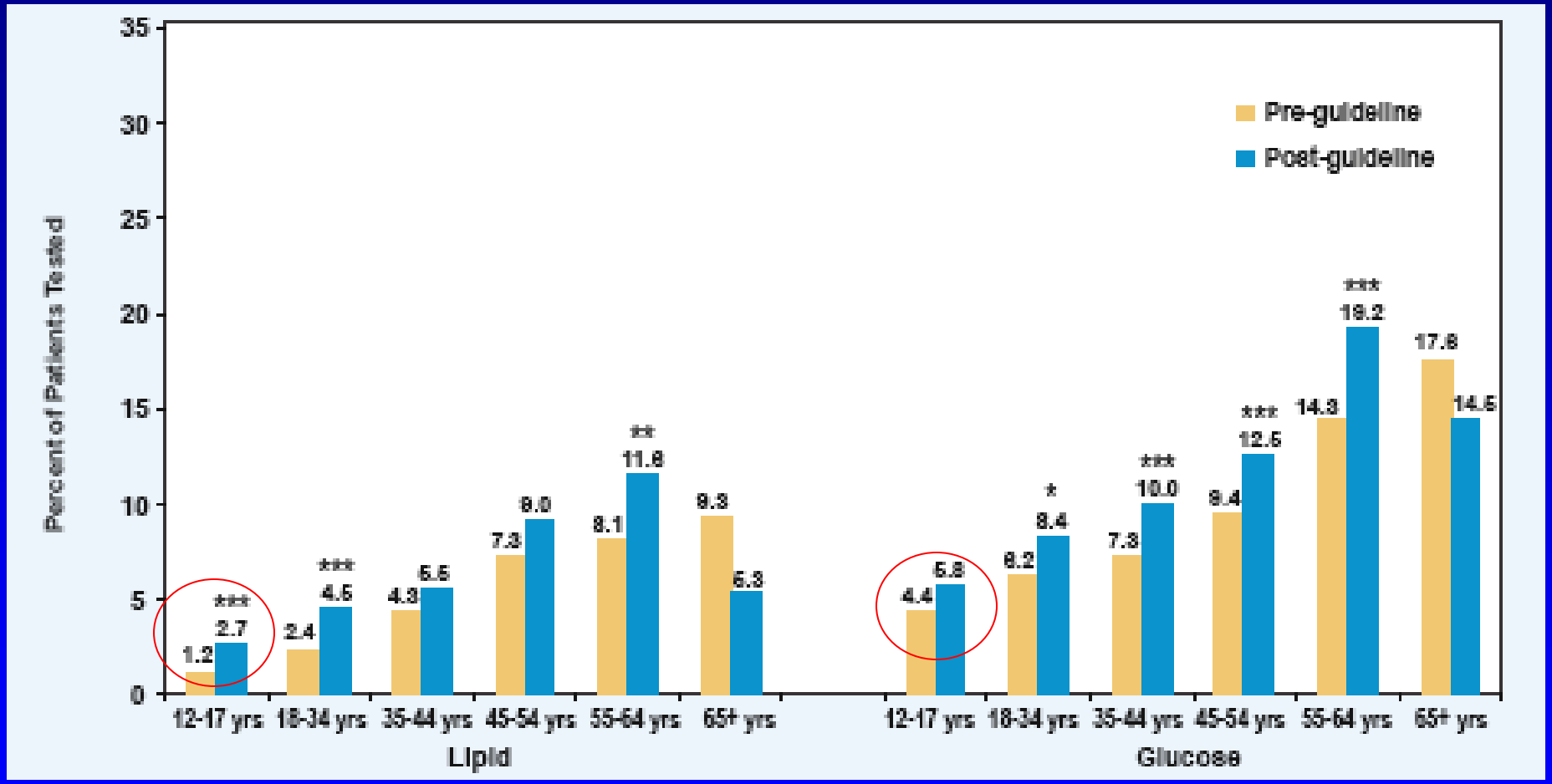
Morrato EH, et al. *J Clin Psychiatry* 2008:69:316-322.

Lipid and Glucose Monitoring Rates 2000-2007



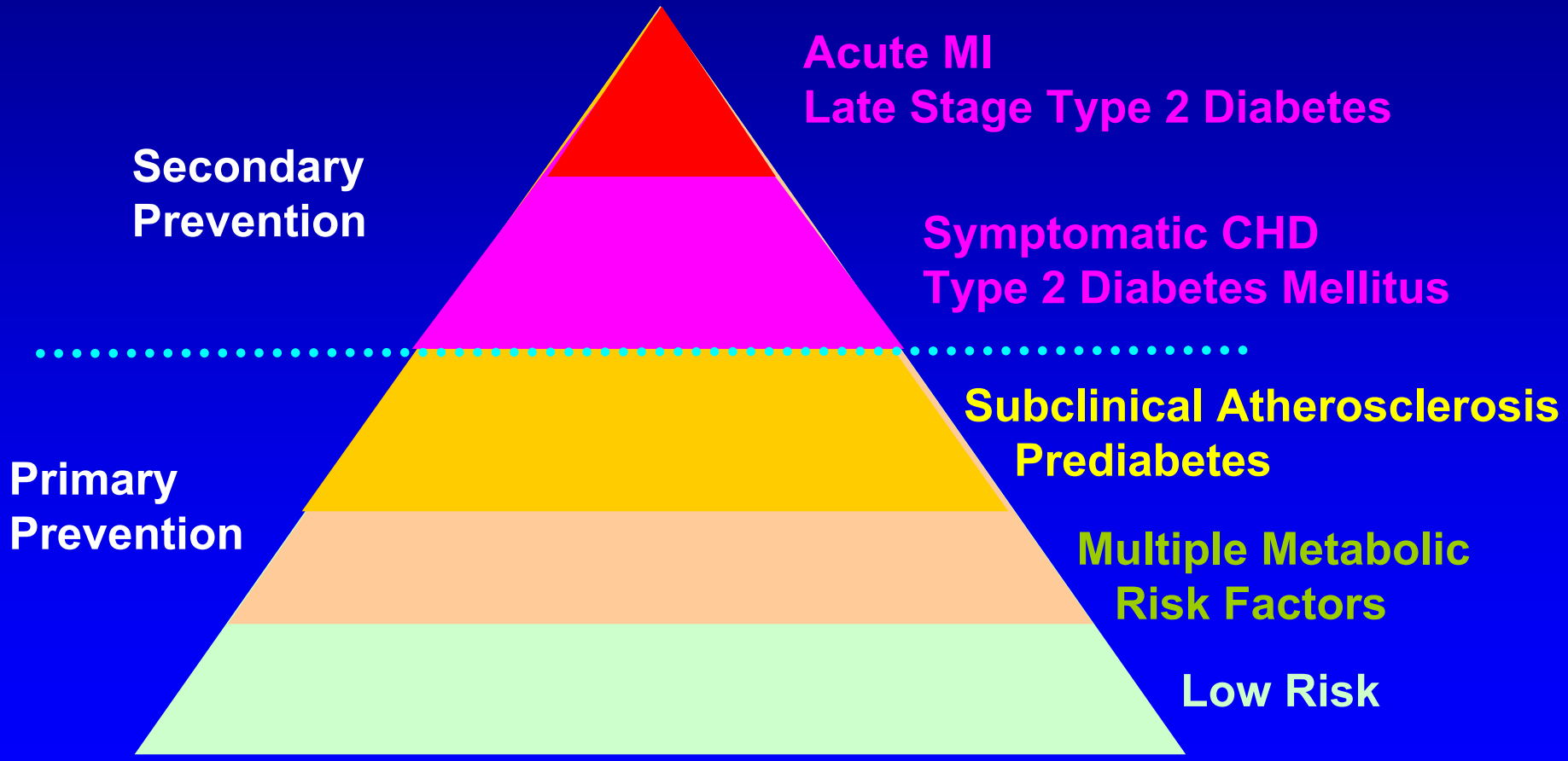
Haupt, et al. Presented at ACNP 2007. Under review.

Week 12 Cohort Comparisons for Lipid and Glucose Testing Rates by Age Category: 2000-2007



Opportunities for Cardiometabolic Prevention:

Differential impact of primary versus secondary prevention



Grundy SM et al. *Circulation.* 1998;97:1876-1887.

Beneficial Effects of Interventions to Reduce Risks of CVD

- Blood cholesterol
  10% ↓ = 30% ↓ in CHD (200-180)
- High blood pressure (> 140 SBP or 90 DBP)
  ~ 6 mm Hg ↓ = 16% ↓ in CHD; 42% ↓ in stroke
- Cigarette smoking cessation
  ~ 50% ↓ in CHD
- Maintenance of ideal body weight (BMI = 18.5-25)
  35%-55% ↓ in CHD
- Maintenance of active lifestyle (~30-min walk daily)
  35%-55% ↓ in CHD

Hennekens CH. *Circulation* 1998;97:1095-1102.
Rich-Edwards JW, et al. *N Engl J Med* 1995;332:1758-1766.
Bassuk SS, Manson JE. *J Appl Physiol* 2005;99:1193-1204.

Institute of Medicine Report: Improving Quality of Health Care for Mental and Substance-use Conditions

- Anticipate comorbidity and perform routine screening
- Collaborate with primary care and relevant specialties
  - -Formal agreements among mental, primary, and other health care providers
  - -Case management of patient care
  - -Co-location of services
  - -Delivery of integrated practices of primary and mental health care providers
  - -Adopt the model to best meet patient needs and allow for easiest transition from current structure

Board on Health Care Services. Available at www.nap.edu/books/0309100445/html/210.html. Accessed September 29, 2006.

Severe Mental Illness and Risk of Cardiovascular Disease

John W. Newcomer, MD
Charles H. Hennekens, MD

CARDIOVASCULAR DISEASE (CVD), INCLUDING CORONARY heart disease (CHD), stroke, and peripheral vascular disease, is the leading cause of death in the United States and most developed Western countries, and will remain so during the 21st century.[1] In 2004, CVD was listed as the underlying cause of death in 871 517 of all 2 398 000 deaths (36.3%), or 1 of every 2.8 deaths in the United States, with CHD accounting for 52% and stroke for 17%.[2] During the past several decades, CVD mortality has markedly declined in the United States, from more than 50% to approximately 36% as the underlying cause of death. Recent data suggest that the decline is largely due to improved diagnosis and treatment rather than to major successes in primary prevention. In contrast, patients with severe mental illnesses, such as schizophrenia, bipolar disorder, and depression that together affect 5% to 10% of the US population,[3] lose 25 or more years of life expectancy, with the majority of the excess premature deaths due to CVD, not suicide.[4] In this Commentary, we summarize disparities in CVD mortality and prevention efforts comparing the general population and individuals with severe mental illnesses and suggest the urgent need for new paradigms.

In the general US population, cigarette consumption has been the leading avoidable cause of all premature deaths, with the amount currently smoked representing a key measure of risk.[5] Smoking rates in the general population have declined from more than 50% in the 1950s to approximately 25% at present.[5] However, among patients with diagnosable mental illness, 50% to 80% are smokers and consume 34% to 44% of all cigarettes in the United States.[6] Although patients with severe mental illness are overrepresented in state programs like Medicaid, some states do not cover any form of tobacco-dependence treatment.[7] In addition, only a few states cover all treatments recommended in the US Preventive Services Task Force guidelines on smoking cessation.[7] Moreover, some states that cover tobacco-dependence treatment require cost sharing, a serious disincentive for disabled patients with fixed income.[7]

Beginning in 1972, the National High Blood Pressure Education Program[8] and, beginning in 1988, the National Cholesterol Education Program (NCEP)[8] have contributed to substantial increases in the proportions of individuals in the general population diagnosed and treated for hypertension and dyslipidemia. With respect to NCEP guidelines, secondary prevention targets are defined as those patients with prior occlusive events involving the heart, brain, or peripheral vessels, as well as other very high-risk patients with 10-year risks of a first CHD event of 20% or greater, and patients with diabetes who have equivalent risk. Although the initial goal for low-density lipoprotein cholesterol was less than 100 mg/dL, recent modifications have defined an optional goal of less than 70 mg/dL.[9] Furthermore, in patients with moderate risk, defined as 10-year risks of a first CHD event of 10% to 19%, the prior goal was 130 mg/dL but the recent modified optional goal is less than 100 mg/dL.[9] These recent modifications are based on randomized trials comparing more intensive vs usual doses of statins.[9] These trials demonstrate that patients who achieve the new optional goals with intensive statin therapy have lower risks of CHD, stroke, and vascular deaths than those who achieve the previous goals with usual statin therapy.

In the general US population during the last decade, most of the observed reductions in CVD mortality were due to improvements in the treatment of acute events and in long-term secondary prevention.[1] For example, decreases in the case fatality rate for hospitalized myocardial infarction (MI) have been attributed to increases in the acute utilization of aspirin, thrombolytics, β-blockers, and angiotensin-converting enzyme (ACE) inhibitors.[10] Subsequent long-term post-MI use of aspirin, β-blockers, ACE inhibitors, and statins, as well as therapeutic lifestyle change, have all contributed to reductions in mortality.[10]

In contrast, patients with severe mental illness who experience an acute MI are significantly less likely than the

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Corresponding Author: John W. Newcomer, MD, Departments of Psychiatry, Psychology, and Medicine, and the Center for Clinical Studies, Washington University School of Medicine, 660 S Euclid Ave, Campus Box 8134, St Louis, MO 63110 (newcomerj@wustl.edu).

general population to receive drug therapies of proven benefit, including thrombolytics, aspirin, β-blockers, and ACE inhibitors.[11] Patients with severe mental illness are also significantly less likely to undergo cardiac catheterizations and receive emergency angioplasties or coronary artery bypass graft surgery. In a study of more than 88 000 Medicare patients hospitalized for MI, mortality in the follow-up period was increased by 19% in the presence of any mental disorder and by 34% in persons with schizophrenia, with increases in mortality related to reductions in the quality of care.[11]

Regarding CVD prevention, individuals with severe mental illness have approximately 1.5 to 2 times the general population prevalence of diabetes, dyslipidemia, hypertension, and obesity.[12-14] The high prevalence of modifiable CVD risk factors can be explained in part by underdiagnosis and undertreatment and in part by contributions related to the mental illness, including effects of the medications used for treatment, some of which have unfavorable effects on various metabolic risk factors for CVD.[14-16]

Among the approximately 1500 patients with chronically treated schizophrenia entering the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) study, which was conducted at 57 US sites spanning a range of academic and public sector treatment settings, 88% of patients with dyslipidemia were receiving no lipid-lowering pharmacotherapy, 30% with diabetes were receiving no antidiabetes medications, and 62% with hypertension were receiving no antihypertensive medications.[17]

In general, screening for hyperglycemia and dyslipidemia occurs at very low rates in individuals with serious mental disorders, even in the context of treatment with medications such as antipsychotics. Evidence from controlled studies including large-scale randomized trials indicates that some but not all antipsychotic drugs can adversely affect adiposity as well as glucose and lipid metabolism.[14-16] A recent cohort study involving Medicaid claims data for 55 436 enrollees with mental illness from 4 states observed that in the 4 months before and after a new antipsychotic prescription, less than one-third of patients overall received any plasma glucose measurement and less than 10% received any plasma lipid measurement.[18] Low levels of screening are likely to contribute to observed low levels of diagnosis and treatment for modifiable CVD risk factors in this population.

The NCEP guidelines recommend that patients with diabetes be treated as aggressively as patients with prior MI or stroke who do not have diabetes.[9] However, patients with diabetes and severe mental illness are less likely than patients with diabetes and no mental illness to receive standard-of-care treatments. In a study of more than 300 000 patients with diabetes in the Veterans Administration system, the presence of mental illnesses like schizophrenia and bipolar disorder significantly increased the risk of not receiving appropriate elements of care, such as eye examinations, plasma lipid testing, and glycated hemoglobin monitoring.[19]

With respect to high-risk prevention targets, the NCEP guidelines define the metabolic syndrome as a constellation of at least 3 of 5 risk factors including abdominal obesity, low high-density lipoprotein, high triglycerides, increased blood pressure, and elevated fasting blood glucose, targeting insulin resistance-related changes in risk for CVD and diabetes.[20] The metabolic syndrome is a common condition in the US general population, especially in the presence of obesity, affecting more than 25% of all adults[21] and 50% to 60% of those with a body mass index of more than 30.[22] Such individuals have a 10-year risk of a first CHD event of approximately 16% to 18%. In the baseline evaluation of patients with chronic schizophrenia entering the CATIE study,[13] prevalence of the metabolic syndrome was approximately twice that of age-matched general population controls, accounted for by increased prevalence of all individual metabolic syndrome criteria.[13]

These considerations all contribute to the markedly reduced life expectancy of patients with severe mental illnesses, in whom the majority of excess premature deaths are due to CVD. These data indicate a crucial need for new approaches for prevention and treatment of CVD in patients with serious mental illnesses, including closer attention to choice of psychotropic drug treatment regimens and more aggressive use of monitoring and interventions to identify and reduce risk. Almost a decade ago, US Surgeon General Satcher suggested that mental health is "inextricably intertwined" with general medical health, and high-quality mental health systems must integrate medical care with psychiatric treatment.[23] Similarly, a recent Institute of Medicine report concerning the need to improve overall health care for patients with mental illness underscored the importance of integrating and co-localizing psychiatric and medical services.[24] However, the need for new approaches and better coordination of services faces short-term and long-term challenges, ranging from fiscal concerns to lack of awareness, knowledge, or comfort among clinicians, administrators, and support staff who might play key roles.

The majority of cardiovascular clinicians who provide care for patients with severe mental illness are primary care physicians or cardiologists who are likely to be less familiar than psychiatrists and other mental health care professionals with the existing situation or the potential solutions. Improvements in secondary prevention will therefore necessarily involve better education and involvement of primary care clinicians, endocrinologists, and cardiologists to reduce disparities in the level and quality of treatment services received by individuals with mental illness requiring treatment for CVD, CVD risk-equivalent conditions like diabetes, and other CVD risk factors. In the short term, substantial effort must come from the existing

mental care system, reallocating existing resources to coordinate screening, interventions including needed referrals, and required follow-up monitoring. Mental health professionals and systems need to improve working relationships with primary care and specialty collaborators, including proactive efforts to facilitate evaluation and follow-up for patients where extra communication and staffing may be needed in relation to either the mental disorder or treatment choices.

Improvements in primary prevention offer the largest potential for reducing CVD mortality in individuals with severe mental illness. Careful attention and future research should be directed at key issues, such as the appropriate role of antipsychotic and other psychotropic drug therapies less likely to adversely affect cardiometabolic risk compared with the role of adjunctive pharmacotherapies that might target excess weight, dyslipidemia, hypertension, and hyperglycemia in this population. New approaches and models that include nonpsychiatric clinicians evaluating more patients with severe mental illness will require access to supportive services and psychiatric consultations necessary to implement recommendations. Without the future collaborative efforts of primary care clinicians, endocrinologists, and cardiologists with psychiatrists, the large burden of avoidable premature mortality from CVD in patients with severe mental illness is likely to continue and increase in severity.

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Primary Care Provider Network

August 5, 2008

79.39% of Licensed Physicians Enrolled with MO HealthNet.

- 21,257 Licensed Physicians (Board of Healing Arts 2/2008 data)
- 16,875 Enrolled Physicians in MO HealthNet (MO HealthNet 7/2008 data)
- Comparison by specialty not completed as Board of Healing Arts data does not include specialty.
- Not able to capture whether enrolled MO HealthNet physicians are accepting new patients.

WHO IS A PRIMARY CARE PROVIDER

- A primary care provider (PCP) may be one of the following:
  - General/Family Practitioner
  - Obstetrics (OB)/Gynecology (GYN)
  - Pediatrician
  - Internist
  - Advance Practice Nurse

PCP to Patient Ratio

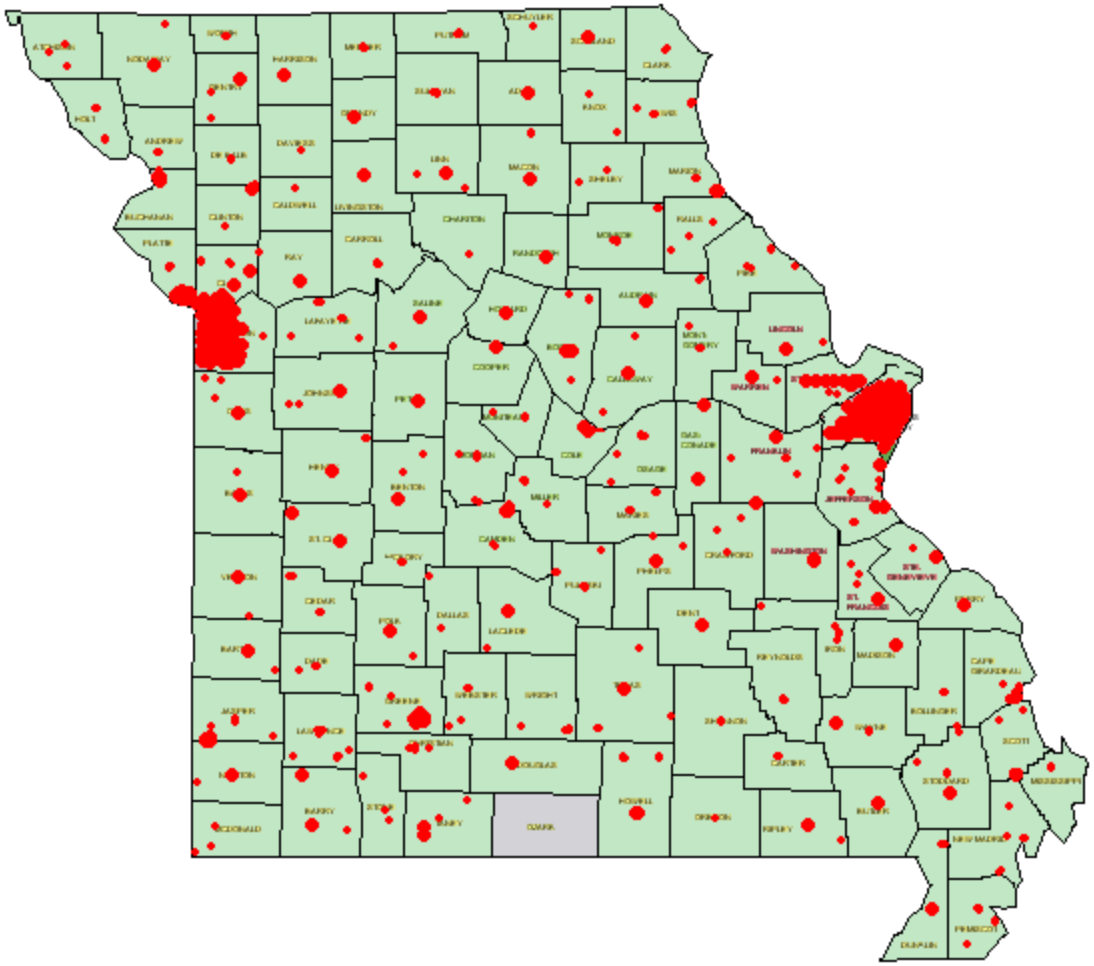
- PCP/Participant ratios in the range of 1:1500 have been used to represent adequate staffing levels in federal health programs.
  (Refer to FAQs at http://www.raconline.org/info_guides/clinics/fqhcfaq.php)

MO HealthNet Fee-for-Service Program
1:53 PCP to Patient Ratio

- 8,487 PCPs Enrolled in MO HealthNet
  - 7,408 Physicians
  - 1,079 Nurse Practitioners
- 453,417 Average Fee-for-Service MO HealthNet Participants (SFY 2008 through April 2008)

Active Primary Care Providers

- Looking at claims data for the last 12 months:
  - 3,755 PCPs submitted claims for 10 or more office visits: PCP-to-Patient Ratio of 1:121
  - 2,091 PCPs submitted claims for 50 or more office visits: PCP-to-Patient Ratio of 1:217
  - 1,333 PCPs submitted claims for 100 or more office visits: PCP-to-Patient Ratio of 1:340



There are no enrolled PCPs in Ozark county. However, there are two (2) enrolled Rural Health Clinics (Gainesville and Theodosia, MO).

	Nurse Practitioner	Fam/Gen Practice	Internal Medicine	OB/GYN	Pediatrics	
ADAIR	18	40	19	5	2	84
ANDREW	0	3	1	0	0	4
ATCHISON	6	4	0	0	0	10
AUDRAIN	3	15	13	2	3	36
BARRY	2	21	5	2	0	30
BARTON	0	6	1	1	0	8
BATES	3	6	3	0	0	12
BENTON	1	6	0	0	0	7
BOLLINGER	1	3	1	0	0	5
BOONE	41	89	162	21	75	388
BUCHANAN	29	38	57	11	12	147
BUTLER	20	29	36	8	8	101
CALDWELL	1	2	1	0	0	4
CALLAWAY	2	27	6	2	0	37
CAMDEN	2	24	22	4	4	56
CAPE GIRARDEAU	42	48	71	14	27	202
CARROLL	0	2	2	0	1	5
CARTER	1	4	0	1	0	6
CASS	1	23	3	0	3	30
CEDAR	0	6	0	2	0	8
CHARITON	2	0	0	0	0	2
CHRISTIAN	7	11	1	0	2	21
CLARK	0	3	0	0	0	3
CLAY	12	56	83	20	15	186
CLINTON	3	9	3	1	0	16
COLE	17	59	39	17	15	147
COOPER	0	9	0	0	0	9
CRAWFORD	3	12	7	2	0	24

	Nurse Practitioner	Fam/Gen Practice	Internal Medicine	OB/GYN	Pediatrics	
DADE	0	3	1	2	0	6
DALLAS	2	1	0	0	0	3
DAVIESS	0	1	0	0	0	1
DeKALB	1	2	0	0	1	4
DENT	1	8	4	0	1	14
DOUGLAS	1	5	1	0	0	7
DUNKLIN	5	14	10	3	5	37
FRANKLIN	8	39	23	6	11	87
GASCONADE	1	9	0	0	0	10
GENTRY	2	8	1	0	1	12
GREENE	96	143	174	49	62	524
GRUNDY	4	7	1	2	0	14
HARRISON	2	3	0	0	0	5
HENRY	4	22	4	5	4	39
HICKORY	0	1	1	0	0	2
HOLT	4	4	1	0	0	9
HOWARD	3	5	0	0	0	8
HOWELL	14	31	13	6	4	68
IRON	1	5	0	0	2	8
JACKSON	226	212	419	96	336	1,289
JASPER	27	47	55	9	10	148
JEFFERSON	15	36	33	8	7	99
JOHNSON	8	11	5	4	2	30
KNOX	1	2	0	0	0	3
LACLEDE	2	6	0	0	1	9
LAFAYETTE	7	15	1	0	0	23
LAWRENCE	3	13	4	1	0	21
LEWIS	2	3	0	0	0	5
LINCOLN	2	10	3	2	4	21
LINN	2	10	3	1	0	16
LIVINGSTON	1	9	4	2	0	16

	Nurse Practitioner	Fam/Gen Practice	Internal Medicine	OB/GYN	Pediatrics	
MACON	2	7	0	0	0	9
MADISON	2	4	2	0	2	10
MARIES	3	4	0	0	0	7
MARION	7	17	15	4	5	48
McDONALD	0	6	0	1	0	7
MERCER	1	3	0	0	0	4
MILLER	2	7	0	0	0	9
MISSISSIPPI	2	2	0	0	0	4
MONITEAU	0	3	1	0	0	4
MONROE	0	4	0	1	0	5
MONTGOMERY	1	5	2	0	0	8
MORGAN	1	14	0	0	0	15
NEW MADRID	2	6	5	0	0	13
NEWTON	36	28	56	12	13	145
NODAWAY	5	13	4	3	2	27
OREGON	1	0	0	0	0	1
OSAGE	2	9	0	0	0	11
OZARK	0	0	0	0	0	0
PEMISCOT	1	10	8	4	3	26
PERRY	4	8	1	2	1	16
PETTIS	5	16	9	4	3	37
PHELPS	12	17	11	2	2	44
PIKE	0	8	1	0	0	9
PLATTE	2	16	3	0	4	25
POLK	4	28	4	1	3	40
PULASKI	3	6	0	0	1	10
PUTNAM	1	3	1	0	0	5

	Nurse Practitioner	Fam/Gen Practice	Internal Medicine	OB/GYN	Pediatrics	
MACON	2	7	0	0	0	9
MADISON	2	4	2	0	2	10
MARIES	3	4	0	0	0	7
MARION	7	17	15	4	5	48
McDONALD	0	6	0	1	0	7
MERCER	1	3	0	0	0	4
MILLER	2	7	0	0	0	9
MISSISSIPPI	2	2	0	0	0	4
MONITEAU	0	3	1	0	0	4
MONROE	0	4	0	1	0	5
MONTGOMERY	1	5	2	0	0	8
MORGAN	1	14	0	0	0	15
NEW MADRID	2	6	5	0	0	13
NEWTON	36	28	56	12	13	145
NODAWAY	5	13	4	3	2	27
OREGON	1	0	0	0	0	1
OSAGE	2	9	0	0	0	11
OZARK	0	0	0	0	0	0
PEMISCOT	1	10	8	4	3	26
PERRY	4	8	1	2	1	16
PETTIS	5	16	9	4	3	37
PHELPS	12	17	11	2	2	44
PIKE	0	8	1	0	0	9
PLATTE	2	16	3	0	4	25
POLK	4	28	4	1	3	40
PULASKI	3	6	0	0	1	10
PUTNAM	1	3	1	0	0	5

	Nurse Practitioner	Fam/Gen Practice	Internal Medicine	OB/GYN	Pediatrics	
RALLS	1	2	0	0	0	3
RANDOLPH	4	11	11	2	3	31
RAY	3	6	2	0	0	11
REYNOLDS	1	1	2	0	0	4
RIPLEY	1	7	2	0	2	12
SALINE	1	20	9	4	2	36
SCHUYLER	0	1	0	0	0	1
SCOTLAND	1	9	1	2	1	14
SCOTT	9	20	20	4	7	60
SHANNON	0	1	1	0	0	2
SHELBY	1	1	0	0	0	2
ST CHARLES	22	66	126	39	33	286
ST CLAIR	4	7	4	1	0	16
ST FRANCOIS	15	45	28	8	6	102
ST LOUIS (City)	116	197	794	141	381	1,629
ST LOUIS (County)	75	236	629	92	194	1,226
STE GENEVIEVE	0	2	3	0	2	7
STODDARD	5	11	8	1	2	27
STONE	2	8	3	0	0	13
SULLIVAN	2	2	0	0	0	4
TANEY	31	130	47	12	13	233
TEXAS	4	10	4	1	0	19
VERNON	3	22	5	1	2	33
WARREN	3	7	2	0	0	12
WASHINGTON	4	5	1	0	1	11
WAYNE	3	5	0	0	0	8
WEBSTER	6	6	0	0	0	12
WORTH	0	1	0	0	1	2
WRIGHT	1	4	1	0	0	6
Total:	1,079	2,327	3,123	651	1,307	8,487

Personal Health Records

MO HealthNet

Oversight Committee

August 5, 2008

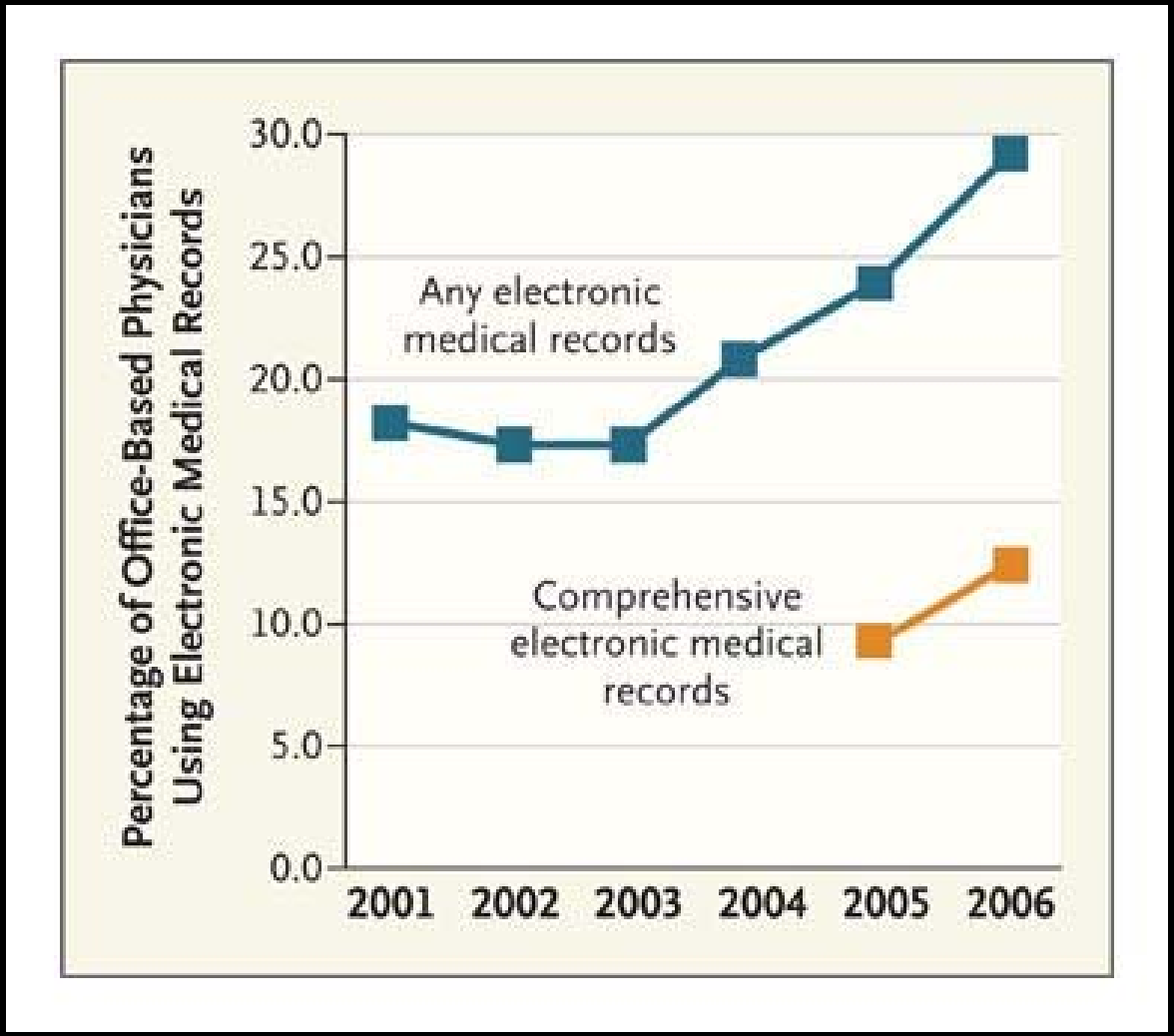
Personal Health Record

- Individual health information defined by that individual
- Web pages for patients to enter their data manually
- Employer/payer portal for claims data
- Physician-hosted portal giving access to personal EHR

Personal Health Record Aims

- **Move beyond the “chart on the shelf” standard**
- **Give patients better access to their own health care data**
- **Enable patients to have more control over their own information**

Percentage of Office-Based Physicians in the United States Using Electronic Medical Records, 2001-2006



Steinbrook R. N Engl J Med 2008;358:1653-1656

Functionalities of an Electronic Health Record System, According to the Institute of Medicine

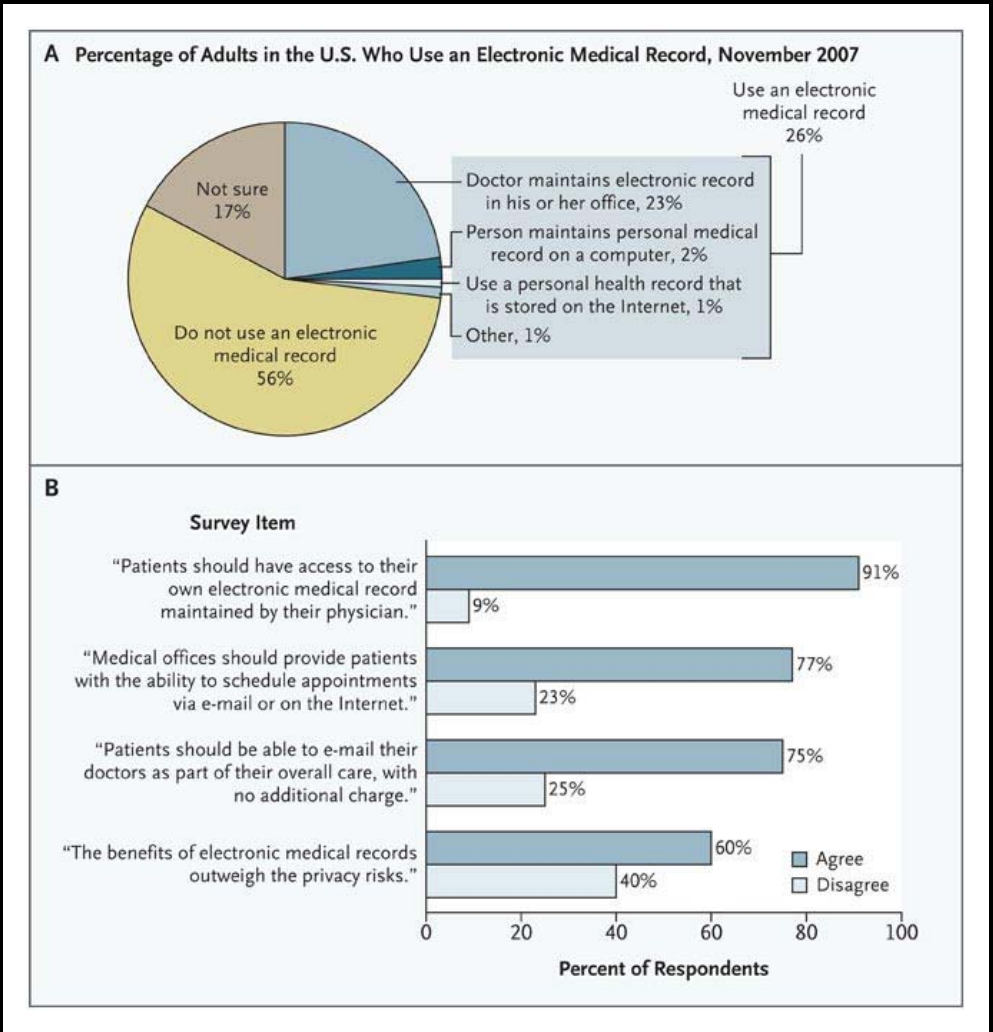
Table 1. Functionalities of an Electronic Health Record System, According to the Institute of Medicine.

Core Functionalities*	Other Functionalities
Health information and data	Electronic communication and connectivity
Results management	Patient support
Order entry and support	Administrative support
Decision support	Reporting and population health management

* These categories were determined by an advisory panel to the federal government's HIT Adoption Initiative to be the core functionalities of an electronic health record.

Blumenthal D and Glaser J. N Engl J Med 2007;356:2527-2534

Use of Electronic Medical Records in the United States, November 2007



Steinbrook R. N Engl J Med 2008;358:1653-1656

Precautions

- Sharing or sale of personal information
- Comprehensive privacy policy
- Allowed advertising
- Fee structure

Selected Sites of Interest

- **Dossia (www.dossia.org)**
- **Microsoft HealthVault (www.healthvault.com)**
- **Google Health (https://www.google.com/health**
- **Myhealthfolders (https://myhealthfolders.com/)**

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Tectonic Shifts in the Health Information Economy

Kenneth D. Mandl, M.D., M.P.H., and Isaac S. Kohane, M.D., Ph.D.

In a recent shift in the health information landscape, large corporations are seeking an integral and transformative role in the management of health care information. The mechanism by which this transformation is likely to take place is through the creation of computer platforms that will enable patients to manage health data in personally controlled health records (PCHRs). Two types of large corporations are involved. Technology companies such as Google and Microsoft see business opportunities,[1] whereas Fortune 100 companies in their role as employers[2,3] see efficiencies and cost savings when patients can securely store, access, augment, and share their own copy of electronic health information. Though this shift in the locus of control of health information is driven largely by a need to provide assistance with clinical care processes, it will also profoundly affect the biomedical research enterprise. We illustrate this shift with a two-part scenario in which a patient fills her PCHR with data from multiple sites of care and then participates in research.

The first part of this scenario involves information integration. The patient, who has inflammatory bowel disease, is treated at a gastroenterology practice and has had an inpatient admission at one hospital, a visit to an emergency department at another hospital, and test results at a laboratory. She logs into her hosted PCHR at a secure Web site. Since she has established subscriptions to automatic updates from each of these clinical entities, her PCHR is current with copies of those data.

The PCHR enables the patient to authorize access to information (views or even copies of the record) to others, including clinical providers, family members, health care proxies, and researchers, and to intelligent software agents such as a disease-management tool.

The second part of this scenario involves participation in research. Through her PCHR interface, the patient signs up for notification of open research studies on inflammatory bowel disease. Her eligibility is determined by a combination of her demographic characteristics, responses to a brief survey, and the clinical contents of her PCHR (e.g., diagnoses and medications). Five study matches are returned, and she chooses to participate in two. The first match is a randomized clinical trial of a medication with local enrollment at the hospital where she visited the emergency department. She makes an appointment and enrolls

in person. The second study is a noninterventional prospective cohort study from an academic medical center located on the opposite coast. There is a small financial incentive to participate. The patient enrolls in this study with an online consent, agreeing to make select contents of records available to study investigators on an ongoing basis and to answer monthly online questionnaires.

This scenario anticipates a new scale of data liquidity, a gush of information from clinical settings — electronic health records, laboratory information systems, and medication-management systems — into PCHR platforms where health care consumers independently decide about subsequent disclosure. If others follow the lead of major health care institutions such as New York–Presbyterian Hospital, which has committed to allow patients to transfer electronic health information into the Microsoft HealthVault personal health record,[4] companies that are new to health care may ultimately house and manage an information repository far larger than any in the academic sector. If the project is successful, patients at New York–Presbyterian Hospital will have the opportunity to individually control a copy of their own data. Collectively, they will control a population database hosted by a third party (at New York–Presbyterian Hospital it is Microsoft, and at Cleveland Clinic it is Google). This database will potentially reflect the entire scope of the hospital's services and outcomes, and patients will determine the parties with whom they subsequently share their data.

Such qualitative and quantitative changes in the health information economy will certainly affect our biomedical research system in ways that cannot be fully predicted. We have produced the reference application for this model, known as the Indivo system,[5,6] and we continue to pursue PCHR-based population-level studies within our academic health center.[7,8] On the basis of our experience, we consider the potential effects of the success of the PCHR model on the clinical research enterprise. We hope that the clinical research community can respond to these changes in an informed and thoughtful manner.

THE INFORMATION LANDSCAPE

PCHRs are a special instance of personal health records[9,10] that include portals. Portals are closed systems that allow patients to view their own clinical data in institutional electronic health record systems or their claims data in payer systems.[11] We contend that PCHRs are a disruptive innovation that inverts the current approach to medical records in that they are created by and reside with patients who grant permission for their use to institutions, clinicians, researchers, public health agencies, and other users of medical information. PCHRs use the subscription model,[6] which facilitates consumer-driven data aggregation (Fig. 1). In some ways, this model, like a health care version of the financial Quicken product, advances the flow of information far more than models requiring interinstitutional data-sharing agreements. Under the subscription model, data from two competing health care networks may reside in the same PCHR without cumbersome agreements between those two networks. The patient asserts a claim to his or her data at each network independently. This consumer-driven model of data aggregation may promote data liquidity far more than competing approaches, such as health information exchanges,[12] which require centralized management of data-sharing agreements between networks and institutions.

On patient approval, companies, governmental and nongovernmental organizations, and health centers can create applications that connect through a programming interface to the major PCHR platforms. These applications should make a PCHR a benefit rather than a chore by enabling services such as the interpretation of laboratory tests, referrals, the provision of customized medical advice, and disease management. How similar this interface (Fig. 1) will be across the major PCHR platforms and how nurturing the various PCHR purveyors will be of patient-directed sharing of data across these platforms remain to be seen.

Clinical research has primarily been the province of and under the control of the health care systems where the patients have received their care. Notable exceptions include studies with broad-based recruitment strategies such as the Framingham Heart Study, which identified subjects through a geographic community, and the Nurses Health Study, which recruited subjects through professional channels. Similarly, PCHRs present a diffusible and scalable mechanism for ready and direct recruitment of cohorts across the boundaries of health systems, managed-care networks, and academic medical centers.

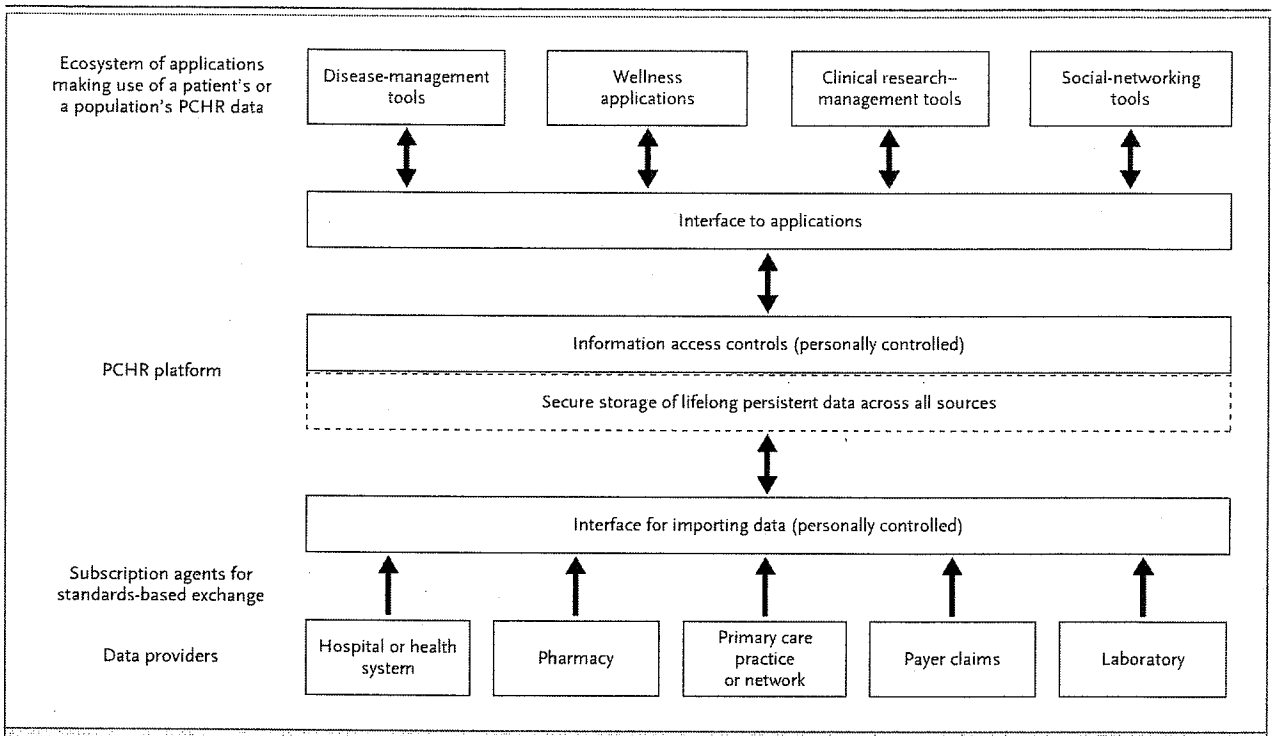

Figure 1. The Platform Model of Personally Controlled Health Records (PCHRs).

KEY ISSUES FOR CLINICAL RESEARCH

If the platform model proves to be successful, the largest, richest, and most up-to-date health care databases will reside on the servers of the companies providing the PCHR platform. If PCHRs are as successful as their proponents project, even large programs such as the National Institutes of Health's multibillion-dollar Clinical and Translational Science Award program may produce smaller, less complete data sets.[13,14] Extensive clinical data sets used by public health agencies, such as those of the Centers for Disease Control and Prevention (CDC) for health surveillance[15] and the Food and Drug Administration (FDA) for the postmarketing surveillance of pharmaceuticals,[16] may have less population coverage and less complete and specific information than those that could reside in PCHR repositories if they receive widespread uptake and are kept up to date.

A number of key questions arise. For instance, do the PCHR service providers themselves have a research mission? Do they intend to look across PCHRs to make observations about population health or the health of particular cohorts of patients — for example, patients taking a particular medication? If so, who will have access to the data, for what purposes, and under what sort of regulation? PCHR companies should all clearly define whether and how they will de-identify or aggregate data[17,18] and how or whether secondary uses of the data sets will be allowed or limited.

Academic medical centers may find themselves struggling to understand these implications before following the lead of New York–Presbyterian Hospital and Cleveland Clinic in making health-system data available to a PCHR company. If they empower their patients by enabling the fluid transfer of health information, does this mean their own researchers will have access to patient data that span institutions and include annotations and supplementary information provided by patients? How would this access be determined? One approach would be to allow individual patients to strictly control access to their data by third-party researchers. As in the scenario above, a consumer might choose to connect her PCHR to a software application hosted by a clinical research organization that enables her to enroll in a clinical trial of a medication. She also might

connect to an FDA postmarketing surveillance program enabling her to contribute her medication, symptom, and outcome data. A consumer also might choose to share information about influenza vaccinations and influenza-like illness with the CDC to augment national surveillance, prevention, and control efforts. Alternatively, she might link her record to a social-networking site, share her data, and engage with patients who have similar conditions.

Another approach would be for the platform company to directly extract data, perhaps de-identified, by polling across PCHRs, removing the patient as the intermediary in the decision. The latter approach is not consistent with a fully personally controlled model[5] (e.g., in Fig. 1, the layer for information access controls would include control by the PCHR platform company in addition to control by the health care consumer), but it could well be chosen by some commercial vendors. Issues with respect to information privacy are discussed below.

Neither tactic provides the institutional control that academic medical centers, health maintenance organizations, and health networks currently have over their patients' health records. There is a reasonable argument that such control has been parochial and has created inefficiencies in fostering scientific discovery[19,20] and in delivering high-quality clinical care. Wide-scale sharing of meticulously collected research data is largely still a work in progress.[21] Nonetheless, if the pendulum swings the other way, an entire generation of clinical researchers in training will find themselves with second-class or no access to the best research resources. For example, a PCHR provider and a partner organization could conceivably, with the best of intentions, generate the largest genetically characterized and phenotyped cohorts, using the PCHR as a vehicle. Indeed, many researchers might have an incentive to work with these PCHR companies to minimize the per capita administrative overhead for their studies or to market research studies directly to consumers with PCHRs.

Whether these new companies will gain access to patients to engage them in prospective studies or even formal therapeutic trials is unknown. Academic medical centers will need to assess whether they will be competing with PCHR vendors even on a local level for the attention and participation of their own patients in research. Public health agencies will need to understand the structure and value of these new sources of population health data. To the degree that commercial interests have been fast in moving into this new era of management of personalized medical records, personalized medical advertisement, and personalized decision support, regulatory authorities and academic medical centers have been slow in moving their focus beyond the challenges of individual cohort studies and controlled trials.

REGULATION OF PCHR-BASED RESEARCH

Our society should make an informed decision about how the goals of improving health care, and the twin beacons of maximizing patient autonomy while minimizing health risk, should be served in the context of a seismic change in the locus of control, curation, interpretation, and guardianship of patient information. The companies providing PCHRs are not covered entities under the Health Insurance Portability and Accountability Act (HIPAA). Unless this changes, a group of researchers may emerge with identical questions but with restrictions and safeguards quite different from those of their colleagues in academic health centers. For example, within HIPAA-covered entities, there are very clear definitions of what constitutes a limited data set and a de-identified data set[22] and what the substantial penalties are for infractions in their use and management.

Consumers navigating the opportunities to share and potentially even monetize their data for research deserve a guidepost such as a certification or a seal of approval with regard to services, software, and projects from a trusted authority. Protections for research subjects in the new, personalized health information economy will arise through a mixture of federal regulation (perhaps, for example, the extension of HIPAA), contractual relationships, certification, and educational programs. Progress in this regard has been slow, even as PCHRs are deployed. Bills introduced in Congress in 2006 and 2007[23,24] would dictate the structure, governance, and financing of personal health records and PCHRs. However, no legislation has been enacted. The Department of Health and Human Services currently funds a private, nonprofit organization to certify electronic health records with respect to interoperability, quality, and privacy protection.[25] Whether this en-

tity will be expanded to certify PCHRs and the software agents and services that connect to PCHRs, whether the industry will attempt to self-regulate or to certify PCHRs, and whether federal laws or regulations will be enacted or amended remain to be seen. Given the posited right of patients to contribute or sell their own data,[7] consumer protections will need to balance a new degree of patient autonomy with transparency and education with regard to the responsibility and risks of data stewardship. For example, they will need to strike a balance between patient control and a paternalistic protection against coercion and false claims made across the multiple channels of communication that are possible between these new research entities and health care consumers. Since some PCHR platforms may allow advertising based on the content of personal information, including Internet search terms, lessons may be derived from experience with federal oversight of direct-to-consumer advertising of pharmaceuticals.[26]

Academic medical centers, federal regulators, and PCHR service providers will probably need to collaborate to ensure that institutional review boards or newly configured oversight bodies can establish protocols for recruiting subjects through PCHRs. Exploratory multistakeholder meetings have already begun.[27,28] Creative and effective online consent processes must be developed and used, since globalization of the research enterprise requires electronic means of researcher–subject interaction. Such consent must reveal clearly and emphatically how identified and de-identified patient data will be handled.

OPPORTUNITIES AND CHALLENGES

We see five important hurdles to overcome if PCHRs are to be used to the full extent of their potential. First, the ready exchange of richer clinical data requires broad agreement on standard data formats. It is encouraging that an emerging consensus[29,30] is dictating how information is imported to, or exported from, the PCHR — including data-exchange standards recently recognized by the Secretary of Health and Human Services.[31] Second, entities controlling clinical data systems (e.g., hospitals and practices) have yet to commit to make data available electronically to patients, and to do so, they need cooperation from their information-system vendors. Third, under the Clinical Laboratory Improvement Amendments (CLIA),[32] laboratories must release test results only to authorized persons, which, depending on individual state laws and regulations, may not always include the patient. Hence, in many circumstances, the current form of CLIA can be interpreted as preventing the communication of laboratory results directly to patients.[33] We think that patients have a fundamental right to view and distribute their own data. Fourth, vast amounts of medical information are still stored on paper. Although saving scanned electronic images of paper records in a PCHR is an important step forward, the full promise of PCHRs will not be realized until there is a greater adoption of electronic health records in health care practice settings[34] that make structured data available for analysis and computation. Fifth, since in the United States there is no universal patient identifier[35] or set of business processes to enable ready authentication of the consumer across the health care system,[36] new approaches to establishing identity and trust are needed.[37]

Despite these challenges, many consumers with PCHRs will soon control a valuable resource — an integrated copy (possibly the only such copy) of their health care information across sites of care and over time as well as the annotations and supplementary information they provide. Under favorable conditions, consumers will benefit considerably as new business models develop, enticing them to engage in research, establishing communication channels between researchers and PCHR owners, and competing for consumer attention over those channels. Just as medicine emerged stronger after Abraham Flexner's 1910 report on medical education,[38] our health care system can be made not only safer for patients but more agile in pursuing translational research if we recognize and help steer these shifts in the medical information economy.

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nies. The core PCHR software produced under this contract is made freely available as part of the open-source code base of Indivo. No other potential conflict of interest relevant to this article was reported.

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Healthcare Information Technology Report Update

August 5, 2008

History

- Report was due January 1, 2008
- Letters dated March 21, 2008 went to Governor Matt Blunt, Honorable Michael Gibbons, and Honorable Rod Jetton indicating funding for the report was before the General Assembly
- Funding was provided in the Supplemental Budget bill

Plan for Report

- MHD contracted with Fox Systems, Inc.
- Build upon existing reports:
  - Missouri Healthcare Information Technology Task Force Final Report, September 2006 www.dhss.mo.gov/HealthInfoTaskForce/Report.pdf
  - The Transformation of Missouri Medicaid to MO HealthNet, December 2006, www.dss.mo.gov/mis/mcdtransform.pdf

Report Elements from §208.978

- Develop and Report and Deliver to the Governor and General Assembly
- Including but not limited to:
  1) Reviewing the current status of healthcare information technology adoption by the healthcare delivery system in Missouri
  2) Addressing the potential technical, scientific, economic, security, privacy, and other issues related to the adoption of interoperable healthcare information technology in Missouri

Report Elements from §208.978

3) Evaluating the cost of using interoperable healthcare information technology by the healthcare delivery system in Missouri
4) Identifying private resources and public/private partnerships to fund efforts to adopt interoperable healthcare information technology
5) Exploring the use of telemedicine as a vehicle to improve healthcare access to Missourians

Report Elements from §208.978

6) Identifying methods and requirements for ensuring that not less than 10% of appropriations within a single fiscal year shall be directed toward the purpose of expanding and developing minority owned businesses that deliver technological enhancements to healthcare delivery systems and networks

7) Developing requirements that ensure not more than 25% of appropriations from the healthcare technology fund in any fiscal year shall be contractually awarded to a single entity

Report Elements from §208.978

8) Developing requirements to ensure the number of contractual awards provided from the healthcare technology fund shall not be fewer than the number of Missouri Congressional districts
9) Recommending best practices or policies for state government and private entities to promote the adoption of interoperable healthcare information technology by the Missouri healthcare delivery system

Project Objectives

- Conduct follow-up survey and present findings
- Research and report on national Health Information Exchange initiatives, issues, and barriers
- Determine cost of adopting interoperable health care technology systems
- Identify private resources and private/public partnerships to fund interoperable technology
- Prepare a report that meets requirements of §208.978

Report Release Timeline – For Discussion

- Draft report review and revision by MHD and Department – in process
- Email to Oversight Committee members for review and recommendations -- return by October 1
- Consider October teleconference among Oversight Committee members for final discussion
- Report release November 2008

Four-Year Plan to Reach Reimbursement Parity

August 5, 2008

Marga Hoelscher, CPA MPA
Deputy Division Director, Finance
MO HealthNet Division

Requirements

- Section 208.152.1(23) requires the MO HealthNet Division to provide General Assembly with four-year plan to reach parity with Medicare reimbursement rates and third-party payer average dental reimbursement rates.
- Amounts to be included in the annual budget request

FY 2009 Average Reimbursements

	Percentage of Medicare
Ambulance	45%
Audiology	65%
Dental	42%
Durable Medical Equipment	95%
Optical	55%
Physician	65%
Rehabilitation Center Therapy	25%

Program Areas Excluded

- Comprehensive Day Rehab
- Home Health
- Hospice
- NEMT
- Pharmacy
- School-Based Therapy
- Cost-Based Reimbursements
  - Hospitals
  - Nursing Facilities
  - State Institutions
  - Federally Qualified Health Center (FQHC)
  - Rural Health Center (RHC)

Parity Comparisons

- Medicare rate if available
- Other state rates with similar Medicaid reimbursement methodology
  - Arkansas
  - Iowa
  - Oklahoma
- Medical care CPI target rate

Projected Costs of Parity Over Life of Plan

	Medicare Comparison	State Proxy	CPI	Dental	Vaccine for Children	Total Cost
Cost	$213 mil	$10.3 mil	$1.5 mil	$59.0 mil	$9.8 mil	$293.9 mil
Savings	($7.5) mil	($1.5) mil	($0) mil	($0.0) mil	($0.0) mil	($9.0) mil
Net Costs	**$205.8 mil**	**$8.8 mil**	**$1.5 mil**	**$59.0 mil**	**$9.8 mil**	**$284.9 mil**
State Share	$78.3 mil	$3.2 mil	$.5 mil	$21.3 mil	$3.5 mil	**$106.8 mil**
Percent of Total Cost	**72.2%**	3.1%	.5%	20.7%	3.5%	

FY 2010 Annual Request

	FY 2009 % Medicare Achieved	Target %	General Revenue Required	Total Funds Including Federal Required
Ambulance	45%	60%	$3.1 mil	$8.1 mil
Audiology	65%	74%	$.05 mil	$.13 mil
Dental	42%	57%	$5.5 mil	$15.2 mil
Durable Medical Equipment	95%	96%	$.4 mil	$1.0 mil
Optical	55%	66%	$1.0 mil	$2.5 mil
Physician	65%	75%	$16.7 mil	$44.2 mil
Rehab Treatment Center	25%	44%	$.1 mil	$.4 mil
Total			$26.7 mil	$71.3