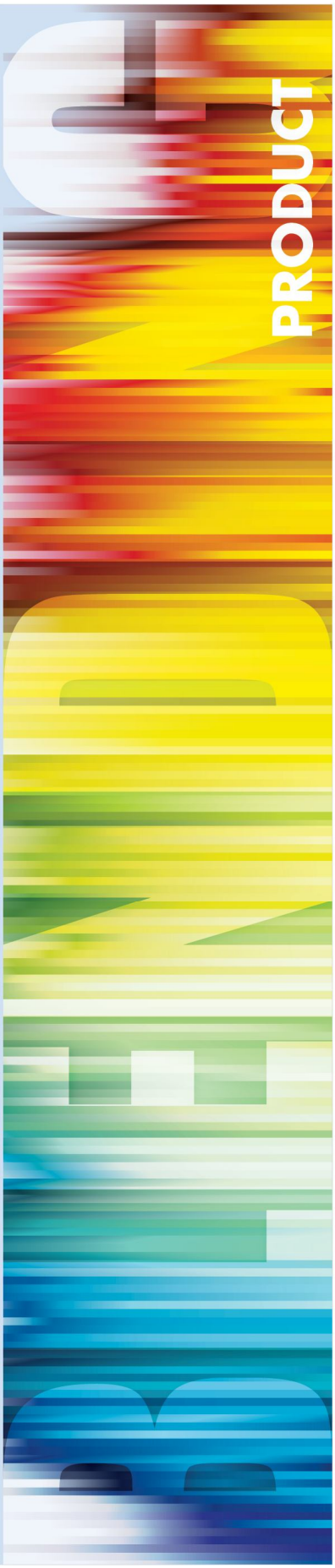
blending initiative
NIDA • SAMHSA

BUPRENORPHINE TREATMENT FOR YOUNG ADULTS



Buprenorphine Treatment for Young Adults

Findings and Strategies from a NIDA Clinical Trials Network Study

Table of Contents

Buprenorphine Treatment for Young Adults
Findings and Strategies from a NIDA Clinical Trials Network Study

Background Information: NIDA/SAMHSA Blending Initiative

The National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) have created a partnership to disseminate information to the addiction treatment field. Through the NIDA-SAMHSA Blending Initiative, special groups called Blending Teams meet to design dissemination strategies and develop research-based products. Members of these Blending Teams come from the NIDA-funded National Drug Abuse Treatment Clinical Trials Network (CTN) and the SAMHSA-funded Addiction Technology Transfer Center (ATTC) Network.

In the year 1999, NIDA created the National Drug Abuse Treatment Clinical Trials Network (CTN). The CTN conducts studies of behavioral, pharmacological, and integrated behavioral and pharmacological treatment interventions in rigorous, multi-site clinical trials to determine effectiveness across a broad range of community-based treatment settings and diverse patient populations. As the CTN research is completed, NIDA researchers work with representatives from the ATTC network to provide the results and strategies for implementing these findings into clinical settings. This will decrease the time it takes for research to be incorporated into treatment settings and will thereby to improve the quality of drug abuse treatment throughout the country.

Focus on Buprenorphine

In 2002, tablet formulations of buprenorphine were approved by the Food and Drug Administration (FDA) for the treatment of opiate addiction. Additionally, the CTN completed several clinical trials related to specific uses of this medication. One of these trials looked at strategies for medically-assisted withdrawal from opioids using buprenorphine with young adults. This training presents the relevant background for the study as well as the procedures and results. The training ends by examining the implications of the results of the study and how these results might shape the way that services are provided in real-world clinical settings.

The Study Participants

The CTN Trial allowed for recruitment of adolescents and young adults ages 14-21. However, the number of participants under the age of 18 was very small (less than 18%). This makes it impossible to generalize results to this age group. Therefore, the implications for the study results will focus on the young adult population (ages 18-21).

However, statistics and other background information will be presented for both adolescents and young adults. In order to fully contextualize the nature of the problem, it is important to understand how adolescents are using opioids and how their use compares to the young adult population. As information is presented, clear description of the population (i.e., adolescents ages 14-17, young adults ages 18-21, or both) being discussed will be made as the information is being presented during the training.

Blending Team Members

- Thomas Freese, Ph.D. – Chair – Pacific Southwest ATTC
- Michael Bogenschutz, M.D. – CTN Southwest Node
- Thomas Durham, Ph.D. – Central East ATTC
- Shannon Garrett, M.S.W., L.G.S.W., CSC-AD – CTP Mid-Atlantic Node
- Laura McNicholas, M.D., Ph.D. – CTN Delaware Valley Node
- Beth Rutkowski, M.P.H. – Pacific Southwest ATTC
- Susan Storti, Ph.D., R.N. – Synergy Enterprises, Inc.
- Geetha Subramaniam, M.D. – CTN Mid-Atlantic Node
- Pamela Waters, M.Ed., C.A.C., C.P.P. – Southern Coast ATTC

What Does the Training Package Contain?

- PowerPoint Training Slides
- Trainer's Guide with detailed instructions for how to convey the information and conduct the interactive exercises.

What Does This Trainer's Manual Contain?

The objectives of this Module are to:

1) Provide a brief overview of opioid use among adolescents and young adults;
2) Describe the procedures and results of a NIDA CTN trial examining use of buprenorphine among young adults; and
3) Explore the meaning and implications of these results for treating adolescents in real-world settings.

This Module can be used as a stand-alone training of approximately 3 hours in length or can be added to the larger Buprenorphine Awareness training to focus additional attention on treatment of young adults.

The notes below contain information that can be presented with each slide. This information is designed as a guidepost and can be adapted to meet the needs of the local training situation. Information can be added or deleted at the discretion of the trainer(s).

How Are the PowerPoint Training Slides Organized?

For this manual, text that is shown in bold italics is a "***Note to the Trainer.***" Text that is shown in normal font relates to the "Trainer's Script" for the slide.

It is important to note that almost every slide in this training contains some animation. Animations are used to call attention to particular aspects of the information or to present the information in a stepwise fashion to facilitate both the presentation of information and participant understanding. Because of this, some information is hidden when slides first appear on the screen and then comes in as the slide is advanced. No special notes are made if the animation simply causes the next row of text to appear. However, when the animations are complex, step by step instructions are provided.

General Information about Conducting the Training

The training is designed to be conducted in small- to medium-sized groups (10-25 people). It is possible to use these materials with larger groups, but the trainer will have to adapt the small group exercises to ensure that there is adequate time to cover all of the material.

Materials Needed to Conduct the Training

- Computer with PowerPoint software installed (2003 or higher version) and LCD projector to project the PowerPoint training slides
- Flip chart paper and easel/white board, and pens to write down relevant information
- Prepared materials for Number Line Exercise (slide 34) and Gallery Walk (slides 81-83)

Overall Training Notes

It is critical that, prior to conducting an actual training, the trainer practice using this guide while showing the slide presentation in Slideshow Mode in order to be prepared to use the slides in the most effective manner.

 Note to speaker

 Activity

 References

Combining the Presentations

The NIDA/SAMHSA Blending Initiative has developed a suite of products on buprenorphine. The Buprenorphine Suite includes the following training curricula:

- Buprenorphine Treatment: A Training for Multidisciplinary Addiction Professionals
- Short Term Opioid Withdrawal Using Buprenorphine: Findings and Strategies From a NIDA Clinical Trials Network Study
- Buprenorphine Treatment for Young Adults: Findings and Strategies From a NIDA Clinical Trials Network Study

Each of these curricula is a self-contained training package that can be used to conduct a stand-alone training program. However, the Blending Team recognized that in many instances trainers may want to incorporate elements of two or all three curricula into a single training experience. Combining slides from the presentations may therefore be necessary. Below are instructions for combining slides for both PowerPoint 2007 and PowerPoint 1997-2003.

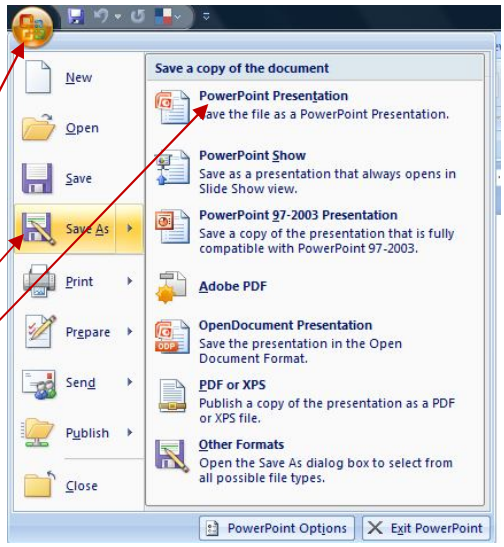
PowerPoint 2007

To combine slides into a single presentation, open all presentations from which you will be drawing slides. Determine which document will be the master document into which slides from the other presentation(s) will be copied. For instance, if you are conducting the *Buprenorphine Treatment: A Training for Multidisciplinary Addiction Professionals*, this would be your master document. It is recommended that you save a new copy of this presentation before altering it in order to preserve the original training content.

I. Save a new copy of your presentation.

(1) Click on the program icon in the upper right corner of your screen and then (2) click on ***Save As*** from the drop down menu. Next, (3) click on ***PowerPoint Presentation***. A dialogue box will appear that will allow you to give the presentation a name and location.

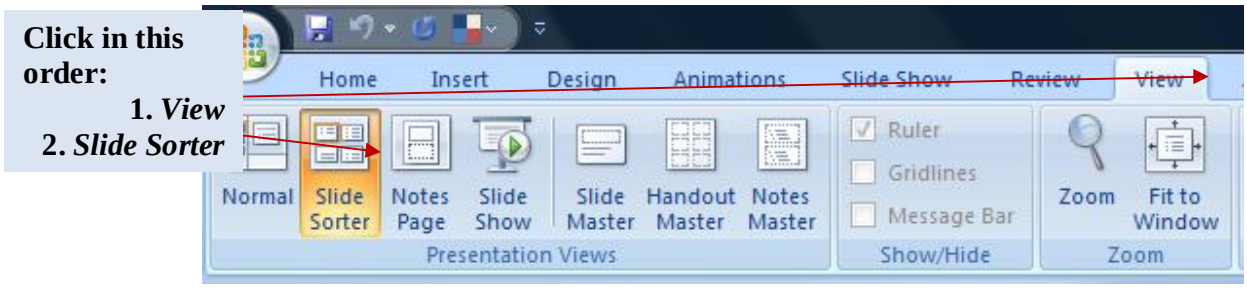
Click in this order:
1. *Program Icon*
2. *Save As*
3. *PowerPoint Presentation*



II. Open the presentation from which slides will be copied.

III. Select Slide Sorter view.

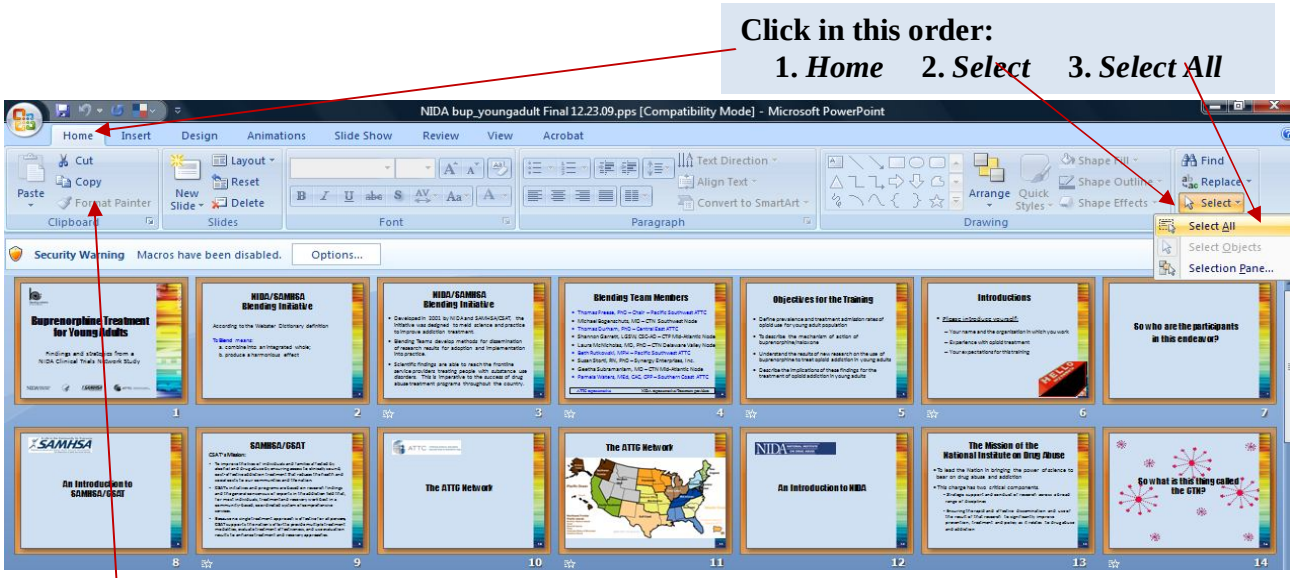
Go to the Slide Sorter view by (1) clicking on ***View*** from the menu at the top of the page and then (2) clicking ***Slide Sorter*** located on the left side of the page near the top.



IV. Select the slides to be copied.

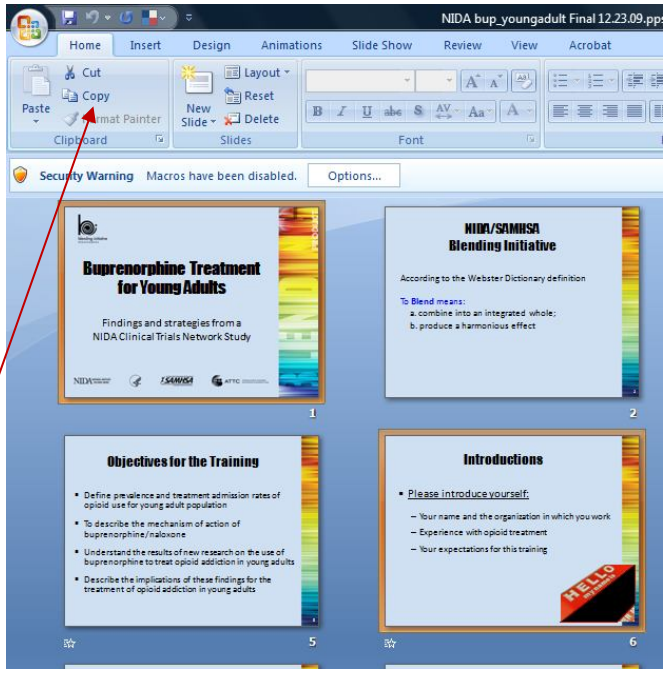
Slides can be copied in two ways. You can select all slides in the presentation, or you can choose only certain slides to copy. Instructions for each are presented below

Select all slides in presentation. Copy all slides in the presentation by (1) clicking on ***Home*** from the menu at the top of the page and then (2) clicking on ***Select*** on the far right side of the page near the top. Next, (3) click on ***Select All*** from the drop down menu. All slides in the presentation will be highlighted in yellow.



Finally, (4) **copy the selected slides to the clipboard** by clicking on ***Copy*** on the upper left of the screen.

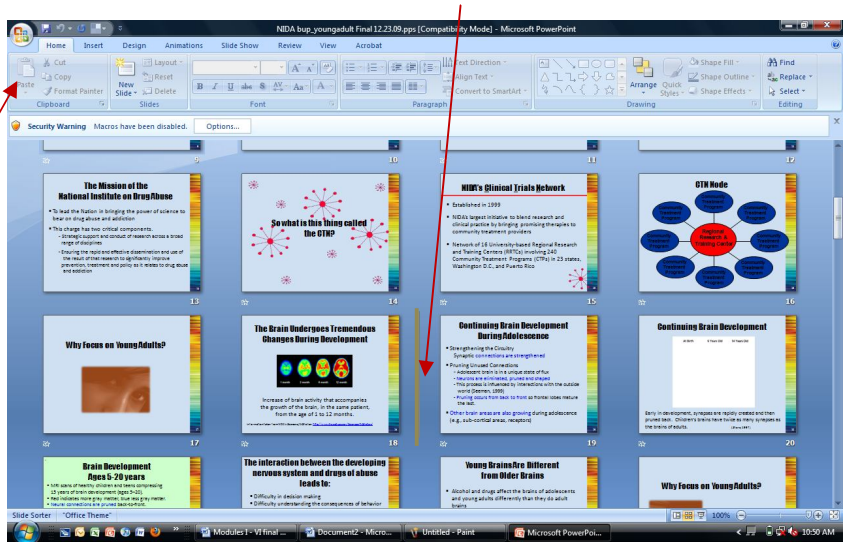
Select specific slides to copy. To copy only certain slides (rather than all of them), on your computer keyboard, hold down the control (***Ctrl***) button. While holding down ***Ctrl***, click on the slides that you want to copy into the combined presentation. Only slides on which you click will be selected (highlighted in yellow). In the close-up example on the right, Slides 1 and 6 are selected (have a yellow box around them). Slides 2 and 5 are not selected.
Once you have clicked on all the slides that you want to select, let go of the ***Ctrl*** key and then click on ***Copy*** on the upper left side of the page.



Note: You may want to practice copying a few slides at a time until you are comfortable with this procedure.

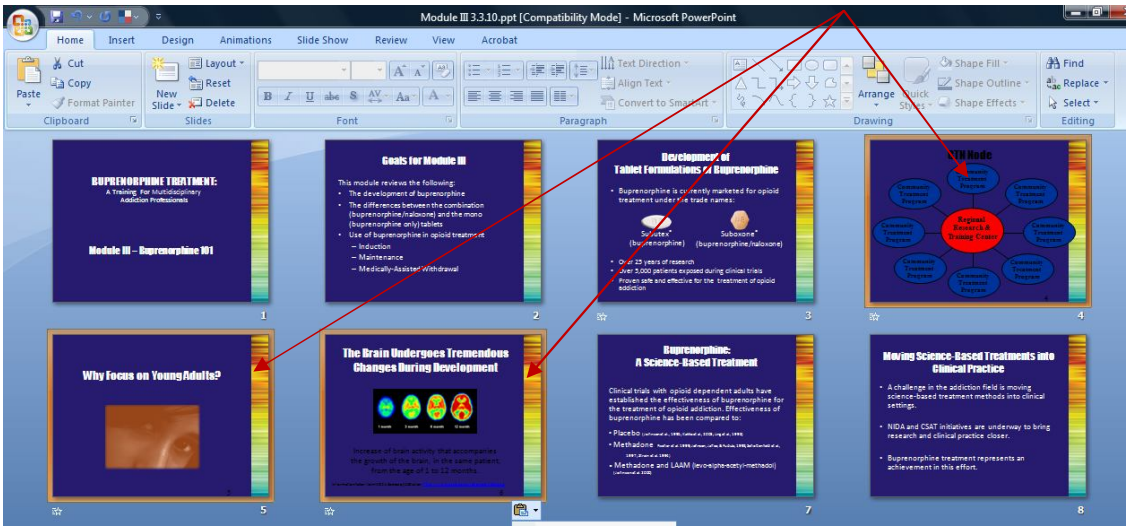
V. Paste the copied slides into your presentation.

Open your master presentation (the presentation into which the slides are to be copied). Again go to the ***Slide Sorter*** view as described in Step III above. (1) Click in the space between the slides where you would like the copied slides to appear. A flashing line will appear between the slides. In this example, the copied slides will appear after Slide 18. Then (2) click on ***Paste*** in the upper left corner.



VI. Maintain original formatting.

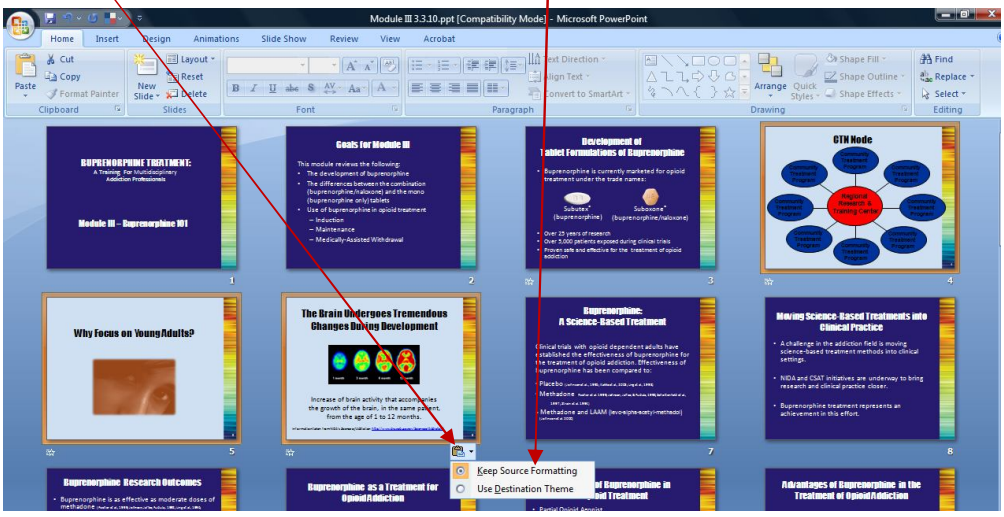
When copying slides from one presentation to the other, the formatting of the copied slides will be altered to match the presentation into which they are inserted. However, this often leads to significant formatting irregularities. In the example below, Slides 4 to 6 were inserted using the method described above. Notice that some of the text is too dark and difficult to read with the new formatting.



To prevent this problem, it is recommended that the inserted slides maintain the formatting of the original presentation. The following steps show how to do this.

After pasting the slides into the presentation, you will notice that a small clipboard appears near the last inserted slides.

(1) Click on the clipboard and then (2) click on ***Keep Source Formatting*** in the drop-down menu that appears.



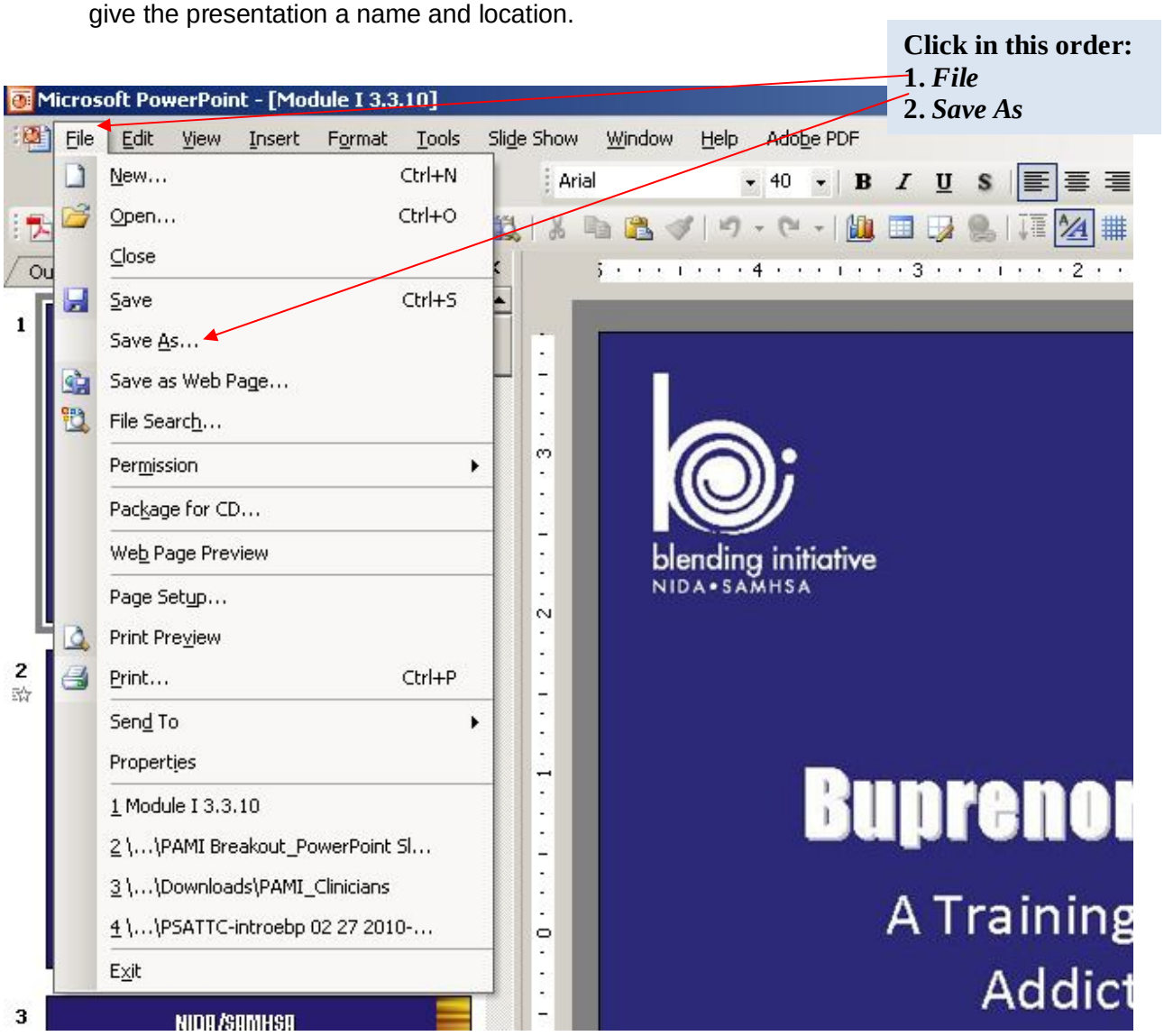
This will restore the formatting from the original presentation and ensure that the slides are legible when projected during a training session.

PowerPoint 1997-2003

To combine slides into a single presentation, open all presentations from which you will be drawing slides. Determine which document will be the master document into which slides from the other presentations will be copied. For instance, if you are conducting the *Buprenorphine Treatment: A Training for Multidisciplinary Addiction Professionals*, this would be your master document. It is recommended that you save a new copy of this presentation before altering it in order to preserve the original training content.

I. Save a new copy of your presentation.

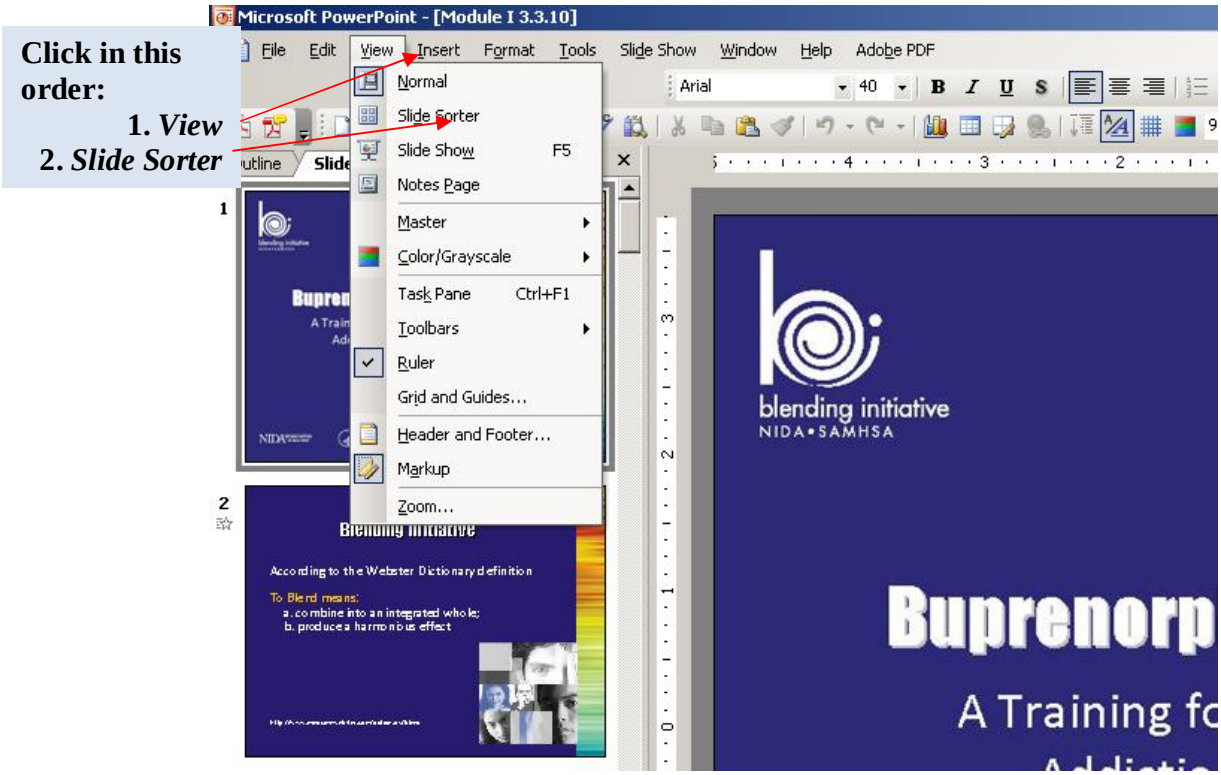
(1) Click on the ***File*** button in the upper left corner of the toolbar and then (2) click on ***Save As*** from the drop-down menu. A dialogue box will appear that will allow you to give the presentation a name and location.



II. Open the presentation from which slides will be copied.

III. Select Slide Sorter view.

Go to the Slide Sorter view by (1) clicking on ***View*** from the menu at the top of the page and then (2) clicking ***Slide Sorter*** from the drop-down menu.

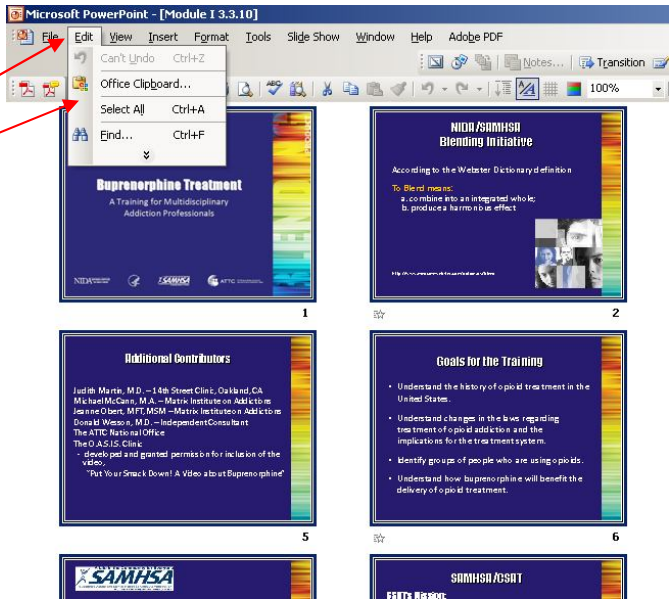


IV. Select the slides to be copied.

Slides can be copied in two ways. You can select all slides in the presentation, or you can choose only certain slides to copy. Instructions for each are presented below.

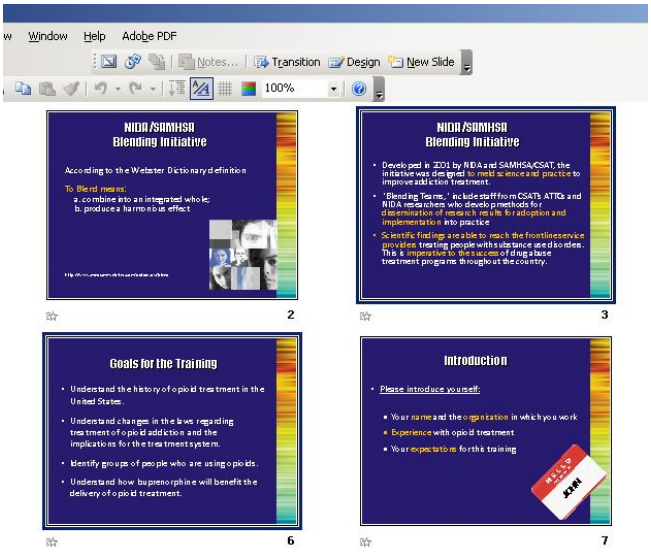
Select all slides in presentation. Copy all slides in the presentation by (1) clicking on ***Edit*** in the top toolbar and then (2) clicking ***Select All*** from the drop-down menu. All slides in the presentation will be highlighted in dark blue.

Click in this order:
1. *Edit*
2. *Select All*



Finally, (3) click on the ***Edit*** button in the top toolbar and then click on ***Copy*** from the drop-down list.

Select specific slides for copying. To copy only certain slides (rather than all of them), on your computer keyboard, hold down the control (***Ctrl***) button. While holding down ***Ctrl***, click on the slides that you want to copy into the combined presentation. Only slides on which you click will be selected (highlighted in dark blue). In the close-up example on the right, Slides 3 and 6 are selected (have a dark blue border around them). Once you have clicked on all the slides that you want to select, let go of the ***Ctrl*** key and then click on the ***Edit*** button in the top toolbar and then click on ***Copy*** from the drop-down menu.



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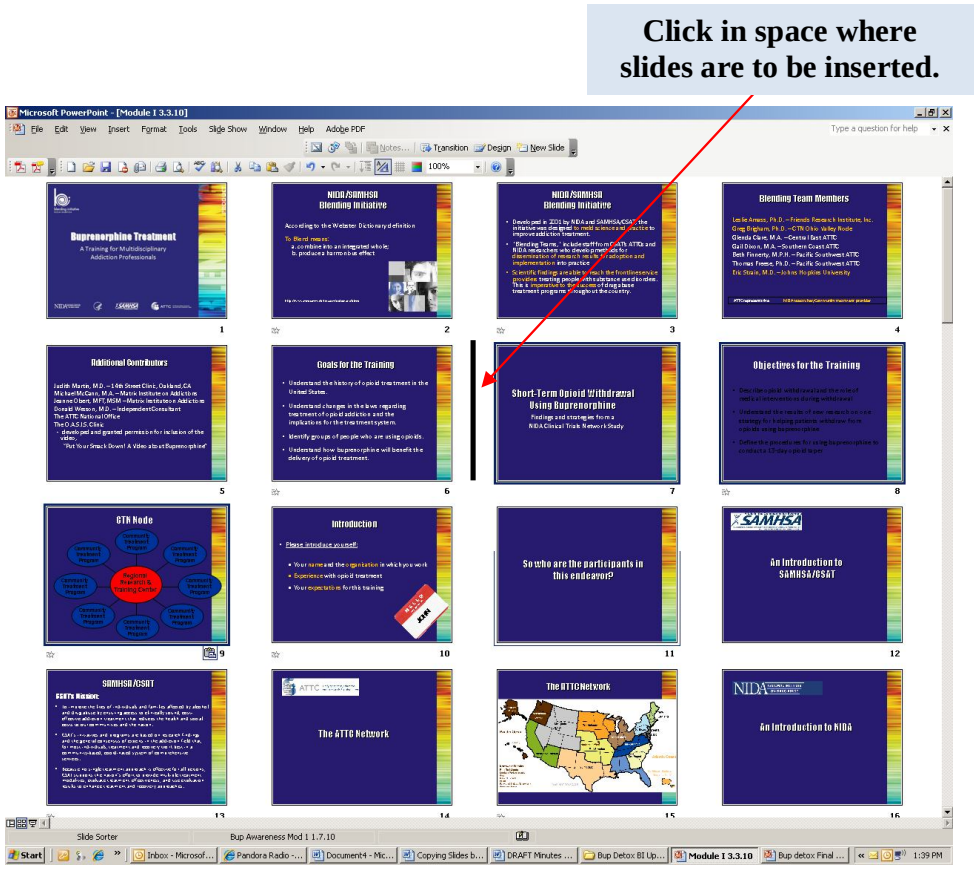
V. Paste the copied slides into your presentation.

Open your master presentation (the presentation into which the slides are to be copied). Again go to the ***Slide Sorter View*** as described in Step III above. (1) Click in the space between the slides where you would like the copied slides to appear. A flashing line will appear between the

slides. In this example, the copied slides will appear after Slide 6. Then (2) click on ***Edit*** and then ***Paste*** in the upper left corner.



VI. Maintain original formatting.

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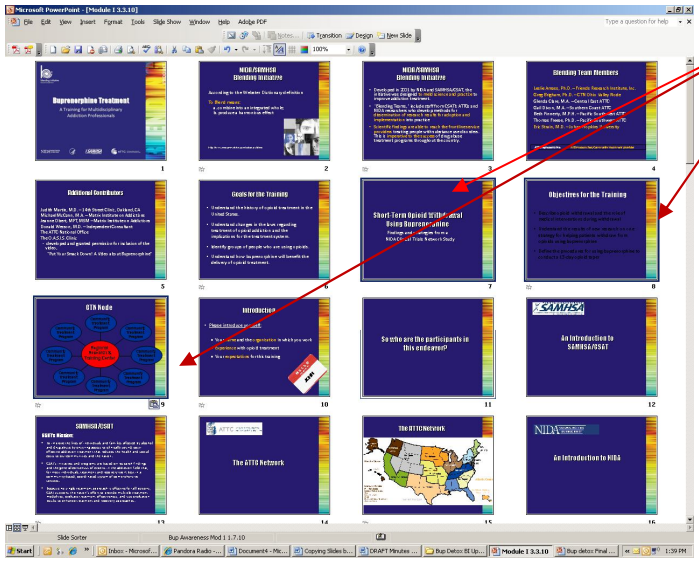
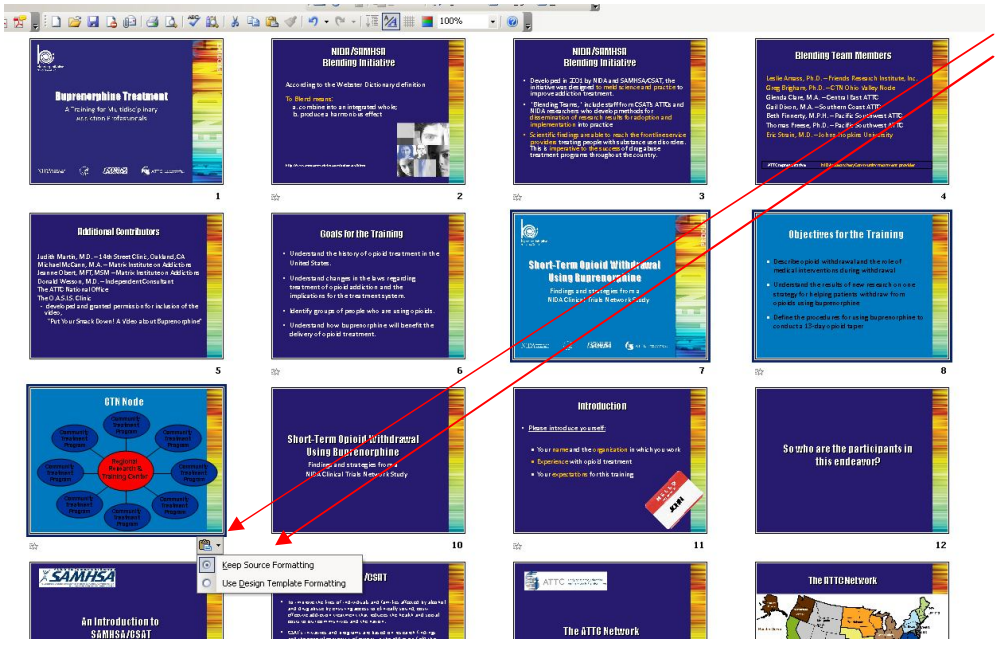


To prevent this problem, it is recommended that the inserted slides maintain the formatting of the original presentation. The following steps will show you how to do this.

After pasting the slides into the presentation, you will notice that a small clipboard appears near the last inserted slide.

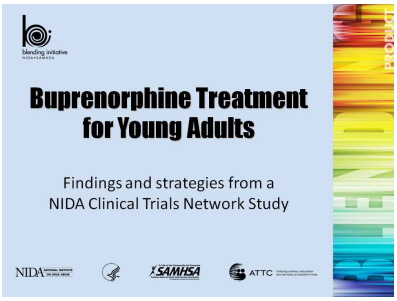
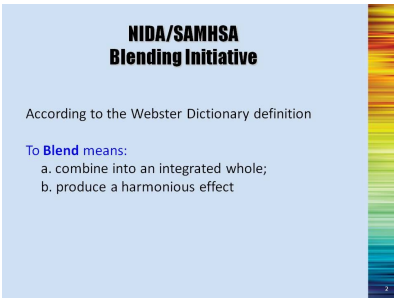


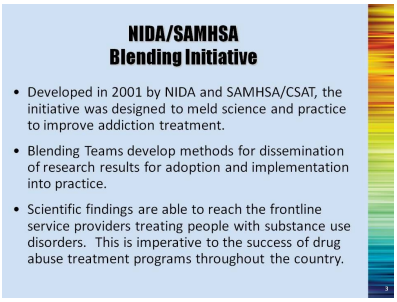
(1) Click on the clipboard and then (2) click on ***Keep Source Formatting*** in the drop-down menu that appears.

This will restore the formatting from the original presentation and ensure that the slides are legible when projected during a training session.

Buprenorphine Treatment for Young Adults
Slide-By-Slide Trainer Notes

The notes below contain information that can be presented with each slide. This information is designed as a guidepost and can be adapted to meet the needs of the local training situation. Information can be added or deleted at the discretion of the trainer(s).

	**Slide 1: Title Slide** ***Welcome participants and take care of housekeeping details such as location of restrooms, turning off cell phones, participate actively, etc.*** ***Briefly describe the development of the Blending Team product, as well as the purpose of the training as described in the introduction to this manual.*** ***It is important to note that this training is introductory and is focused on building awareness and encouraging multidisciplinary addiction professionals to learn more about buprenorphine and its role in opioid treatment. It is NOT designed to provide an expert level of competency in utilizing buprenorphine for the treatment of opioid addiction.*** ***Reiterate that throughout the training, the term "patient" has been used to refer to the individual seeking treatment. This terminology reflects the medicalized nature of buprenorphine treatment and underscores the fact that the treatment is largely physician-driven. The use of this term may be inconsistent with the vocabulary in common usage in the addiction treatment setting.***	**Slide 1** 
	**Slide 2: NIDA/SAMHSA Blending Initiative** ***Share the definition of "blend" based upon the Webster dictionary.*** <u>Reference:</u> blend. (2010). In *Merriam-Webster Online Dictionary*. Retrieved March 16, 2010, from http://www.merriam-webster.com/dictionary/blend	**Slide 2** 



Slide 3: NIDA/SAMHSA Blending Initiative

Developed in 2001 by the National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment, the **NIDA/SAMHSA Blending Initiative** is designed to meld science and practice together to improve substance use disorder treatment. The primary goal of this initiative is to disseminate research findings that will accelerate the adoption and implementation of research-based drug abuse treatment into community-based practice.

Blending Products are designed to shorten the time that it takes scientific findings to become available in a usable way for frontline service providers. This is imperative for successful outcomes of clients in addiction treatment programs throughout the country.

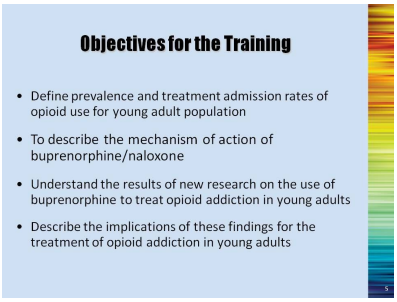
Slide 3

Slide 4: Blending Team Members

Blending Teams are composed of NIDA-funded researchers, community-based substance abuse treatment practitioners and trainers from SAMHSA's Addiction Technology Transfer Center (ATTC) Network who work closely together to develop the NIDA/SAMHSA Blending products.

Note to the Trainer(s): *Acknowledge the members of the Blending Team who created this module. Note that the membership consisted of four ATTC representatives and four NIDA-funded researchers and community treatment providers.*

Slide 4



Slide 5: Objectives for the Training

There are four primary objectives for this training:

- To define the prevalence of and treatment admission rates for non-medical use of opioids among young adults
- To describe the mechanism of action of buprenorphine/ naloxone
- To explore and increase understanding of the results of new research on using buprenorphine to treat opioid addiction in young adults
- To describe the implications of these findings for the treatment of opioid addiction in young adults

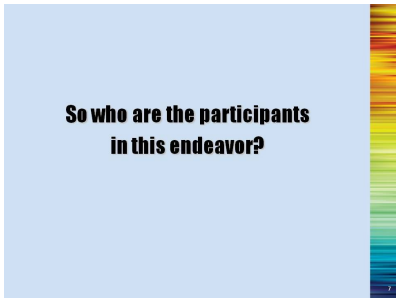
Slide 5

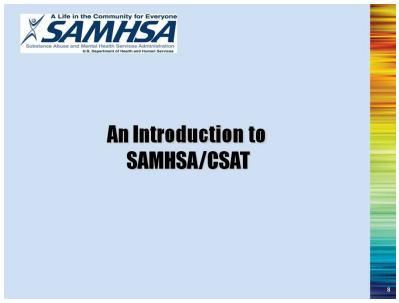
<table>
<tr>
<td> 
</td>
<td>Slide 6: Introductions

<u>For smaller groups (20 or less):</u> Begin the training by asking participants to briefly introduce themselves by providing their name and the agency for which they work, their experience with opioid treatment, and what they expect to gain from the training.

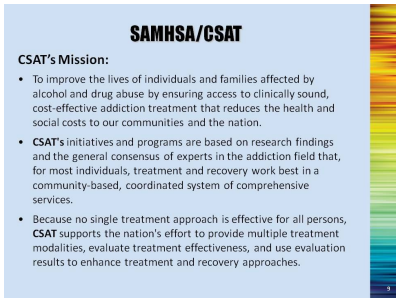
<u>For larger groups:</u> Personal introductions will take too much time to complete. Omit this slide and proceed by asking people to identify their role in the treatment system by raising their hand.

At minimum, ask:
Who is:
• A direct treatment provider
• A counselor
• A nurse
• A physician
• A social worker
• An administrator
• An educator
• Anyone that I missed?</td>
<td>Slide 6

  </td>
</tr>
<tr>
<td> 
</td>
<td>Slide 7: So who are the participants in this endeavor?

So now we will introduce the key participants who helped put these materials together.</td>
<td>Slide 7</td>
</tr>
<tr>
<td> 
</td>
<td>Slide 8: An Introduction to SAMHSA/CSAT

The Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services (DHHS), was created in October 1992 with a congressional mandate to expand the availability of effective treatment and recovery services for alcohol and drug problems.</td>
<td>Slide 8</td>
</tr>
</table>

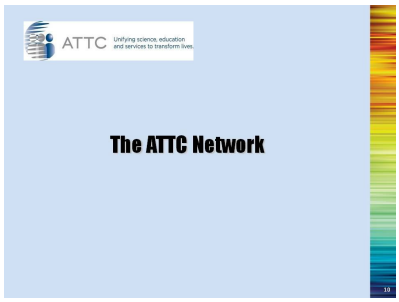


Slide 9: SAMHSA/CSAT

Read CSAT mission.

Note to the Trainer(s): *Highlight the importance of the research base in all of CSAT's programming and educating the field about the advances of science to continually improve the quality of services provided.*

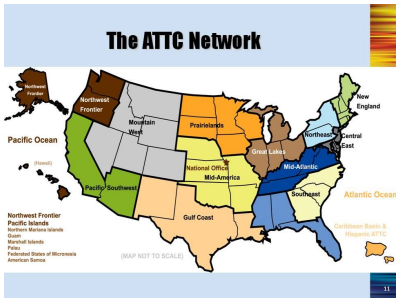
Slide 9



Slide 10: The ATTC Network

One of the major vehicles that SAMHSA has for ensuring that the workforce is adequately trained is the Addiction Technology Transfer Center (ATTC) Network.

Slide 10



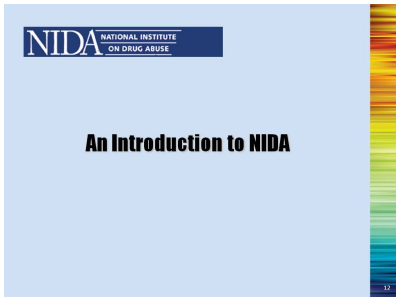
Slide 11: The ATTC Network

Fourteen regional Centers and a National Office comprise the ATTC Network, which is dedicated to identifying and advancing opportunities for improving addiction treatment.

The vision of the ATTC Network is to unify science, education and services to transform the lives of individuals and families affected by alcohol and other drug addiction.

Serving the 50 United States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands and the Pacific Islands, the ATTC Network delivers cutting-edge knowledge and skills that develop a powerful workforce.

Slide 11

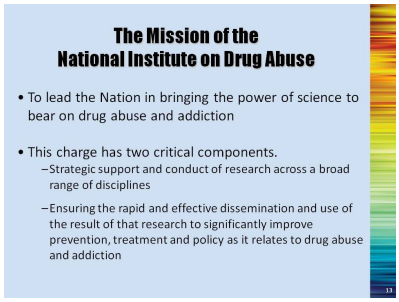
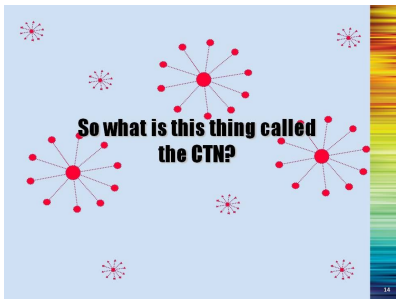
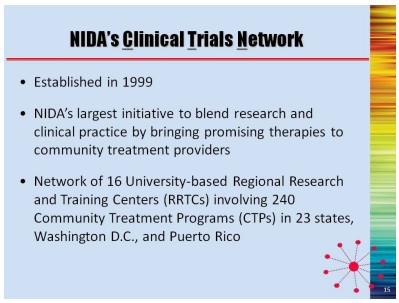


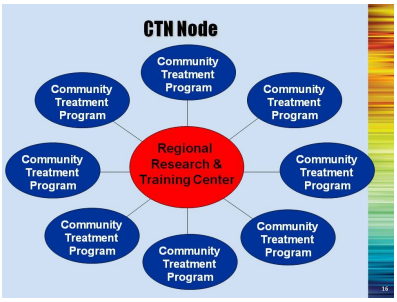
Slide 12: An Introduction to the National Institute on Drug Abuse

The National Institute on Drug Abuse (NIDA) was established in 1974, and in October 1992 it became part of the National Institutes of Health, Department of Health and Human Services.

Recent scientific advances have revolutionized our understanding of drug abuse and addiction. The majority of these advances, which have dramatic implications for how to best prevent and treat addiction, have been supported by the National Institute on Drug Abuse (NIDA).

Slide 12

	**Slide 13: The Mission of NIDA** NIDA is not only seizing upon unprecedented opportunities and technologies to further the understanding of how drugs of abuse affect the brain and behavior, but also *working to ensure the rapid and effective transfer of scientific data to policy makers, drug abuse practitioners, other health care practitioners, and the general public*. The scientific knowledge that is generated through NIDA-funded research is a critical element to improving the overall health of the Nation. The goal of NIDA is to ensure that science, not ideology or anecdote, forms the foundation for all of our Nation's drug abuse reduction efforts.	**Slide 13**
	**Slide 14: So what is this thing called the CTN?** To date, the efficacy of new treatments for drug addiction has been demonstrated primarily in specialized research settings, with somewhat restricted patient populations. This presents a problem when trying to apply these findings about new treatments into community-based treatment programs, which typically serve diverse populations. To address this problem, the National Institute on Drug Abuse (NIDA) established the National Drug Abuse Treatment Clinical Trials Network (CTN).	**Slide 14**
	**Slide 15: NIDA's Clinical Trials Network** The mission of the CTN is twofold: • Conduct studies of behavioral, pharmacological, and integrated behavioral and pharmacological interventions to determine therapeutic effect in rigorous, multisite clinical trials to determine effectiveness across a broad range of community-based treatment settings and diversified patient populations; and • Transfer the research results to physicians, providers, and their patients to improve the quality of drug abuse treatment throughout the country using science as the vehicle.	**Slide 15**



Slide 16: CTN Node

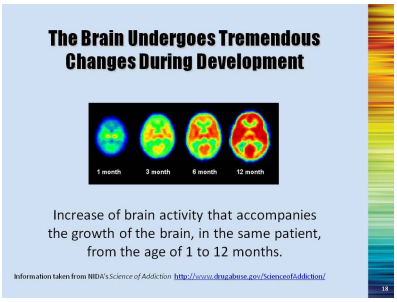
The CTN is comprised of Nodes that are dispersed across the country. Each Node has one Regional Research Training Center (RRTC) and 5 – 10 affiliated community treatment programs (CTP). CTN research is conducted in the CTPs. CTPs are chosen to participate in a given research protocol based on match between the study questions and requirements and the populations served by the CTP. For instance, in the buprenorphine studies, a CTP could be chosen if they served an opioid dependent population from whom they could recruit study participants.

Slide 16

Slide 17: Why Focus on Young Adults

Many social and developmental changes take place during adolescence and into young adulthood. Social and parental control lessens during this period, and young people become freer to choose behaviors (for example, drug use or heavy drinking) and lifestyles that are not constrained by others. Because some emerging adults will maintain or increase their problematic drug or alcohol use over time (rather than mature out of such use and related problems), it is important to intervene effectively before they develop long-lasting drug use patterns or disorders.

Slide 17



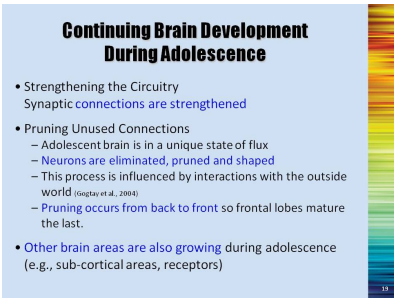
Slide 18: The Brain Undergoes Tremendous Change

It is common knowledge that the brain undergoes tremendous changes early in development. This slide shows increases in activity across the brain during the first year after birth. The more red exhibited, the more activity is seen in that area.

Reference:

NIDA. (2007). Drugs Brains, and Behavior: *The Science of Addiction* (NIH Pub No. 07-5605). Downloaded from http://www.drugabuse.gov/ScienceofAd

Slide 18



Slide 19: Continuing Brain Development for Adolescents and Young Adults

Substantial changes continue throughout adolescence and into young adulthood. Early in childhood, the brain produces an extremely large number of connections across the brain, many more than will be needed later in adulthood.

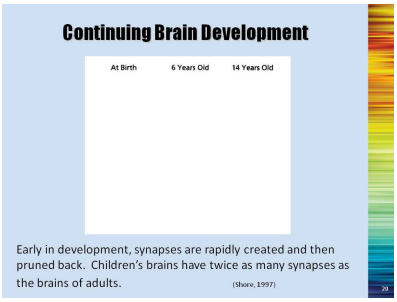
During adolescence and young adulthood, the brain strengthens important connections.

At the same time, it eliminates and shapes connections to increase efficiency. The pruning of neurons occurs from the back of the brain to the front of the brain, so that frontal lobes are the last to fully form.

Reference:

Gogtay, N., et. al. (2004). Dynamic mapping of human cortical development during childhood through early adulthood. *Proceedings of the National Academy of Sciences, 101,* 8174-8179.

Slide 19



Slide 20: Continuing Brain Development

This drawing illustrates the pruning process.

Move forward to reveal first picture
Between birth and 6 years of age…

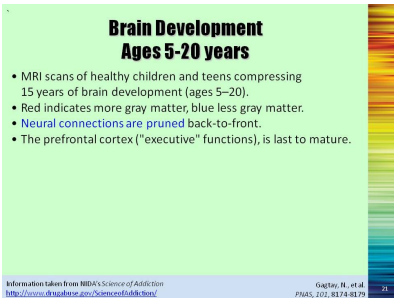
Move forward to reveal second picture
…there is a tremendous proliferation of neural connections.

Move forward to reveal final picture
This is followed by sustained thinning starting around puberty. Scientists think this process reflects greater organization of the brain as it prunes redundant connections, and increases in myelin, which enhance transmission of brain messages.

Reference:

Shore, R. (1997). *Rethinking the brain.* New York: Families and Work Institute.

Slide 20



Slide 21: Brain Development, Ages 5 - 20 Years

Slide 21

Important note on this slide:
This slide has complex animations and the trainer should practice prior to training. A step-by-step guide is provided below.

The first bullet comes in automatically at the beginning of the slide. Provide the following description:

- This slide demonstrates the neural pruning through animations. This is a series of MRI scans from healthy children showing brain development as they age from 5 to 20 years.

Move forward to reveal the next bullet, and present the information:

- Red indicates more gray matter and blue indicates less gray matter.

Move forward and a small brain image will briefly appear on the lower right and then a short movie will automatically play full screen showing brain maturation. Once it stops, the small image of the brain will appear again on the lower right of the slide. Move forward to reveal the next bullet:

- As you can see, the pruning occurs from the back of the brain toward the front.

Move forward to reveal the last bullet:

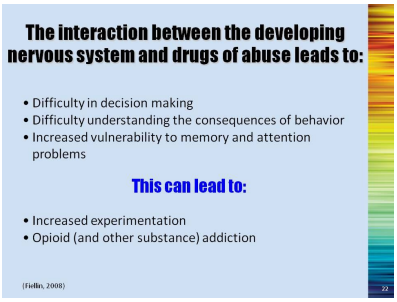
- This means that the prefrontal cortex (responsible for executive functioning, like decision-making) is the last to mature.

Point out that the animation is replaying so that people can see it again. A static image of the progression will appear on the lower left as well. When people have had time to observe, move forward to next slide.

References:

NIDA. (2007). Drugs Brains, and Behavior: *The Science of Addiction* (NIH Pub No. 07-5605). Downloaded from http://www.drugabuse.gov/ScienceofAd

Gogtay, N., et. al. (2004). Dynamic mapping of human cortical development during childhood through early adulthood. *Proceedings of the National Academy of Sciences, 101,* 8174-8179



Slide 22: The interaction between the developing nervous system and drugs of abuse can contribute to:

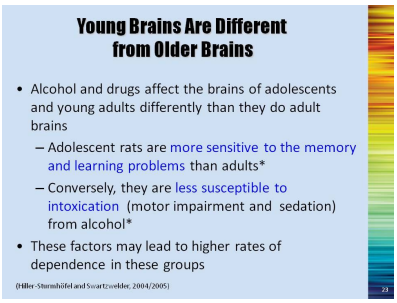
In reality, the exact impact of substance use on the developing brain is not known. However, when we look at the impact on the adult brain and understand normal development, several things seems true about this interaction, including that it may lead to difficulties in decision making and understanding the consequences of behavior (Fiellin, 2008). Additionally, it may increase the risk of memory and attention problems.

These impairments, in turn, may lead to increased experimentation across a variety of behaviors; and increase the risk of addiction to a variety of substances (Fiellin, 2008).

Reference:

Fiellin, D. A. (2008). Treatment of adolescent opioid dependence: No quick fix. *Journal of the American Medical Association, 300*(17), 2057-2059.

Slide 22



Slide 23: Young Brains are Different from Older Brains

The brain continues to develop into adulthood and undergoes dramatic changes during adolescence. This means that young brains are different from older brains. One example of this difference is evidenced by the fact that adolescent rats are:

- more susceptible to the effects of alcohol on memory and learning, but
- less susceptible to the motor and sedative effects.

These factors may combine to increase the vulnerability to substance dependence in adolescents and young adults.

Reference:

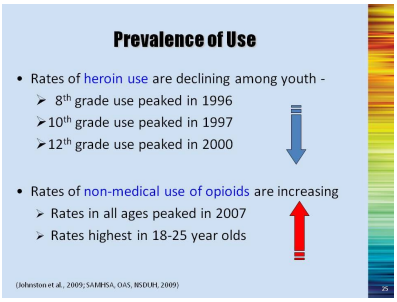
Hiller-Sturmhofel, S., & Swartzwelder, H. S. (2004/2005). Alcohol's effects on the adolescent brain: What can be learned from animal models. *Alcohol Research & Health, 28*(4), 213-221.

Slide 23

Slide 24: Why Focus on Young Adults?

Young adults have been shown to have increased vulnerability to, and the potential for increased problems from, substance use. The next series of slides will look specifically at prevalence of opioid use in this population.

Slide 24



Slide 25: Prevalence of Use

Recent concern has focused on opioid use among adolescents and young adults. Rates of heroin use are on the downturn among youth, however the rates of non-medical use of opioids have been steadily increasing.

The annual prevalence of heroin use among youth rose in the mid- and late 1990s, reaching peak levels in 1996 among 8th graders (1.6%), in 1997 among 10th graders (1.4%), and in 2000 among 12th graders (1.5%). Since those peak levels, heroin use has declined among students in all three grade levels to 0.7-.09% (Johnston, O'Malley, Bachman, and Schulenberg, 2009).

However, for the general population over 12 years of age, recent data show that 13.4% of individuals who reported new use of heroin in the past 13 to 24 months meet criteria for substance dependence (SAMHSA, OAS, 2008).

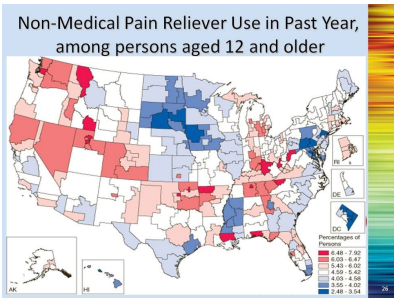
Slide 25

References:

Johnston, L. D., O'Malley, P. M., Bachman, J. G., & Schulenberg, J. E. (2009). *Monitoring the Future national survey results on drug use, 1975-2008. Volume I: Secondary school students* (NIH Publication No. 09-7402). Bethesda, MD: National Institute on Drug Abuse.

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (February 5, 2009). *The NSDUH Report: Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007.* Rockville, MD.

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (March 27, 2008). *The NSDUH Report: Substance Use and Dependence Following Initiation Following Alcohol or Illicit Drug Use.* Rockville, MD.



Slide 26: Non-Medical Pain Reliever Use in the Past Year Among Persons Aged 12 or Older

Percentages, Annual Averages Based on 2004, 2005, and 2006 National Survey on Drug Use and Health (NSDUH)

Move forward to reveal first animation

Data indicate that past year non-medical use of pain relievers ranged from a low of 2.48 percent in a ward of the District of Columbia…

Move forward to reveal next animation

…to a high of 7.92 percent in northwest Florida.

Move forward to reveal next animation

- Of the 15 substate regions with the highest rates of nonmedical use of pain relievers, 10 substate regions were in southern States and 5 were in western States

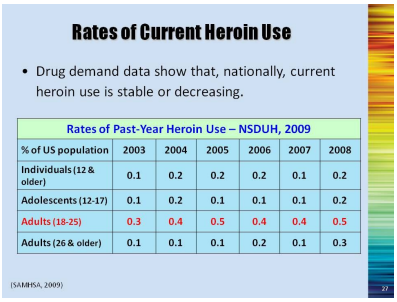
Move forward to reveal next animation

- Of the 15 substate regions with the lowest rates of nonmedical use of pain relievers, 7 substate regions were in southern States, 4 were in midwestern States, 3 were in northeastern States, and 1 was in a western State.

Reference:

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (June 19, 2008). *The NSDUH Report -- Nonmedical Use of Pain Relievers in Substate Regions: 2004 to 2006*. Rockville, MD.

Slide 26



Slide 27: Rates of Current Heroin Use

Drug prevalence data from multiple National Surveys on Drug Use and Health (SAMHSA, 2009) indicate that rates of use for heroin have been stable or have declined for most age groups. These data show that past year rates of heroin use did not significantly change in any measured age group during that same period, except 18-25 year olds, where the 2008 estimate was significantly higher than the 2003 estimate, with the highest level of usage among young adults aged 18-25 (SAMHSA, 2009).

Additional Information for the Trainer(s):

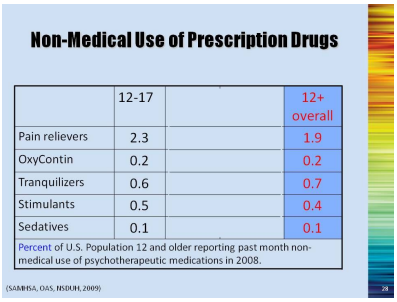
The National Drug Intelligence Center (US Department of Justice) reports that although heroin use is stable, it could increase as more prescription narcotic abusers switch to heroin. Officials who were surveyed in treatment facilities throughout the country reported that many abusers of prescription opiates, such as OxyContin, Percocet, and Vicodin, eventually begin abusing heroin because it is typically cheaper and easier to obtain, and it provides a more intense high. Treatment officials also reported that once an individual switches from prescription opiates to heroin, he or she rarely switches back to exclusively abusing prescription opiates (National Drug Intelligence Center, 2007).

References:

Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.

National Drug Intelligence Center. (2007). *National Drug Threat Assessment 2008.* (Document ID: 2007-Q0317-003). Washington, DC: U.S. Department of Justice

Slide 27



Slide 28: Non-Medical Use of Prescription Drugs

Data for adolescents and young adults is hidden to focus attention on adults (26+) and all populations aged 12 and older

According to the 2008 National Survey on Drug Use and Health, the percent of U.S. household population aged 12 and older reporting past month non-medical use of various psychotherapeutic medications is shown in the table.

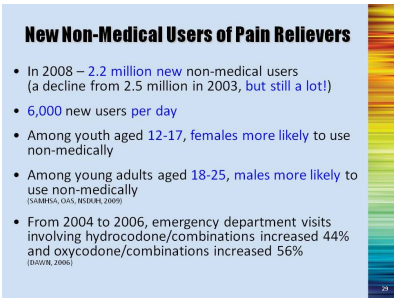
Move forward to reveal data for adolescents and young adults

Opiate drugs show the highest prevalence in this classification with the highest rates of use among young adults aged 18-25; pain relievers were the most abused prescription drugs overall.

Reference:

Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.

Slide 28



Slide 29: New Non-Medical Users of Pain Relievers

Data from the 2008 NSDUH show that 2.2 million people, aged 12 or older, initiated nonmedical use of prescription pain relievers within the past year. This averages to approximately 6,000 initiates (new users) per day (SAMHSA, 2009).

Among youth aged 12 to 17, females were more likely than males to have used pain relievers non-medically in the past year, whereas males aged 18 to 25 and males aged 26 to 34 had higher rates than their female counterparts (SAMHSA, OAS, 2007).

Emergency room data from the Drug Abuse Warning Network (DAWN) (SAMHSA, 2008) showed that emergency department visits involving hydrocodone/combinations increased 44% and oxycodone/combinations increased 56% from 2004 to 2006.

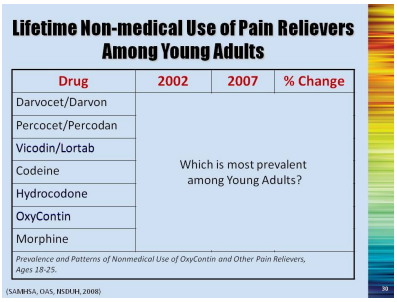
References:

Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (April 6, 2007). *The NSDUH Report: Patterns and Trends in Nonmedical Prescription Pain Reliever Use: 2002 to 2005*. Rockville, MD.

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits*. DAWN Series D-30, DHHS Publication No. (SMA) 08-4339, Rockville, MD, 2008.

Slide 29



Slide 30: Lifetime Non-medical Use of Pain Relievers Among Young Adults

Data is hidden to focus attention on the question for discussion. After orienting people to the slide ask the question:

"Which of these substances do you think is most prevalent among young adult users?"

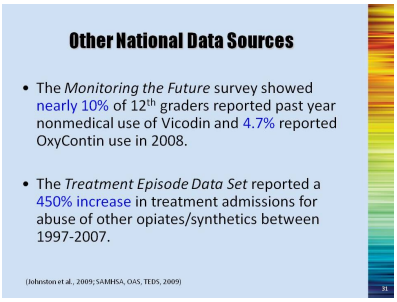
Move forward to reveal data:

The rates of past year nonmedical use of pain relievers are even more alarming when you compare these rates with those from just five short years ago.

Reference:

Substance Abuse and Mental Health Services Administration, Office of Applied Studies (2008). *Results from the 2007 National Survey on Drug Use and Health: National Findings* (NSDUH Series H-34, DHHS Publication No. SMA 08-4343). Rockville, MD.

Slide 30



Slide 31: Other National Data Sources

The 2008 Monitoring the Future Survey indicated a continuing high rate of prescription drug abuse among teens, with little change seen in the past six years. Nearly 10% of high school seniors reported past year nonmedical use of Vicodin, and 4.7% report abusing OxyContin, both powerful opioid painkillers (Johnston et al., 2009).

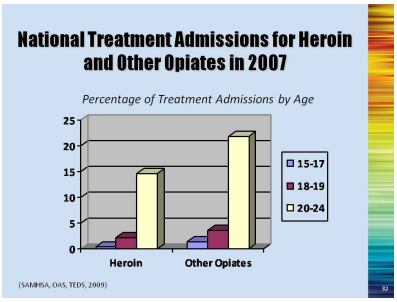
Treatment facilities also report higher rates of admittance by abusers of other opiates/synthetics. According to the Treatment Episode Data Set (TEDS), between 1997 and 2007, treatment admissions for abuse of other opiates/synthetics grew more than 450% (SAMHSA, OAS, 2009).

References:

Johnston, L. D., O'Malley, P. M., Bachman, J. G., & Schulenberg, J. E. (2009). *Monitoring the Future national results on adolescent drug use: Overview of key findings, 2008* (NIH Publication No. 09-7401). Bethesda, MD: National Institute on Drug Abuse.

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Treatment Episode Data Set (TEDS). Highlights - 2007. National Admissions to Substance Abuse Treatment Services,* DASIS Series: S-45, DHHS Publication No. (SMA) 09-4360, Rockville, MD, 2009.

Slide 31



Slide 32: National Treatment Admissions for Heroin and Other Opiates in 2007

Slide 32

The Treatment Episode Data Set (TEDS) also reports that from 1997 to 2007, the number of persons who were admitted to treatment programs across the U.S. with a primary problem with opiates other than heroin increased from 16,274 to 90,516 (SAMHSA, OAS, 2009). The table shows the "primary drug" data for treatment admissions in 2007 by age breakouts for adolescents and young adults. Of the age categories shown on this slide, the highest percentage of treatment admissions are among young adults aged 20 to 24 for both heroin (14.5%) and other opiates (21.8%).

Reference:

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Treatment Episode Data Set (TEDS). Highlights - 2007. National Admissions to Substance Abuse Treatment Services,* DASIS Series: S-45, DHHS Publication No. (SMA) 09-4360, Rockville, MD, 2009.

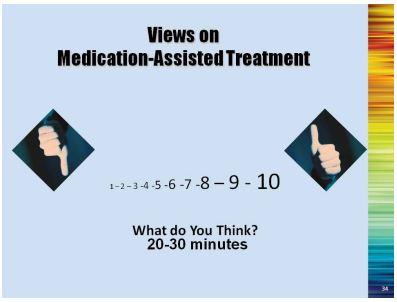
Slide 33: Treatment for Opioid Addiction

Slide 33

The usual treatment for opioid-addicted young adults is short-term detoxification and individual or group therapy in residential or outpatient settings over weeks or months. Clinicians report that relapse is high, yet many programs remain committed to this approach. Other than treating withdrawal, most programs do not use agonist medication, such as buprenorphine.

Many clinicians believe that buprenorphine is a medication for adults. However, buprenorphine is FDA-approved for treatment of individuals age 16 and older. Recent studies have been completed on the use of buprenorphine on this young population.

The National Institute on Drug Abuse (NIDA) undertook a study in six sites within the CTN. Because of the dangers associated with untreated opioid addiction, the commitment of programs treating opioid-addicted youth with non-medication therapies, and favorable results using buprenorphine in other studies, the CTN conducted a randomized trial of extended treatment including the use of buprenorphine versus the usual short-term detoxification among opioid-dependent youth.



Slide 34: Views on Medication-Assisted Treatment

Preparation prior to the training is needed for this activity. Prepare one sign that says "1 Strongly Disagree" and one that says "10 Strongly Agree." Prior to the training, identify an area where participants can line up, shoulder to shoulder across the room. Post one sign on either side of this area. This will clearly demark the scaling ruler area for this activity.

Before we examine the findings of the CTN study, let's talk about your views on the use of medications in the treatment of substance use disorders – also known as pharmacotherapy. Medications are playing an increasingly important role as adjuncts to psychosocial strategies of addiction treatment. Although problems associated with the use of alcohol and other drugs often appear in adolescence, most studies of pharmacotherapy for drugs of abuse have been conducted with adults. Because young adults may react differently than adults to both the therapeutic and potentially harmful effects of medications, the applicability of existing data to young adults who abuse alcohol and other drugs often remains unclear.

ACTIVITY – 20 to 30 minutes

The purpose of this activity is to increase awareness about counselor attitudes regarding the use of medication for substance use disorders in young adults, and foster open-mindedness to new pharmacotherapies. The activity consists of a "virtual" scaling ruler that spans the training room or other convenient location. The side of the virtual ruler that has a "1" means that the participants "Strongly Disagree" with the statements that are being read. The side of the virtual ruler that is marked with a "10" means that participants "Strongly Agree" with the statements that are being read.

(Instruction continued below)

Slide 34

	Slide 34: Views on Medication-Assisted Treatment (continued) ***Read three of the statements below related to counselor willingness to try new therapies in general, reliance upon research or colleagues to guide new treatment practices, and attitudes about medication-assisted treatment. Instruct participants to stand on the virtual scaling ruler depending upon how they feel about the statement – from Strongly Disagree to Strongly Agree. For each statement, facilitate a discussion by asking participants to share their reasons or beliefs that impact where they stand on the scaling ruler. In a motivational interviewing style, you can also selectively ask participants what it would take to move their beliefs, values or attitudes in either direction.***	**Slide 34**
	Statements for the Activity: 1. I like to use new types of therapy or interventions to help my clients. 2. I stay abreast of clinical research to help in guiding treatment interventions for my clients. 3. Medications should only be used with adolescents as a treatment of last resort. 4. The use of medications for adolescents and young adults can play a key role in treating their substance use disorders. 5. The goal of pharmacotherapy with adolescents should be withdrawing them from the medication as quickly as possible. ***Sample Script: Sally, when asked how you feel about the use of medications in the treatment of substance abuse in young adults, you indicate you are a 4 on the scale. Why are you a 4? Why are you a 4 instead of a 2? What would it take for you to move to an 8 on the scale?***	

Slide 35: The Big Question (Video Clip)

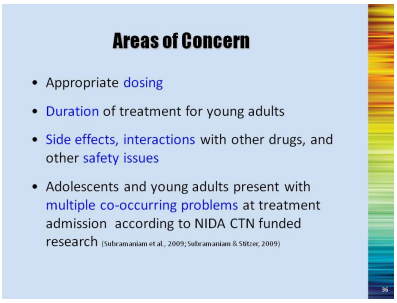
Slide 35

While many providers are willing to consider using medications such as buprenorphine with older, long-term opioid users, they do not want these medications used with their young clients.

Here is how one provider felt about medication assisted treatment with the young clients that he served.

Move mouse over black box. It will turn into an image of a hand. Click on the black box and the movie will play.

<u>Discussion:</u> Facilitate a discussion with participants gathering reactions to the video clip.



Slide 36: Areas of Concern

Slide 36

Many doctors have been reluctant to treat young adults with pharmacotherapy for addictive disorders because research on the safety and efficacy of these drugs in this population was lacking, therefore, there was relatively little guidance on:

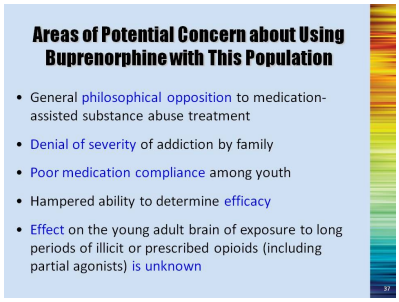
- appropriate dosing;
- duration of medication treatment; and
- medication side effects, interactions with other drugs, and other safety issues.

Additionally, NIDA research shows that adolescents and young adult opioid users present for treatment with multiple co-occurring issues that complicate treatment and must be addressed for treatment to be effective.

<u>References:</u>

Subramaniam, G. A., & Stitzer, M. A. (2009). Clinical characteristics of treatment-seeking prescription opioid vs. heroin-using adolescents with opioid use disorders. *Drug and Alcohol Dependence, 101*(1-2), 13-19.

Subramaniam, G. A., Stitzer, M. L., Woody, G., Fishman, M. J., & Kolodner, K. (2009). Clinical characteristics of treatment-seeking adolescents with opioid versus cannabis/alcohol use disorders. *Drug and Alcohol Dependence, 99*, (1-3), 141-149.

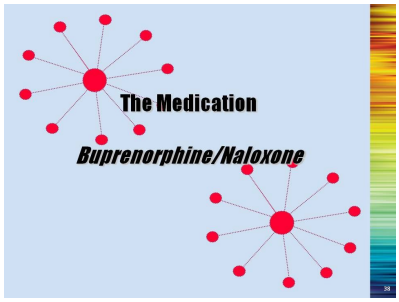


Slide 37: Areas of Potential Concern about Using Buprenorphine with this Population

Other issues that compound the reluctance to use buprenorphine with young adults are:

- general philosophical concerns among clinicians against medication-assisted treatment for substance abuse;
- denial of severity of addiction by family;
- poor medication compliance among youth;
- hampered ability to determine efficacy of medications due to denial, and poor compliance with both psychosocial treatment and the taking of medications; and
- the effect on the young adult brain of exposure of illicit or prescribed opioids (including partial agonists) is unknown.

Slide 37

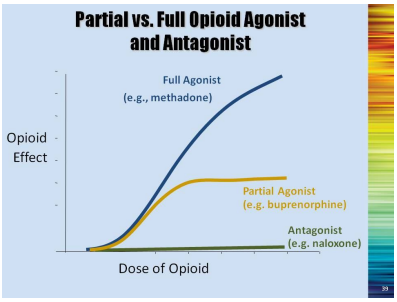


Slide 38: The Medication Buprenorphine/Naloxone (Transition Slide)

It is clear from the previously presented statistics that opioid use is a significant problem among this population.

In order to understand the results of the study using this medication with young adults, it is important that we understand how the medication (buprenorphine/naloxone) works. In the next section, we will look at the mechanism of action of this medication and issues pertaining to its efficacy and safety.

Slide 38



Slide 39: Partial vs. Full Opioid Agonist and Antagonist

Slide 39

This slide graphically depicts the different types of opioids (whether they are prescribed medications such as Vicodin or methadone, or an illicit substance like heroin).

Move forward to reveal first line (full agonist)

Full agonists (e.g., heroin, opium, Vicodin, methadone, etc.), fully activate the receptors so that the more you use, the more effect you experience. If someone continues to use, they will eventually experience overdose and, possibly, death.

The following metaphor may be helpful in explaining the differences between the types of opioids:

Opioid agonists work like having the right key to a door. You put the key in the lock, the lock turns and the door opens completely.

Move forward to reveal the next line (antagonists)

Opioid antagonists (e.g., naltrexone, naloxone) fill the receptors and block the action of other opioids. If the person has used an opioid agonist, the antagonist will replace it on the receptor and the person will experience withdrawal. If the person is stable on an antagonist, and uses another opioid, the antagonist will block the effects, preventing the user from experiencing the high.

The door metaphor continued:

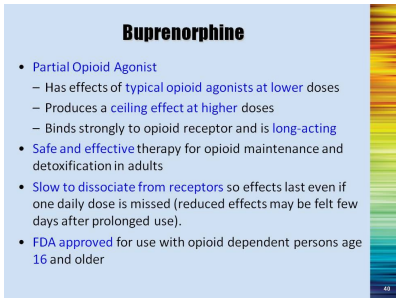
Opioid antagonists work like having the wrong key to a door. You put the key in the lock; the door remains locked and will not open. Additionally, since the key is in the lock, no other key can be put in the lock (even if it is the right key for that door) until the wrong key is removed.

Move forward to reveal the last line (partial agonists)

Opioid partial agonists (e.g., buprenorphine) are in the middle. At lower doses, they work just like agonists, filling the receptor and preventing withdrawal symptoms. However, as the dose increases, a ceiling effect occurs so that if more is used, no more effect is achieved. This ceiling effect applies both to opioid euphoria (they don't feel high), and to the respiratory suppression (making overdose less likely).

The door metaphor continued:

Opioid partial agonists work like having the right key to a door, but the chain is on the door. The key goes in and opens the door, but it will only open so far.



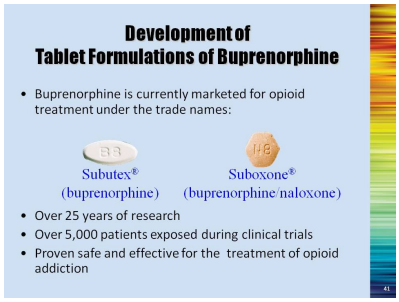
Slide 40: Buprenorphine

Slide 40

As mentioned in the previous slide, buprenorphine is a partial agonist. It has been shown to be safe and effective for the treatment of opioid dependence both as a maintenance agent and for use during withdrawal from opioids.

Buprenorphine binds to the receptors very strongly and comes off very slowly. This makes it a very long lasting medication that continues to be effective even if a dose is missed.

Another advantage is that the FDA approval for the medication is for opioid dependent individuals age 16 and older. *It is possible to use the medication with younger adolescents if determined medically appropriate (benefits outweigh the risks). However, this would be off-label use and the patients must be monitored very closely due to the lack of clinical research data.*



Slide 41: Development of Tablet Formulations of Buprenorphine

Slide 41

Buprenorphine was developed by a pharmaceutical company called Reckitt Benckiser. They have/had exclusive marketing rights until Fall 2009, and distribute the medication as

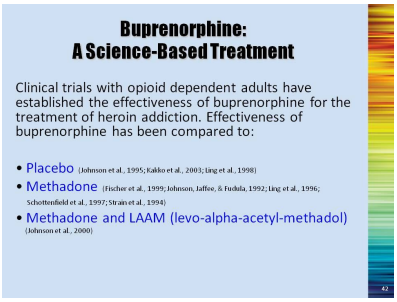
Subutex® = a sublingual tablet containing buprenorphine hydrochloride only

Suboxone® = a sublingual tablet containing both buprenorphine hydrochloride and naloxone hydrochloride in a 4:1 ratio

Reckitt Benckiser's exclusive rights expire/expired in the fall of 2009, so generic versions of the medication may become available in the future.

Buprenorphine/naloxone is the focus of U.S. marketing efforts, even though both formulations are available in the U.S.

These medications have a tremendous amount of research behind them to show that they are both safe and effective in the treatment of opioid addiction.



Slide 42: Buprenorphine: A Science-Based Treatment

In the development of the medication, the effectiveness of buprenorphine has been compared to that of other currently available medications. These studies have shown that buprenorphine treatment:

- is more effective than placebo; and
- has similar effectiveness to moderate doses of methadone and LAAM.

References:

Fischer, G., Gombas, W., Eder, H., Jagsch, R., Peternell, A., Stuhlinger, G., et al. (1999). Buprenorphine versus methadone maintenance for the treatment of opioid dependence. *Addiction, 94*(9), 1337-1347.

Johnson, R. E., Jaffe, J. H., & Fudala, P. J. (1992). A controlled trial of buprenorphine treatment for opioid dependence. *Journal of the American Medical Association, 267*, 2750–2755.

Johnson, R. E., Eissenberg, T., Stitzer, M. L., Strain, E. C., Liebson, I. A., & Bigelow, G. E. (1995) A placebo controlled clinical trial of buprenorphine as a treatment for opioid dependence. *Drug and Alcohol Dependence, 40*(1), 17-25.

Johnson, R. E., Chutuape, M. A., Strain, E. C., Walsh, S. L., Stitzer, M. L., & Bigelow, G. E. (2000). A comparison of levomethadyl acetate, buprenorphine, and methadone for opioid dependence. *New England Journal of Medicine, 343*(18), 1290-1297.

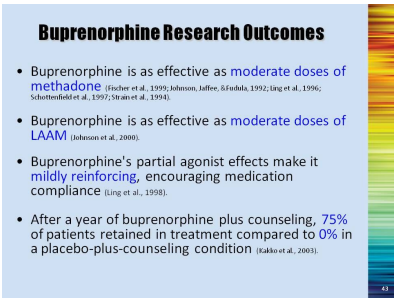
Kakko, J., Svanborg, K., Kreek, M., & Heilig, M. (2003). 1-year retention and social function after buprenorphine-assisted relapse prevention treatment for heroin dependence in Sweden: A randomised, placebo-controlled trial. *The Lancet, 361*(9358), 662-668.

Ling, W., Charuvastra, C., Collins, J. F., Batki, S., Brown, L. S., Jr., Kintaudi, P., et al. (1998) Buprenorphine maintenance treatment of opiate dependence: A multicenter, randomized clinical trial. *Addiction, 93*, 475–486.

Schottenfeld, R. S., Pakes, J. R., Oliveto, A., Ziedonis, D., & Kosten T. R. (1997). Buprenorphine vs methadone maintenance treatment for concurrent opioid dependence and cocaine abuse. *Archives of General Psychiatry, 54*, 713–720.

Strain, E. C., Stitzer, M. L., Liebson, I. A., & Bigelow, G. E. (1994). Comparison of buprenorphine and methadone in the treatment of opioid dependence. *American Journal of Psychiatry, 151*, 1025–1030.

Slide 42



Slide 43: Buprenorphine Research Outcomes

Clinical trials have established the effectiveness of buprenorphine for the treatment of opioid addiction. The clinical studies have shown the following about buprenorphine:

Bullet #1: Patients on buprenorphine did as well as patients on a moderate dose of methadone (e.g., 60mg).

Bullet #2: Patients on buprenorphine did as well as patients on a moderate dose of LAAM (70mg/70mg/85mg on a Monday/Wednesday/Friday schedule).

Bullet #3: Patients found that taking buprenorphine was a pleasant experience, which encouraged them to be compliant.

Bullet #4: When compared to placebo-plus-counseling, 3/4 of the patients receiving buprenorphine and counseling were still in treatment after one year. None of the placebo patients were retained.

References: Bullet #1

Fischer, G., Gombas, W., Eder, H., Jagsch, R., Peternell, A., Stuhlinger, G., et al. (1999). Buprenorphine versus methadone maintenance for the treatment of opioid dependence. *Addiction, 94*(9), 1337-1347.

Johnson, R. E., Jaffe, J. H., & Fudala, P. J. (1992). A controlled trial of buprenorphine treatment for opioid dependence. *Journal of the American Medical Association, 267*, 2750–2755.

Schottenfeld, R. S., Pakes, J. R., Oliveto, A., Ziedonis, D., & Kosten T. R. (1997). Buprenorphine vs methadone maintenance treatment for concurrent opioid dependence and cocaine abuse. *Archives of General Psychiatry, 54*, 713–720.

Strain, E. C., Stitzer, M. L., Liebson, I. A., & Bigelow, G. E. (1994). Comparison of buprenorphine and methadone in the treatment of opioid dependence. *American Journal of Psychiatry, 151*, 1025–1030.

Reference: Bullet #2

Johnson, R. E., Chutuape, M. A., Strain, E. C., Walsh, S. L., Stitzer, M. L., & Bigelow, G. E. (2000). A comparison of levomethadyl acetate, buprenorphine, and methadone for opioid dependence. *New England Journal of Medicine, 343*(18), 1290-1297.

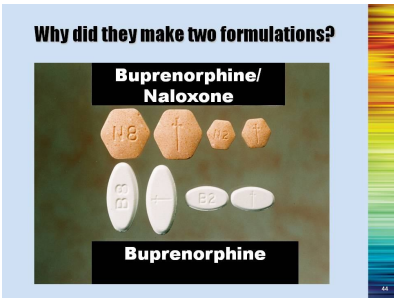
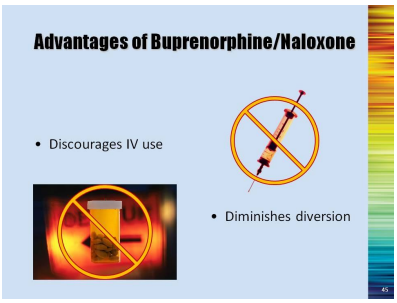
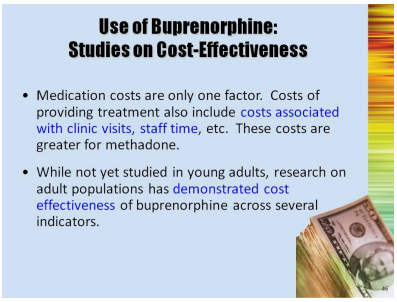
Reference: Bullet #3

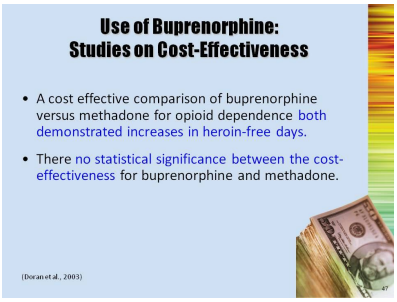
Ling, W., Charuvastra, C., Collins, J. F., Batki, S., Brown, L. S., Jr., Kintaudi, P., et al. (1998) Buprenorphine maintenance treatment of opiate dependence: A multicenter, randomized clinical trial. *Addiction, 93*, 475–486.

Reference: Bullet #4

Kakko, J., Svanborg, K., Kreek, M., & Heilig, M. (2003). 1-year retention and social function after buprenorphine-assisted relapse prevention treatment for heroin dependence in Sweden: A randomised, placebo-controlled trial. *The Lancet, 361*(9358), 662-668.

Slide 43

	**Slide 44: Why did they make two formulations?** As previously stated, the focus of marketing in the U.S. and the formulation used in the CTN studies is the buprenorphine/naloxone combination. Understanding why this combination was made is critical.	**Slide 44**
	**Slide 45: Advantages of Buprenorphine/Naloxone** The buprenorphine/naloxone formulation has some advantages compared with the buprenorphine only formulation: • It discourages injection of the product because, when injected, the naloxone will lead to withdrawal, whereas when taken sublingually as prescribed, it will not have that effect. • Because of the above point, the combination tablet lowers the likelihood that the medication will be diverted.	**Slide 45**
	**Slide 46: Use of Buprenorphine: Studies on Cost-Effectiveness** There has been much discussion regarding the costs associated with the use of buprenorphine for the treatment of opioid dependence. When considering the costs of providing treatment you must also include costs associated with clinic visits, staff time, and general operating and facility expenditures. Recently, research conducted on adult populations has demonstrated the utilization of buprenorphine is cost effective across several indicators.	**Slide 46**



Slide 47: Use of Buprenorphine: Studies on Cost-Effectiveness

Slide 47

Doran and colleagues (2003) conducted a clinical trial designed to assess the safety, efficacy and cost-effectiveness of buprenorphine versus methadone in the management of opioid dependence. The trial utilized a flexible dosing regime that was tailored to the clinical need of the patients, with high maximum doses, using the marketed tablet formulation, under double-blind conditions. A total of 405 subjects were randomized to a treatment at one of three specialist outpatient drug treatment centers in Adelaide and Sydney, Australia. The perspective of the cost-effectiveness analysis was that of the service provider and included costs relevant to the provision of treatment. The primary outcome measure used in the economic analysis was change in heroin-free days from baseline to the sixth month of treatment.

Key findings included:

- Both buprenorphine and methadone demonstrated increases in heroin-free days; and
- There was no statistical significance between the cost-effectiveness for buprenorphine and methadone.

Reference:

Doran, C. M., Shanahan, M., Mattick, R. P., Bell, J., White, J., & Ali, R. (2003). Buprenorphine versus methadone maintenance: A cost effectiveness analysis. *Drug and Alcohol Dependence, 71(3):* 295 – 302.

Slide 48: Use of Buprenorphine: Studies on Cost-Effectiveness, cont'

Slide 48

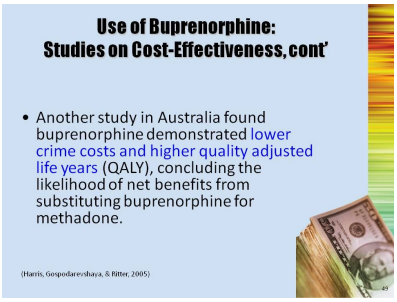
Another study conducted by Kaur and McQueen (2008) found that the treatment with buprenorphine/naloxone was associated with a reduction in opioid utilization and cost in the first year of follow-up.

Doran (2008) conducted a systematic review of the literature and found a number of studies supporting buprenorphine as a cost-effective approach to opioid treatment.

References:

Doran, C. M. (2008). Economic evaluation of interventions to treat opiate dependence: a review of the evidence. *Pharmocoeconomics, 26(5),* 371-393.

Kaur, A. D., McQueen, A. & Jan, S. (2008). Opioid drug utilization and cost outcomes associated with the use of buprenorphine-naloxone in patients with a history of prescription opioid use. *Journal of Managed Care Pharmacy, 14(2),* 186-194.



Slide 49: Use of Buprenorphine: Studies on Cost-Effectiveness, cont'

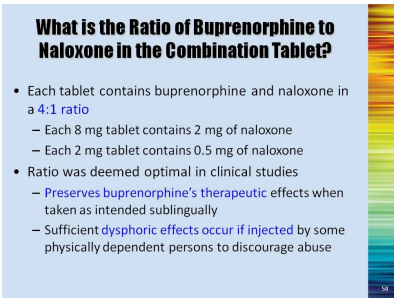
Slide 49

This study was the first to examine the cost effectiveness of buprenorphine as maintenance treatment for heroin dependence in a primary care setting. The study was a randomized, open-label, 12-month trial of 139 heroin-dependent patients in a community setting receiving individualized treatment regimens of buprenorphine or methadone. The study took a broad societal perspective and included health, crime and personal costs. The main outcomes were incremental cost per additional day free of heroin use and per the quality adjusted life years (QALY).

The researchers found that buprenorphine demonstrated lower crime costs and higher quality adjusted life years.

Reference:

Harris, A. H., Gospodarevskaya, E., & Ritter, A. J. (2005). A randomised trial of the cost effectiveness of buprenorphine as an alternative to methadone maintenance treatment for heroin dependence in a primary care setting. *Pharmocoeconomics, 23(1),* 77-91.

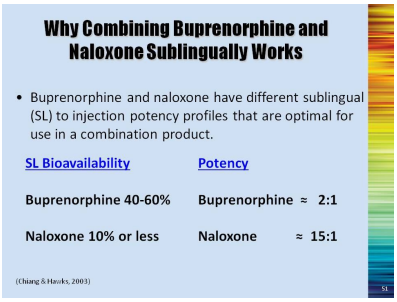


Slide 50: What is the Ratio of Buprenorphine to Naloxone in the Combination Tablet?

Slide 50

The combination includes buprenorphine and naloxone in a ratio of 4:1.

This ratio was found to maintain the clinical effects when taken sublingually as intended, BUT cause sufficient discomfort if injected by a physically dependent patient (to discourage them from doing so).



Slide 51: Why Combining Buprenorphine and Naloxone Sublingually Works

Digestive juices would kill buprenorphine's effects if you were to swallow it. By administering it sublingually, the medication dissolves under the tongue and is absorbed directly into the blood stream. Buprenorphine and naloxone have very different absorption rates when taken this way.

When taken under the tongue, the person receives approximately 40-60% of the buprenorphine available, but only 10% of the naloxone.

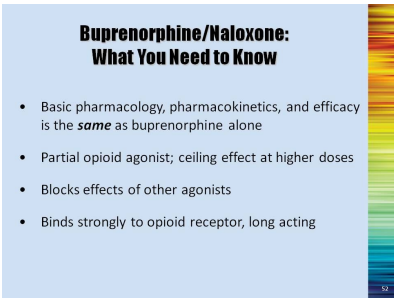
However, when you look at the relative potency comparing sublingual administration to injection, buprenorphine is approximately twice as strong when injected as when taken sublingually. Naloxone, on the other hand, is 15 times more effective by injection.

This means that when taken by injection, the naloxone is the stronger medication and the antagonist effects dominate.

Reference:

Chiang, C.N, & Hawks, R.L., (2003). Pharmacokinetics of the combination tablet of buprenorphine and naloxone. *Drug and Alcohol Dependence, 70,* S39-S47.

Slide 51



Slide 52: Buprenorphine/Naloxone: What You Need to Know

- The effect of the combination tablet is virtually identical to the buprenorphine-only product when taken sublingually.
- Both formulations demonstrate the ceiling effect at higher doses.
- Both formulations prevent the intoxicating effects if someone decides to also use another opioid.
- They are long-acting because of the high receptor affinity; meaning they bind strongly to the receptor site.

Additional Information for the Trainer(s):

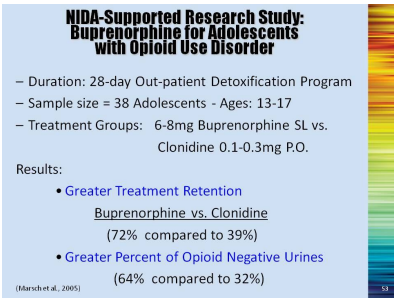
Safety

Because of its ceiling effect and poor bioavailability, buprenorphine is safer in overdose than opioid full agonists. The maximal effects of buprenorphine appear to occur in the 16–32 mg dose range for sublingual tablets. Higher doses are unlikely to produce greater effects.
Respiratory depression from buprenorphine (or buprenorphine/ naloxone) overdose is less likely than from other opioids. There is no evidence of organ damage with chronic use of buprenorphine, but increases in liver enzymes are sometimes seen. There is no evidence of significant disruption of cognitive or psychomotor performance with buprenorphine maintenance dosing.

Side Effects

Side effects of buprenorphine are similar to those of other opioids and include nausea, vomiting, and constipation. Buprenorphine and buprenorphine/naloxone can precipitate the opioid withdrawal syndrome. Additionally, the withdrawal syndrome can be precipitated in individuals maintained on buprenorphine.

Slide 52



Slide 53: NIDA-Supported Research Study: Buprenorphine for Adolescents with Opioid Use Disorder

Marsch and colleagues (2005) conducted a randomized controlled trial where participants were assigned to a 28-day, outpatient, medication-assisted withdrawal treatment with either buprenorphine or Clonidine. Both medications were provided along with thrice weekly behavioral counseling and incentives contingent on opiate abstinence.

Study findings indicated that a significantly greater percentage of adolescents who received buprenorphine were retained in treatment (72%) relative to those who received clonidine (39%). For those in the buprenorphine group, a significantly higher percentage of scheduled urine test results were opiate negative (64% vs 32%).

Overall, it was found that combining buprenorphine with behavioral interventions was significantly more efficacious in the treatment of opioid-dependent adolescents relative to combining clonidine and behavioral interventions.

Reference:

Marsch, L. A., Bickel, W. K., Badger, G. J., Stothart, M. E., Quesnel, K. J., Stanger, C., et al. (2005). Comparison of pharmacological treatments for opioid-dependent adolescents: a randomized controlled trial. *Archives of General Psychiatry, 62(*10), 1157-1164.

Slide 53

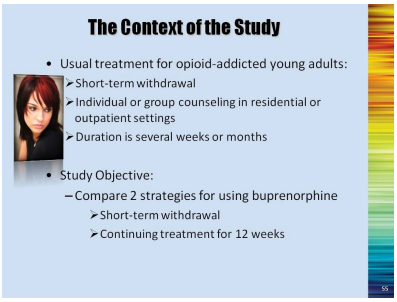
Slide 54: Extended vs. Short-term Buprenorphine-Naloxone for Treatment of Opioid-Addicted Young Adults: The CTN Clinical Trial

The next series of slides will present information on the NIDA CTN clinical trial conducted by Dr. George Woody comparing a 14-day vs. 12-week taper using buprenorphine/naloxone with young adults.

Reference:

Woody, G. E., Poole, S. A. Subramaniam, G., Dugosh, K., Bogenschutz, M., Abbott, P., et al. (2008). Extended vs short-term buprenorphine-naloxone for treatment of opioid-addicted youth: a randomized trial. *Journal of the American Medical Association, 300*(17), 2003-2011.

Slide 54



Slide 55: The Context of the Study

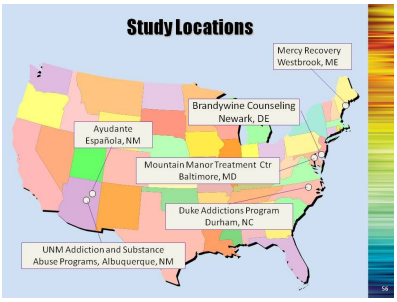
Adult clinical trials using buprenorphine to help people withdraw from opioids have shown it to be effective. However, the number of young adults in these studies is so small that generalizing the findings to this population is not possible.

Additionally, current standard practice is to withdraw young adults quickly using clonidine, buprenorphine or methadone, followed by weeks or months of counseling.

The CTN Trial compares two strategies for tapering young adults off of opioids. One group received a short-term (14-day) taper (comparable to standard practice) and the other group received longer treatment, which included stabilization and a taper over a 12-week period.

The goal of the study was to determine the relative efficacy of doing longer versus shorter medically-assisted withdrawal (detoxification) using buprenorphine.

Slide 55

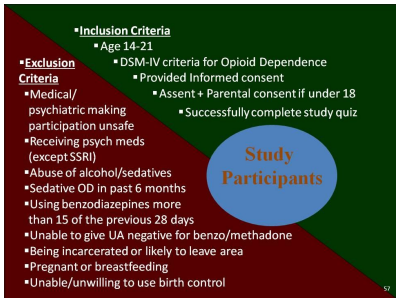


Slide 56: Study Locations

Move forward and site locations will appear one at a time.
This slide shows the sites that participated in the clinical trial. There were three sites in the eastern U.S. and two in the west.

Additional Information for the Trainer(s):
The CTN works to ensure diversity among participating sites (geography, client demographics, etc.) to maximize generalizability. CTN Nodes self-select community treatment programs for participation in a protocol based on interest in the protocol and the ability to recruit appropriate participants into the study (i.e., clients served by the agency are representative of the target population for the study).

Slide 56



Slide 57: Inclusion and Exclusion Criteria

Move forward to reveal the five inclusion and nine exclusion criteria one at a time. After the last exclusion criterion, the bubble with the words "Study Participants" will appear automatically after a few seconds.

Inclusion Criteria (notes for each bullet are below):

- While the lower age limit was 14, very few participants under the age of 18 were enrolled, limiting generalizabilty of results to those 18-21.
- All participants were opioid dependent.
- All participants were able to understand the requirements of the study and provide informed consent.
- If participant was under 18 years of age, parent/guardian provided consent and the minor provided their assent to participate.
- All participants (and parents where appropriate) were required to complete and pass a study quiz to document their understanding of the requirements of participation.

Exclusion Criteria (notes for each bullet are below):

- Clients were excluded from participation if they were determined to have a medical or psychiatric condition that would make their participation unsafe.
- They were also excluded if they had a psychiatric condition of sufficient severity to warrant medical treatment, except for SSRI medication.
- Clients who were unlikely to finish the protocol because they were going to be incarcerated or were likely to leave the area were excluded.

Because of the risks of combining buprenorphine with CNS depressants, several criteria addressed this issue:
Participants were excluded if they:

- met DSM-IV criteria for abuse of alcohol or sedatives;
- had a sedative overdose in the previous 6 months;
- were determined to have used benzodiazepines (benzos) more than 15 of the past 28 days; or,
- were unable to provide a urinalysis (UA) that was negative for both benzos and methadone during the screening process.

Because buprenorphine is not approved for use in pregnancy, female clients were excluded if:

- they were pregnant or breastfeeding; or,
- were unable or unwilling to commit to using an approved method of birth control.

Participants who met all inclusion and no exclusion were eligible for randomization into the trial.

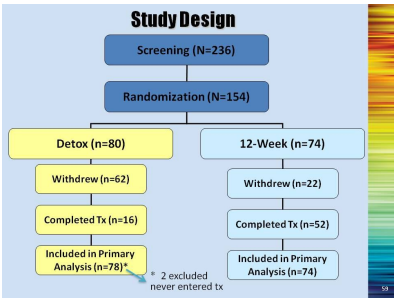
Slide 57

Slide 58: Counseling

All participants in the trial were asked to participate in a minimum of one individual and one group counseling session per week, but more frequent sessions could be scheduled.

The counseling provided at each site included methods shown to be successful and have been published in NIDA treatment manuals, including Cognitive Behavioral Therapy (CBT), referrals to additional treatment, and referrals to age-appropriate self-help groups.

Slide 58



Slide 59: Study Design

Move forward to reveal first row of chart (Screening)

A total of 236 individuals completed the consent process and entered screening.

Move forward to reveal next row of chart (Randomization)

Of these 236 individuals, 154 met all of the inclusion criteria, and none of the exclusion, and were randomized into the study.

Move forward to reveal next row of chart (Detox/12-Week)

The randomization resulted in 80 participants in the short-term detoxification group and 74 people in the 12-week group.

Move forward to reveal next row of chart (Withdrew). After the row appears, a box will automatically fly in from the bottom showing the reasons why participants withdrew.

More people withdrew from the detoxification group than the 12 week group. The reasons for withdrawal and the numbers in each group are depicted in the black box. Reasons included: not taking the medication as prescribed, leaving the study to enroll in another treatment program, voluntarily withdrawing, and being incarcerated. One person in the 12-week group died. Upon investigation, he was found to have dropped out of the study very early and died from an overdose of methadone.

Move forward to reveal next row of chart (Completed Tx)

Of the randomized people in each group, 20% (16/80) completed in the detoxification group and 70% (54/74) completed in the 12-week group.

Move forward to reveal final row of chart (Included in Primary Analysis)

Once enrolled, all participants (completed treatment or withdrew) were included in the final analysis, except for 2 individuals in the detoxification group who were randomized, but left the study prior to receiving their first dose of study medication.

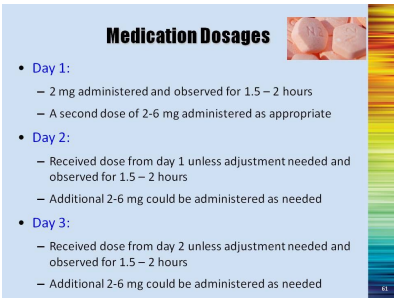
Slide 59

Slide 60: Medication Dosages

The medication for all participants was the buprenorphine/naloxone combination tablet. Medication was administered at the study site five or seven days per week. Some of the sites were closed on the weekends, so medications were administered on-site five days per week and take home doses were provided to participants for days that the program was closed.

All doses administered on-site were directly observed by study personnel.

Slide 60



Slide 61: Medication Dosages

Medication dosages were identical for all participants on the first three study days.

On Day 1, all participants were administered a 2-mg dose and observed for 1.5 to 2 hours. A second dose of 2 to 6 mg could be administered as determined by the study physician.

On Day 2, participants received the total dose received on Day 1 and then were observed for 1.5 to 2 hours. Again, an additional dose of 2 to 6 mg could be administered, as needed.

On Day 3, participants received the total dose received on Day 2 and they were observed for 1.5 to 2 hours. Again, an additional dose of 2 to 6 mg could be administered, as needed.

Slide 61

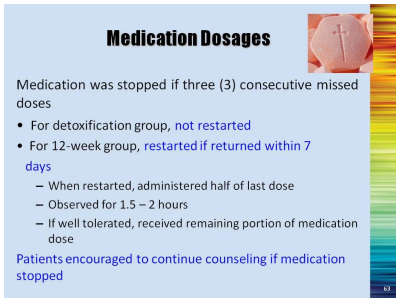
Slide 62: Medication Dosages

Beginning on Day 4, medication dosages were determined according to study group assignment.

In the Detoxification Group, the maximum allowable dose was 14 mg; the taper was begun immediately and scheduled so that it was completed by Day 14.

In the 12-week Group, the maximum allowable dose was 24 mg. Participants were stabilized on the clinically appropriate dose for the first 8 weeks. Beginning at Week 9, the taper was begun and scheduled so that it was completed by the end of Week 12.

Slide 62



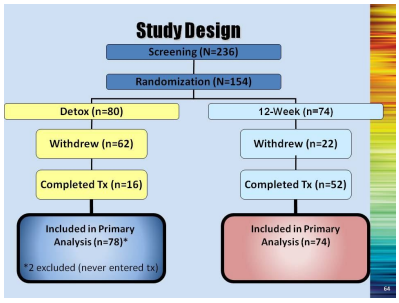
Slide 63: Medication Dosages

Slide 63

According to the study protocol, medication was stopped if three consecutive doses were missed. What happened then depended on group assignment:

- For the Detoxification Group, the medication was not restarted once it was stopped.
- For the 12-week Group, the medication was restarted if the participant returned for dosing within 7 days. It was restarted at half of the last dose administered, and the participant was observed for 1.5 to 2 hours. If the medication was well tolerated, the remaining portion of the dose was administered.

Regardless of which group they were in, all participants were encouraged to continue in counseling if the medication was stopped.

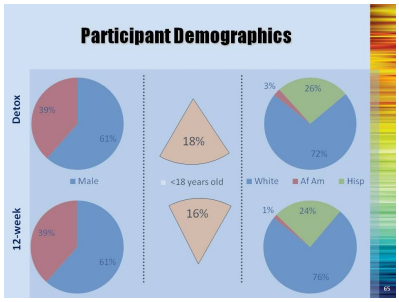


Slide 64: Study Design

Slide 64

This slide serves as a reminder of the participants included in the final analysis.

Call attention to the bottom boxes and remind people that all participants who were enrolled in the trial were included in the analysis, even those who dropped out early. The only exception to this is the two participants who were randomized, but never received treatment. These two were excluded from the analysis, resulting in 78 in the Detoxification Group and 74 in the 12-week Group.



Slide 65: Study Demographics

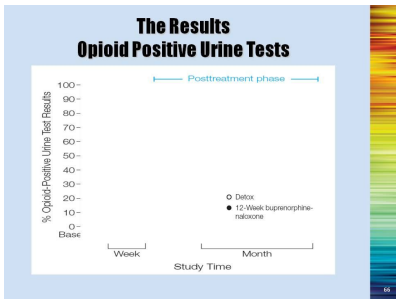
Demographic information was similar across the two groups.

Move forward to reveal first column (% Male)
Participants were mostly male.

Move forward to reveal next column (% < 18)
Very few were under the age of 18 years. These percentages indicate that only 14 Detoxification and 12 12-week participants were in this age group. This limits generalizability.

Move forward to reveal last column (% Ethnicity)
Participants were roughly ¾ Caucasian and ¼ Hispanic. While this reflects the current demographics of young users, the low number of African-Americans limits generalizabilty of findings to this population.

Slide 65



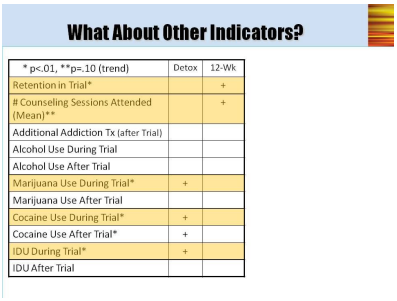
Slide 66: The Results: Opioid Positive Urine Tests

Move forward to reveal data for Weeks 4 and 8.
Results were that Detoxification patients were more likely to provide opiate-positive urine test results at Week 4 and Week 8…

Move forward to reveal data for Week 12
…but not week 12. This is significant as it is between Weeks 8 and 12 that the people in the 12-week Group are tapered off of the buprenorphine/naloxone.

Move forward to reveal data for months 6-12
At the 6-, 9-, and 12-month follow-up points, participants in the Detoxification Group provided higher proportions of positive urine results than patients in the 12-week buprenorphine-naloxone Group. Further research is needed to determine if this effect is associated with the treatment received in this study.

Slide 66



Slide 67: What About the Other Indicators?

Slide 67

This table shows the results of comparisons on a variety of additional indicators of treatment success. The plus signs indicate the variables that were statistically different.

We will look at each variable that show a difference between groups.

First, retention in the trial. The plus sign under 12-week indicates that the participants in the 12-week group were retained in the trial longer than the participants in the Detoxification group.

Move forward to the first graph (Retention in Trial)

As this graph indicates, at each time point during the active trial, the percentage of 12-week participants that were active in trial was higher than in the Detoxification group.

Move forward to the next graph (# Counseling Sessions)

While not statistically significant, there was a trend indicating a possible difference in the number of counseling sessions attended, with the 12-week Group attending more sessions on average than the Detoxification Group.

Move forward to the next graph (Marijuana Use During Trial)

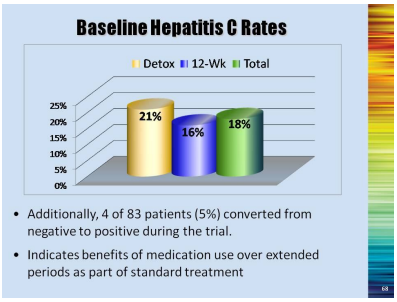
The investigators also looked at other drug use during the trial and during the follow-up period. Marijuana use was higher in the Detoxification group at all three timepoints during the trial. However, it is of note that the groups did not differ in marijuana use after the trial.

Move forward to the next graph (Cocaine Use During and After Trial)

In the adult population, cocaine use is frequently seen among opioid users. In this trial, cocaine use was higher among the Detoxification Group both during the trial and during the follow-up period.

Move forward to the final graph (IDU During Trial)

Injection drug use was found to be higher in the Detoxification Group during the trial period. However, during the follow-up period, the groups again did not differ in their use of needles.



Slide 68: Baseline Hepatitis C Rates

Slide 68

One disease that frequently occurs with substance use is Hepatitis C, especially for those drugs that are used by injection, but Hepatitis C can also be spread in other ways as well (e.g., sharing straws while using intranasally).

Because of the high co-morbidity, investigators examined both baseline rates of Hepatitis C in the study sample and during their participation in the study.

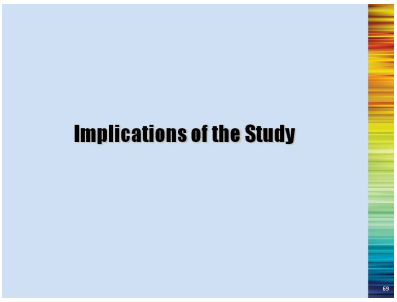
It was shown that nearly one in five participants were Hepatitis C positive upon entering the trial. This clearly indicates the high prevalence in the population from which the sample was drawn, and therefore the risk of exposure and infection.

It is of additional note that 4 of the 83 participants who were Hepatitis C negative at baseline, converted to positive during the fairly short duration of this trial. This again, clearly indicates the risk of infection with this disease.

One of the benefits of appropriate treatment with medications such as buprenorphine, is that it eliminates (or at least reduces) the risky behavior associated with illicit substance use, thereby reducing comorbid factors, such as Hepatitis C. This is another indicator that use of these medications over longer (rather than shorter) periods of time may be warranted as part of standard care (Thiede, Hagan & Murril, 2000).

Reference:

Thiede, H., Hagan, H., & Murrill, C.S. (2000). Methadone treatment and HIV and hepatitis band C risk reduction among injectors in the Seattle area. *Journal of Urban Health, 77,* 331-45.



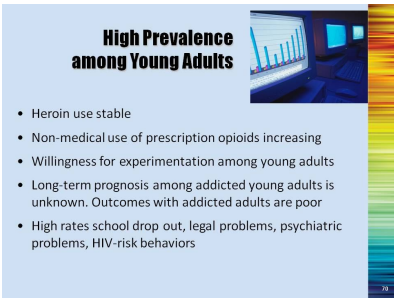
Slide 69: Implications of the Study

Slide 69

The study by Woody et al. (2008) provided implications for effective treatment of adolescents and young adults through longer-term opioid antagonist treatment. This was demonstrated by the fact that opioid-depended adolescents and young adults showed significantly greater abstinence and treatment retention while receiving buprenorphine/naloxone.

Reference:

Woody, G. E., Poole, S. A. Subramaniam, G., Dugosh, K., Bogenschutz, M., Abbott, P., et al. (2008). Extended vs short-term buprenorphine-naloxone for treatment of opioid-addicted youth: a randomized trial. *Journal of the American Medical Association, 300*(17), 2003-2011.



Slide 70: High Prevalence among Young Adults

Though heroin use has been deemed stable, there continues to be a high prevalence of opioid use among young adults and adolescents. In fact, much concern has been voiced with regards to non-medical use of prescription opioids among the current adolescent generation.

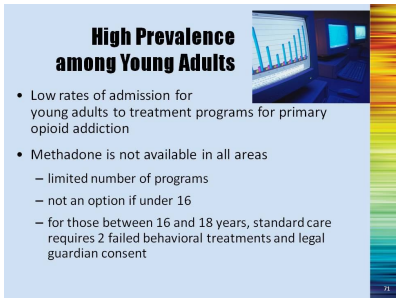
Other concerns regarding adolescent use of opioids include the willingness of many adolescents to experiment with drugs while not being knowledgeable of neurobiological changes that accompany opioid abuse and dependence (Fiellin, 2008).

Although we know that long-term outcomes among addicted adults are poor, there are many unknowns regarding long-term prognosis among addicted young adults. Lack of knowledge, coupled with the fact that most adolescents' brains have not yet reached maturity, leads to a dangerous, vicious cycle of experimentation, impairment, and dependence. This has also led to high rates of school drop out, legal problems, psychiatric problems, and high risk behaviors.

Reference:

Fiellin, D. A. (2008). Treatment of adolescent opioid dependence: No quick fix. *Journal of the American Medical Association, 300*(17), 2057-2059.

Slide 70



Slide 71: High Prevalence among Young Adults

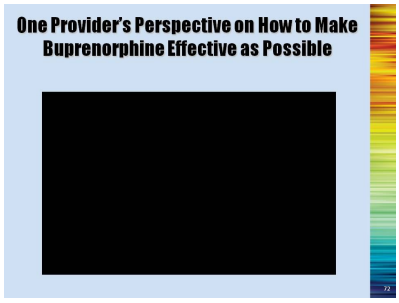
Review the bullets on the slide and ask participants what they think are some of the reasons for low rates of admission for young adults into treatment programs for opioid addiction.

If it is not mentioned, bring up the fact that one of the challenges associated with the use of prescribed medications is the stigma associated with the use of medication as an aid to one's recovery, not just among the general population but also those in the addiction counseling profession, even though research seems to indicate more benefits of prescribed medications than risks.

Other challenges to discuss:

- Common long-term treatment for opioid addiction (methadone maintenance) is not readily available to young adults and adolescents and is not an option for patients under 16 years of age.
- A requirement by many programs and/or jurisdictions is that those between 16 and 18 can only be admitted for treatment if they have had two failed behavioral treatment episodes along with a legal guardian's consent.

Slide 71

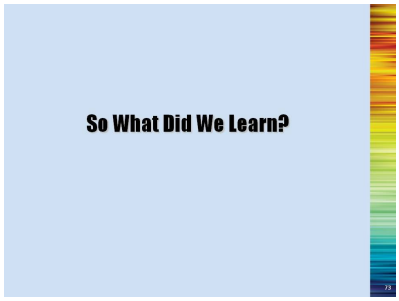


Slide 72: One Provider's Perspective on How to Make Buprenorphine as Effective as Possible (Video Clip)

After gaining experience with buprenorphine, Shannon Garret understood how effective this treatment can be. However, he emphasized the importance of a multidisciplinary approach to treatment.

Move mouse over black box. It will turn into an image of a hand. Click on the black box and the movie will play.

Slide 72



Slide 73: So What Did We Learn?

In summary, let's look at the lessons that were learned from comparing a 14-day versus 12-week taper using buprenorphine/naloxone with young adults.

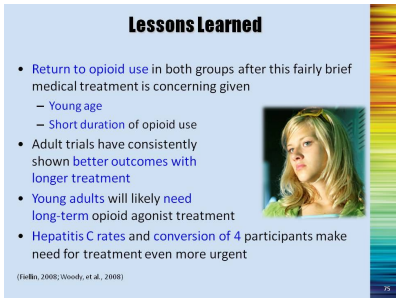
Slide 73

Slide 74: Lessons Learned

The information in the next three slides reviews the findings of this CTN research trial indicating that longer-term treatment with buprenorphine/naloxone may be more effective for young patients than short-term term detoxification.

Review each bullet and facilitate discussion by asking participants what they think are some of the reasons why longer term treatment works better than short-term detoxification for this age group.

Slide 74



Slide 75: Lessons Learned

Continue reviewing bullets and allowing for discussion about the meaning of each one to the training participants.

In addition, re-emphasize the following findings for participants in the 12-week buprenorphine/naloxone Group when compared with the short-term Detoxification Group:

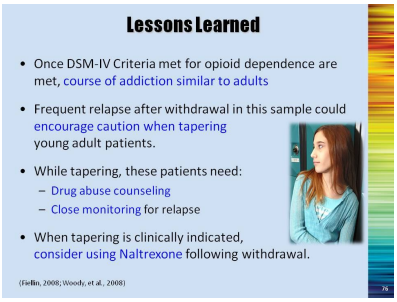
- Less use of opioids, cocaine, and marijuana
- Better treatment retention
- Less injection of drugs
- Less need for additional treatment

Slide 75

<u>References:</u>

Fiellin, D. A. (2008). Treatment of adolescent opioid dependence: No quick fix. *Journal of the American Medical Association, 300*(17), 2057-2059.

Woody, G. E., Poole, S. A. Subramaniam, G., Dugosh, K., Bogenschutz, M., Abbott, P., et al. (2008). Extended vs short-term buprenorphine-naloxone for treatment of opioid-addicted youth: a randomized trial. *Journal of the American Medical Association, 300*(17), 2003-2011.



Slide 76: Lessons Learned

Continue reviewing bullets and allowing for discussion about the meaning of each one to the training participants.

It is important to continue providing supportive counseling during the taper period.

Ask participants to give examples in their practice of how they provide support to their patients during such a taper process.

Also, discuss the efficacy of using naltrexone following the buprenorphine taper. Include the following in the discussion:

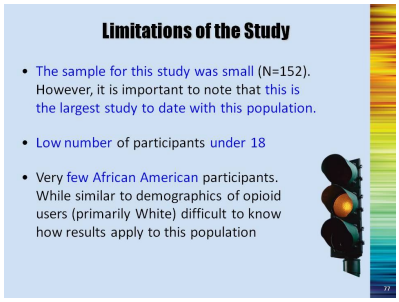
- Naltrexone is an opioid receptor antagonist;
- It can only be used after discontinuation of buprenorphine;
- It blocks the ability of endogenous opioids to stimulate the receptor; and
- It can assist the patient in remaining drug free as part of a long-term recovery counseling program.

References:

Fiellin, D. A. (2008). Treatment of adolescent opioid dependence: No quick fix. *Journal of the American Medical Association, 300*(17), 2057-2059.

Woody, G. E., Poole, S. A. Subramaniam, G., Dugosh, K., Bogenschutz, M., Abbott, P., et al. (2008). Extended vs short-term buprenorphine-naloxone for treatment of opioid-addicted youth: a randomized trial. *Journal of the American Medical Association, 300*(17), 2003-2011.

Slide 76



Slide 77: Limitations of the Study

Slide 77

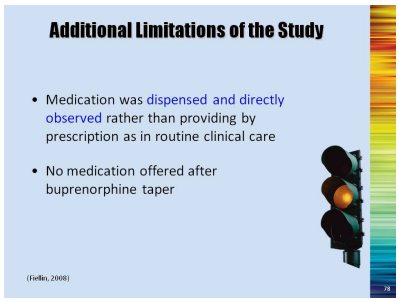
Although a need for extended medication-assisted treatment for young adults seems to exist (Subramaniam, et al., 2009), there is a call for further research to substantiate the efficacy of extended buprenorphine/naloxone treatment for this age group. The following limitations were discussed in the study by Woody, et al. (2008):

- The number of participants under the age of 18 was rather small;
- There was a total absence of African-American participants in the study;
- The study lacked a significant number of blind evaluators;
- There was missing follow-up data, making estimates on those achieving full recovery difficult; and
- The number of participants was too small to capture any adverse effects of the medication.

References:

Subramaniam, G. A., Stitzer, M. L., Woody, G., Fishman, M. J., & Kolodner, K. (2009). Clinical characteristics of treatment-seeking adolescents with opioid versus cannabis/alcohol use disorders. *Drug and Alcohol Dependence, 99*, (1-3), 141-149.

Woody, G. E., Poole, S. A. Subramaniam, G., Dugosh, K., Bogenschutz, M., Abbott, P., et al. (2008). Extended vs short-term buprenorphine-naloxone for treatment of opioid-addicted youth: a randomized trial. *Journal of the American Medical Association, 300*(17), 2003-2011.



Slide 78: Additional Limitations of the Study

Slide 78

Additional limitations of the study, as discussed by Fiellin (2008) included:

- Naltrexone was not offered to patients following buprenorphine/naloxone taper, thus potentially adversely effective abstinence;
- The medication was dispensed from offices or clinics and not provided by prescription, which may have confounded the study;
- Counseling was only offered twice each week, which may have increased the drop out rate; and
- The trial was too small to form conclusions relating to the safety of buprenorphine/naloxone for adolescents.

Reference:

Fiellin, D. A. (2008). Treatment of adolescent opioid dependence: No quick fix. *Journal of the American Medical Association, 300*(17), 2057-2059.

Slide 79: Further Research Needed

Address the bullets on the next two slides with a discussion of further research.

There is a need for developing prevention strategies for opioid use among young adults; further research on initial opioid use for this age group will be helpful in this effort.

More research is also needed on the efficacy of offering other medications, either as alternatives to buprenorphine, or as a narcotic antagonist following buprenorphine taper.

Research should also be conducted to compare buprenorphine treatment to non-medical approaches.

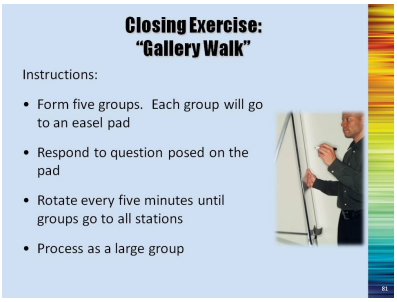
Slide 79

Slide 80: Further Research Needed

Continue the discussion on further research by reviewing the bullets on this slide. Ask participants for their input on further research needs. Include in the discussion the following:

- Little is known about using medication-assisted treatment for longer terms with young adults. More research is needed to broaden our understanding of the safety and effectiveness and the optimal length for such treatment.
- While medication-assisted treatment is known to reduce risk behaviors for HIV, HCV and other comorbidities in adults, more research is needed with young adults.
- Finally, the most effective components of psychosocial treatments to use in combination with buprenorphine treatment are unknown. Further research is needed to maximize the impact of both interventions (medical and psychosocial).

Slide 80



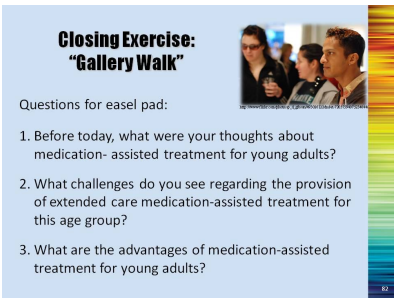
Slide 81: Closing Exercise: "Gallery Walk"

<u>Preparation prior to the training is needed for this activity</u>.

Prior to the exercise, tape an easel pad sheet at each of five stations around the room, each with a question written on the top of the sheet. Be sure to spread them around the room so that no two stations are too close together. Use the five questions listed on slides 82 and 83.

Among the participants, form five groups and assign each group to one of the stations. Give each group about 5 minutes to brainstorm and respond to the question and write responses on the chart paper, then ask each group to rotate clockwise to the next station. Let them know that you expect there to be overlap with regards to responses. Continue the process until each group arrives back to where they started.

Slide 81

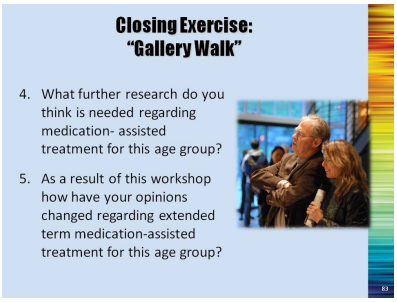


Slide 82: Closing Exercise: "Gallery Walk"

The following are the first three questions:

- ***Before this workshop, what were your general thoughts about the use of medicated-assisted treatment for adolescents?***
- ***What roadblocks or challenges do you see with regards to the provision of extended–care, medication-assisted treatment for adolescents and young adults addicted to opioids?***
- ***What are the advantages in providing medication-assisted treatment for adolescents and young adults addicted to opioids?***

Slide 82



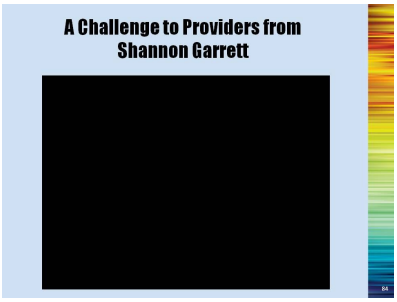
Slide 83: Closing Exercise: "Gallery Walk"

The following are the final two questions:

- ***What further research do you think is needed regarding medication-assisted treatment for adolescents and young adults addicted to opioids?***
- ***As a result of this workshop, how (if any) have your opinions changed regarding the use of extended–care, medication-assisted treatment for adolescents and young adults addicted to opioids?***

When all groups have contributed to all five questions, ask them to rotate one more time to the station where they started. Ask each group to read what was added to their original responses. Then process the exercise by asking a spokesperson for each group to summarize the answers at each respective station.

Slide 83



Slide 84: A Challenge to Providers from Shannon Garrett (Video Clip)

After participating in a clinical trial on buprenorphine and gaining additional experience with the medication following the research, Shannon Garrett summarized his feelings about buprenorphine with a challenge to participants.

Move mouse over black box. It will turn into an image of a hand. Click on the black box and the video will play.

Slide 84

Visit the Blending Initiative website for more information and Blending products: http://nida.nih.gov/blending.

NIDA NATIONAL INSTITUTE ON DRUG ABUSE