Welcome to the OPA Webinar!

Title X Program Guidelines Revision Process

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Centers for Disease Control and Prevention

The webinar will begin momentarily- please stand by...

Expert Work Group Meeting

Presentation Overview:

1. Background and purpose of the Title X Program Guidelines

2. Overall goal of Title X Program Guidelines revision

3. Review of the Title X Program Guidelines revision process, progress to date and next steps

Program Guidelines

- DHHS uses Program Guidelines in lieu of or in addition to codified program regulations

- Program Guidelines are the agency's opportunity to tell applicants and recipients what their project should consist of, as well as other relevant information

- Program staff generally develop Program Guidelines to clarify the Program Statute/Regulations and provide information to potential recipients about how to implement the program

Purpose of the Title X Guidelines

- To assist **current and prospective grantees** in understanding and utilizing the family planning service grants program:
  - **Grant application and award process**
  - **Project management & administration**
  - **Financial management**
  - **Clinic management and clinical service requirements**

- Although primary target audience of the guidelines is Title X grantees, these guidelines can and do serve as a "standard of care" for other stakeholders

Brief Background

- Original guidelines established in 1970 following the enactment of Public Health Service Act 42 U.S.C. 300 authorizing the establishment of the Title X program

- Current guidelines were updated in 1980 and in 2001

- Address largely legal and regulatory requirements of Title X program

Why Revise the Title X Guidelines?

OPA's perspective on the limitations of existing guidelines:

- Guidance on clinical practices do not meet current nationally recognized standards of care and in some instances are too prescriptive or restrictive

- Guidelines do not incorporate evidence-based standards of care and best practices

- Do not allow for timely updates and revisions based on medical, technological, and other advancements

Why Revise the Title X Guidelines?

OPA's perspective on the limitations of existing guidelines:

- Current structure organizes all content--legal, administrative, and clinical expectations into one comprehensive document

- Updating or augmenting content relating to clinical expectations requires review of the entire document including content relating to the law, statute, and administrative requirements

- Updating/revision is slow due to the fact that all content (even that which has not changed) must be reviewed

"Ideal" Guidelines

- Should address current Title X priorities

- Should provide clear guidance on administrative, financial and clinical program requirements without being too prescriptive or restrictive

- Should be consistent with national standards of care

- Should be current and reflect strong evidence base and best practices

- Should lend themselves to update/revision in a timely manner

Overall Goal of Revision Process

Goal of the revision process: to update the Title X Program Guidelines and make them more responsive to emerging issues
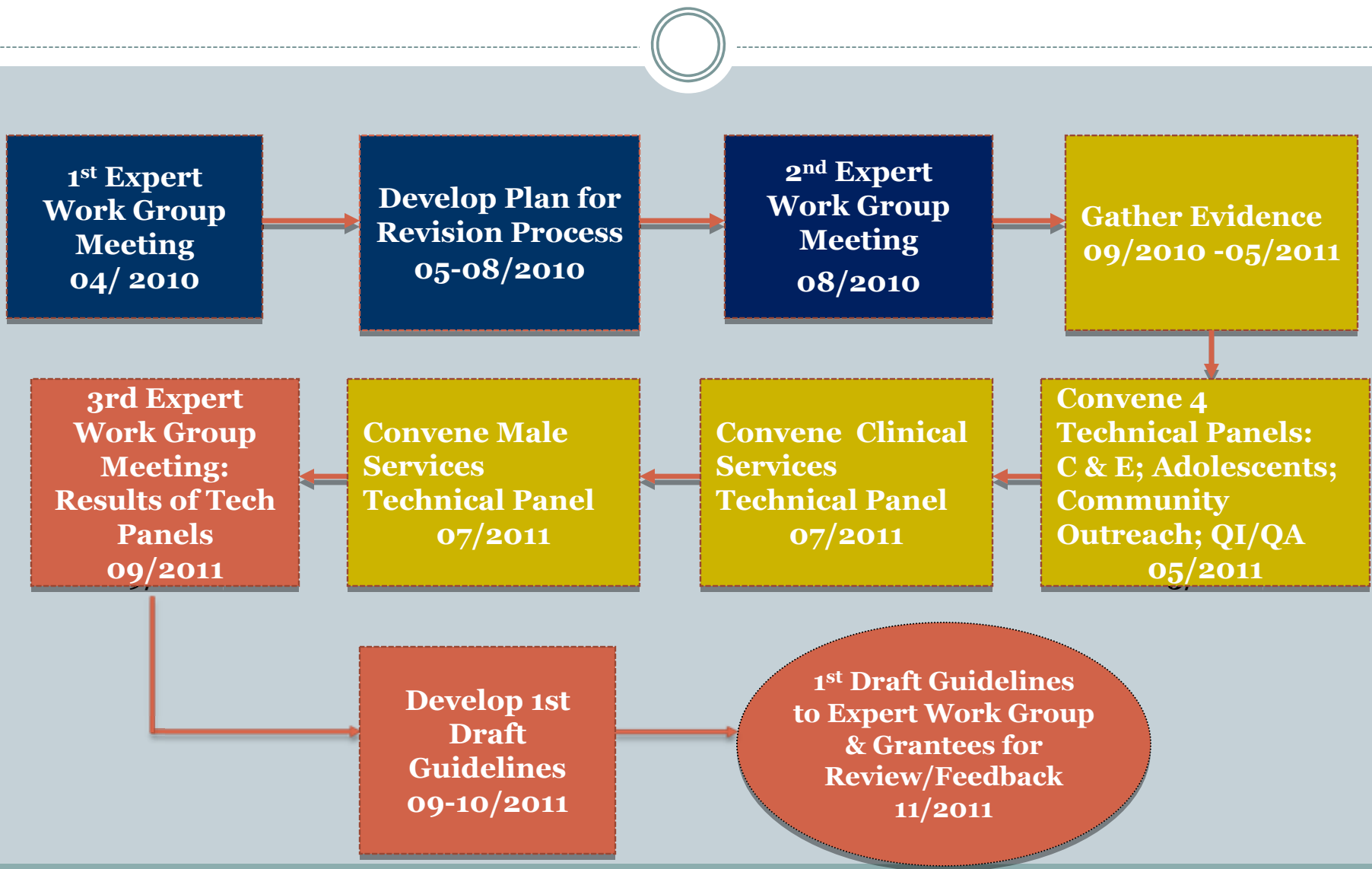
Objective 1: identify a structure for the guidelines that:

- **advises grantees about administrative, management and clinical expectations and requirements**
- **incorporates the most current national standards of care and evidence-based and best practices**

Objective 2: identify content areas/domains that guidelines should encompass

Objective 3: establish a process through which guidelines can be regularly maintained and updated

Guidance Revision Process: Phase 1

1st Expert Work Group Meeting 04/ 2010 → **Develop Plan for Revision Process 05-08/2010** → **2nd Expert Work Group Meeting 08/2010** → **Gather Evidence 09/2010 -05/2011**

Convene 4 Technical Panels: C & E; Adolescents; Community Outreach; QI/QA 05/2011 ← **Convene Clinical Services Technical Panel 07/2011** ← **Convene Male Services Technical Panel 07/2011** ← **3rd Expert Work Group Meeting: Results of Tech Panels 09/2011**

Develop 1st Draft Guidelines 09-10/2011 → **1st Draft Guidelines to Expert Work Group & Grantees for Review/Feedback 11/2011**

Guidance Revision Process: Phase 2

Collate and Review All Feedback 12/2011 → **4th Expert Work Group Meeting Review & Feedback 01/2012** → **Develop 2nd Draft Guidelines 01-02/2012** → **2nd Draft Guidelines to Expert Work Group & Grantees for Final Comment 03/2012**

Final Approval Process 08-10/2012 ← **Final Draft Guidelines 05-08/2012**

Final Guidelines Released Fall 2012 ← **Expanded 5th Work Group Meeting Focused on Dissemination 08-10/2012** ← **Final Draft Guidelines 05-08/2012**
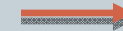
Expert Work Group Members
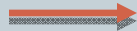
| 1st Expert Work Group Meeting 04/ 2010 | → | Develop Plan for Revision Process 05-08/2010 | → | 2nd Expert Work Group Meeting 08/2010 |

- IOM
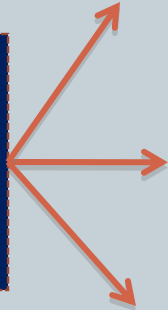- CMS
- ACOG
- PPFA
- HRSA
- ARHP
- CHC

- FP RTC
- FP MTC
- FP CTC
- NFPRHA
- SFPA
- FPCA

Expert Work Group Meeting Objectives

Expert Workgroup consultation

- Explore possible paradigms and structures for the Title X Guidelines (Expert WG Meeting #1)

- Explore requirements and domains of content that should be addressed by the Title X Guidelines (Expert WG Meeting #2)

- Explore processes for ensuring that the guidelines are updated in a timely manner and reflect current standards of care and best practices

Work Group Meeting #1: April 15-16, 2010

Explore possible paradigms and structures for the Title X Guidelines

Questions the Work Group Addressed:

- What are the strengths and weaknesses of the current Title X Guidelines structure?

- What are advantages or disadvantages of other possible structures or paradigms?

- What paradigm would be most useful or effective for Title X grantees?

Between the Expert Work Group Meetings: April-August 2010

OPA and CDC:

- Identified key steps and detailed the Guidelines revisions process/timeline
- CDC reviewed relevant literature (IOM; Bruce 1990; Becker 2007)
- OPA identified the "Must" requirements in the current Title X Guidelines that are substantiated by Statute or Regulations, as well as those that are not
- CDC drafted a possible "Organizing Framework" for portions of the Program Guidelines
- OPA and CDC mapped the Title X "Must" requirements and "Should" recommendations to the organizing framework as a usability test

Work Group Meeting #2: August 30-31, 2010

Explore requirements and domains of content that should be addressed by the Title X Guidelines

Questions the Work Group Addressed:

- Are the requirements and domains in the current guidelines appropriate for the intended use?

- What criteria should be used in the selection of domains?

- What other areas should be included? What is missing?

- What terminology for the Guidelines should be used?

Major Meeting Outcomes

Expert Work Group provided feedback on :

1. Possible structure/paradigm for the Program Guidelines

2. Those requirements/domains that are important/essential for quality family planning services (e.g., must be included in Title X Guidelines) and should be included in evidence search

3. Those requirements/domains that may be important to include in Title X Guidelines, but need evidence-based guidance or other justification that validates/supports why it should be included or how to perform effectively

DRAFT Title X Program Requirements and Program Guidance Sections

Derived from:
Title X Statute
Title X Regulations
Grants Policy
Statement & Others

Informed by:
CDC; ACOG;
ACS; USPSTF &
Others

Program Requirements

- Introduction
- Title X Statute, Regulations and Legislative Mandates
- Applicable Federal Law and Regulations
- Project Administration & Management
- Required Services

Program Guidance

- Introduction
- Title X Clinical Requirements
- Quality Clinical Services
- Effective Service Delivery Infrastructure

DRAFT Title X Program Requirements Section:
Under Construction

DRAFT Program Requirements Section

Derived from:
Title X Statute
Title X Regulations
Grants Policy
Statement & Others

Program Requirements

Introduction

Title X Statute, Regulations and Legislative Mandates

Applicable Federal Law and Regulations

Project Administration & Management

Required Services

DRAFT Program Requirements Section

Program Requirements Section will:

- Generally interpret the Title X Statute and Regulations in operational terms

- Provide a general orientation to the Federal perspective on family planning

- Provide guidance on other Federal and grants management requirements

- Succinctly present Program Requirements, according to law and regulation

DRAFT Program Requirements Section

This section will be derived from:

- Title X Statute
- Legislative Mandates
- Title X Regulations
- Federal Administrative Regulations
- OMB Circulars
- Grants Management Policy
- OPA Program Instructions

DRAFT Title X Program Guidance Section:
Under Construction

DRAFT Program Guidance Section

Program Guidance

- Introduction
- Title X Clinical Requirements
- Quality Clinical Services
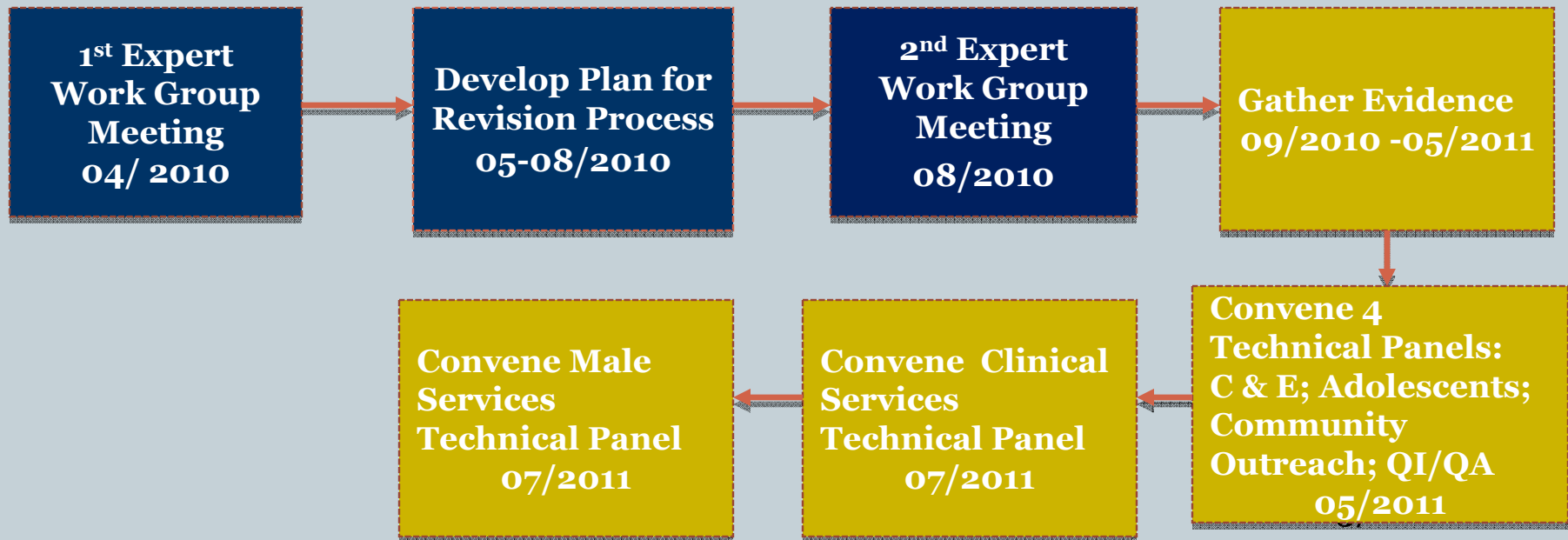- Effective Service Delivery Infrastructure

Informed by: CDC; ACOG; ACS; USPSTF & Others

Domains for Evidence Search

- Community Outreach, Participation and Barriers to Access

- Contraceptive Counseling and Education

- Adolescent Services

- Quality Assurance/Quality Improvement

- Clinical services for female clients

- Clinical services for male clients

Guidance Revision Process: Current Efforts

1st Expert Work Group Meeting 04/ 2010	→	Develop Plan for Revision Process 05-08/2010	→	2nd Expert Work Group Meeting 08/2010	→	Gather Evidence 09/2010 -05/2011

Convene Male Services Technical Panel 07/2011	←	Convene Clinical Services Technical Panel 07/2011	←	Convene 4 Technical Panels: C & E; Adolescents; Community Outreach; QI/QA 05/2011

Gathering the Evidence

- Systematic reviews of the scientific literature
- Documentation of "innovative practices"
- Synthesis of professional recommendations on clinical aspects of care

Systematic Reviews: Key Steps
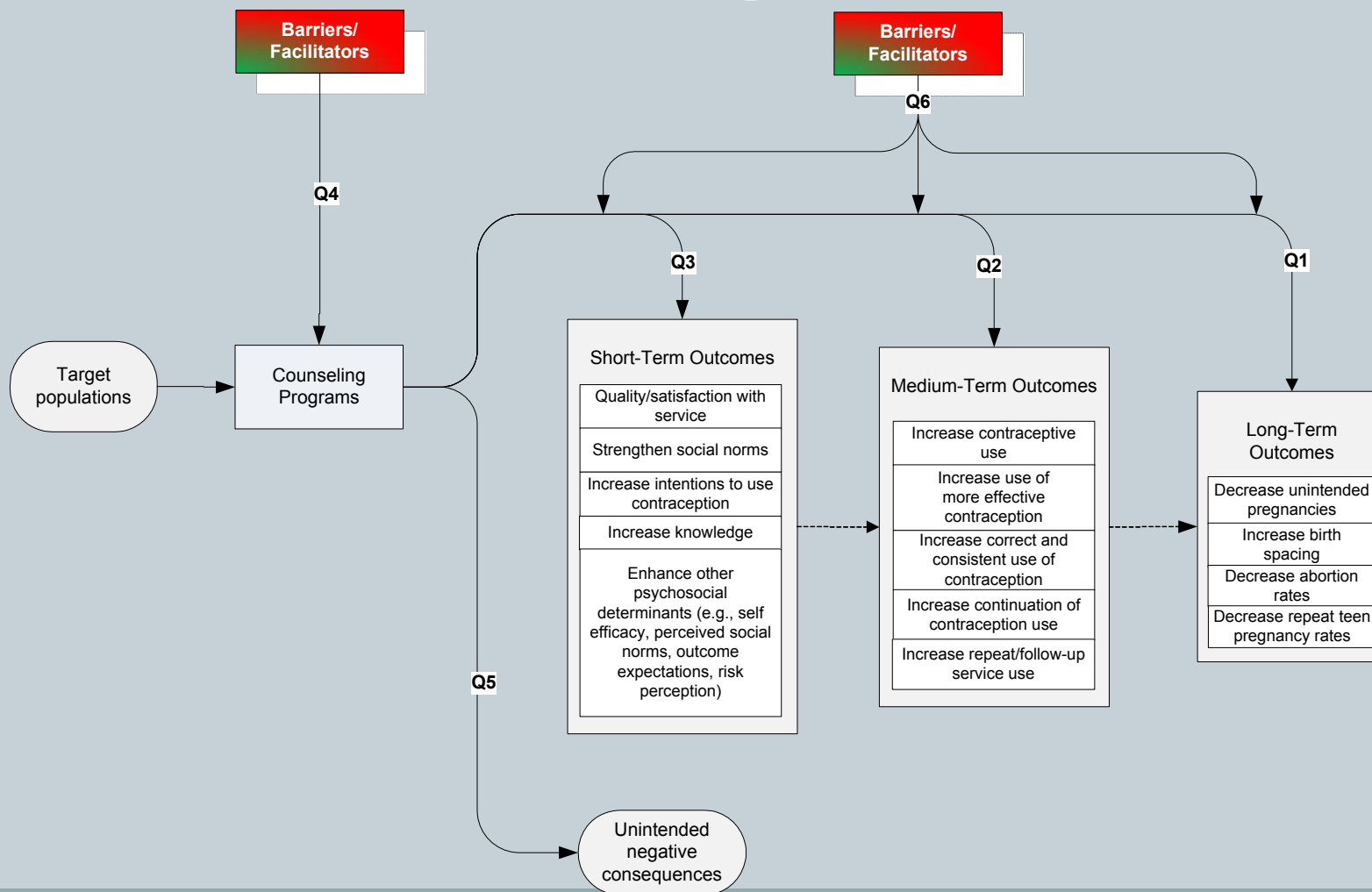
- Define terms
- Develop key questions
- Develop search terms/strategy
  - Key terms to capture appropriate literature
  - Define inclusion & exclusion criteria
- Search in multiple electronic databases
- Screen abstracts to identify those that meet retrieval criteria
- Review full papers – apply inclusion criteria
- Grade the 'quality' of identified studies
- Summarize the evidence base

Key Questions for Counseling & Education

Key Question #	Question
1	Is there a relationship between counseling programs and improved long-term outcomes of family planning services (e.g., decrease unintended pregnancies, increase birth spacing, decrease abortion rates, decrease repeat teen pregnancy rates)?
2	Is there a relationship between counseling programs and improved medium-term outcomes of family planning services (e.g., increase contraceptive use, increase use of more effective contraception, increase correct and consistent use of contraception, increase continuation of contraception use, increase repeat/follow-up service use)?
3	Is there a relationship between counseling programs and improved short-term outcomes of family planning services (e.g., improve quality/satisfaction with service, strengthen social norms, intentions to use contraception, increase knowledge, enhance other psychosocial determinants)?
4	What are the barriers and facilitators facing clinics to adopting and implementing counseling programs in the family planning setting?
5	Are there any unintended negative consequences associated with counseling programs when used in the family planning setting?
6	What are the barriers and facilitators facing clients to adopting positive outcomes after receiving counseling in the family planning setting?

Analytic Framework
for COUNSELING & EDUCATION

**Barriers/
Facilitators**

**Barriers/
Facilitators**

Q6

Q4

Q3

Q2

Q1

Target
populations

Counseling
Programs

Short-Term Outcomes

Quality/satisfaction with service

Strengthen social norms

Increase intentions to use contraception

Increase knowledge

Enhance other psychosocial determinants (e.g., self efficacy, perceived social norms, outcome expectations, risk perception)

Medium-Term Outcomes

Increase contraceptive use

Increase use of more effective contraception

Increase correct and consistent use of contraception

Increase continuation of contraception use

Increase repeat/follow-up service use

Long-Term Outcomes

Decrease unintended pregnancies

Increase birth spacing

Decrease abortion rates

Decrease repeat teen pregnancy rates

Q5

Unintended
negative
consequences

Electronic Databases Searched

Database	Data limits	URL for search platform
Cumulative Index to Nursing and Allied Health Literature (CINAHL)	01/01/1985 through 02/28/2011	http://ebscohost.com/
The Campbell Library	01/01/1985 through 02/28/2011	http://www.campbellcollaboration.org/library.php
The Cochrane Library	01/01/1985 through 02/28/2011	www.thecochranelibrary.com
Database of abstracts of reviews of effects (DARE)	01/01/1985 through 02/28/2011	http://www.crd.york.ac.uk/crdweb/
EMBASE	01/01/1985 through 02/28/2011	http://ebscohost.com/
MEDLINE	01/01/1985 through 02/28/2011	http://ebscohost.com/
PsycINFO	01/01/1985 through 02/28/2011	www.apa.org/psychinfo
PubMed (pre MEDLINE)	01/01/1985 through 02/28/2011	http://ebscohost.com/
UK National Health Service Economic Evaluation Database (NHS EED)	01/01/1985 through 02/28/2011	http://www.crd.york.ac.uk/crdweb/
US National Guideline Clearinghouse (NGC)	01/01/1985 through 02/28/2011	www.guidelines.gov
HealthSTAR	01/01/1985 through 02/28/2011	http://www.kfinder.com/newweb/Products/hstar.html
POPLINE	01/01/1985 through 02/28/2011	http://www.popline.org/
Education Resource Information Center (ERIC)	01/01/1985 through 02/28/2011	http://www.eric.ed.gov/
UK National Institute of Clinical Excellence (NICE)	01/01/1985 through 02/28/2011	http://www.nice.org.uk/
Evidence for Policy and Practice Information (EPPI) database of evidence	01/01/1985 through 02/28/2011	http://eppi.ioe.ac.uk/cms/
TRIP	01/01/1985 through 02/28/2011	http://tripdatabase.com/

Search Terms - Counseling

PubMed Search Strategy: Counseling

Set Number	Concept	Search Statement	Number of Hits
1	Family Planning	"Family Planning Services"[Mesh] OR "Family Planning Policy"[Mesh] OR "Reproductive Health Services"[Mesh] OR "Family Planning" OR ("Title X") OR ("Planned Parenthood")	51053
2	Contraception	"Contraception"[Mesh] OR "Contraceptive Agents"[Mesh] OR "Contraceptive Devices"[Mesh] OR ("Birth control") OR "Contraception Behavior"[Mesh]	64662
3	Counseling	"Counseling"[Mesh]	27592
4	Education	"Health Education"[Mesh] OR "Health Education"[All Fields] OR ("Health Educator")	128823
5	Adolescents	"Adolescent"[Mesh] OR "Adolescent Behavior"[Mesh] OR "Adolescent Development"[Mesh] OR "Pregnancy in Adolescence"[Mesh] OR "Adolescent"[All Fields] OR "Adolescent Behavior"[All Fields] OR "Adolescent Development"[All Fields] OR "Pregnancy in Adolescence"[All Fields]	1378164
6	Combine all sets (excluding Adolescent set)	(#1 OR #2) AND (#3 OR #4)	7732
7	Combined all sets with adolescents	#6 AND #5	3182
8	Limit	#6 AND (only items with abstracts, Publication Date from 1985/01/01 to 2010/12/03; not Editorial, Letter, Comment, News, Newspaper Article)	**4440 Endnote**
9	Limit	#7 AND (only items with abstracts, Publication Date from 1985/01/01 to 2010/12/03; not Editorial, Letter, Comment, News, Newspaper Article)	**2077**

Retrieval Criteria

- Published between 1985 - present
- Published in the English language
- Article must describe a study that speaks to at least one of the six key questions addressed by this evidence report
- Article must describe a study that occurred in a clinic-based setting where family planning services were provided
- If the same study is reported in multiple publications, the most complete publication will be the long-term reference. Data will be extracted to avoid double-counting individuals
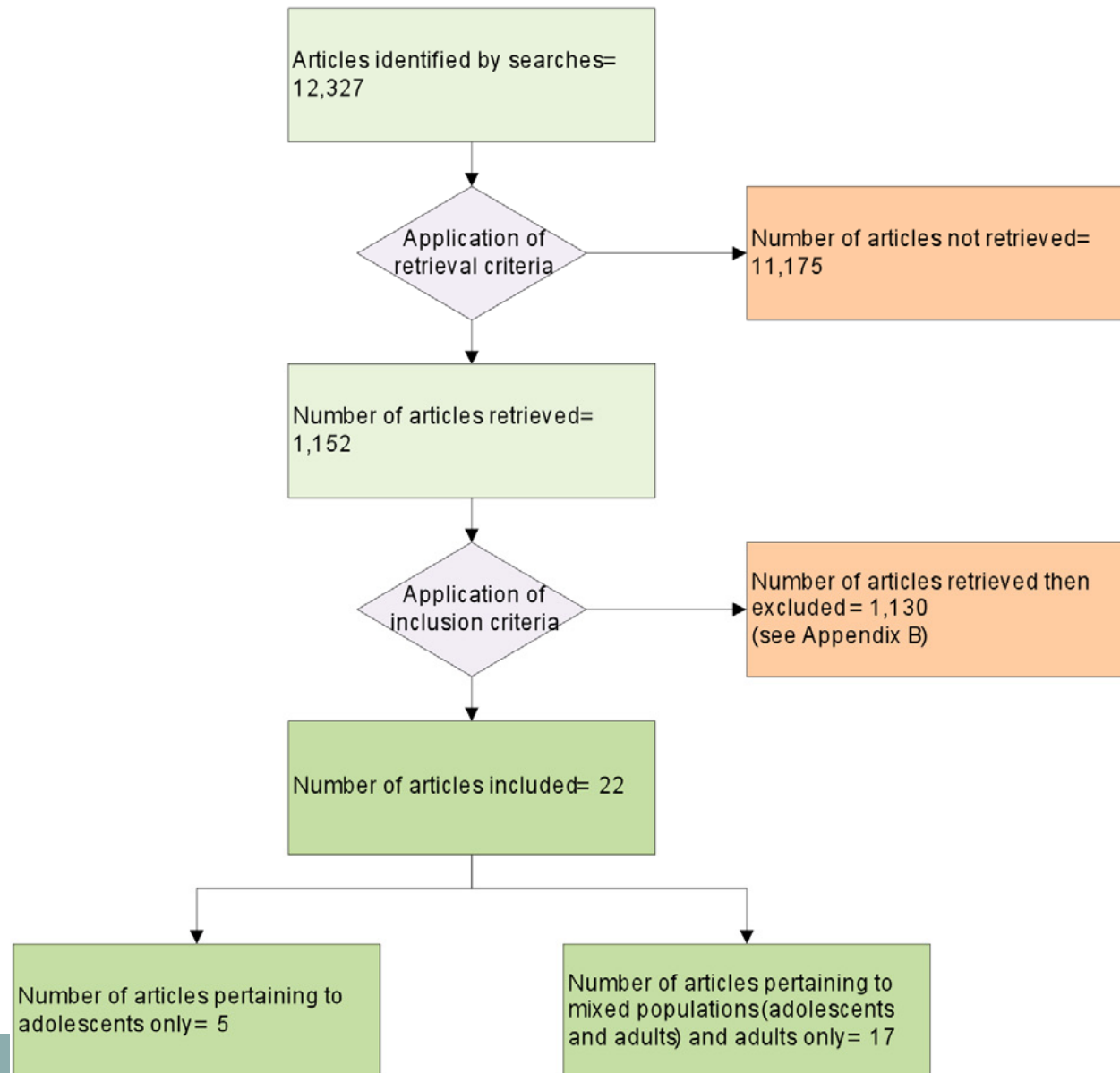
Inclusion Criteria

Key Questions 1 through 3

- Case reports/program descriptions will not be included
- Article must describe a study that attempted to determine if counseling programs in family planning services impact at least one <u>long-term</u>, <u>medium-term</u>, or <u>short-term</u> outcome
- Article must describe a study that includes a comparison e.g., experimental or quasi-experimental design, pre-post test design, case control, or comparing two or more groups in a cross-sectional survey

Flow Diagram Showing Evolution of Databases

Articles identified by searches= 12,327

Application of retrieval criteria

Number of articles not retrieved= 11,175

Number of articles retrieved= 1,152

Application of inclusion criteria

Number of articles retrieved then excluded= 1,130 (see Appendix B)

Number of articles included= 22

Number of articles pertaining to adolescents only= 5

Number of articles pertaining to mixed populations(adolescents and adults) and adults only= 17

Innovative Practices

- Practices that:
  - Addressed priority areas (counseling, community outreach, adolescents, QA/QI)
  - Were developed by practitioners in the field
  - Have some evidence of success
  - Could be replicated (e.g., manuals or procedures documented)

- Requested nominations, then every nomination was fully described

- 44 innovative practices were identified:
  - 17 – adolescents
  - 7 – counseling
  - 13 – community outreach and participation
  - 7 – quality assurance/quality improvement
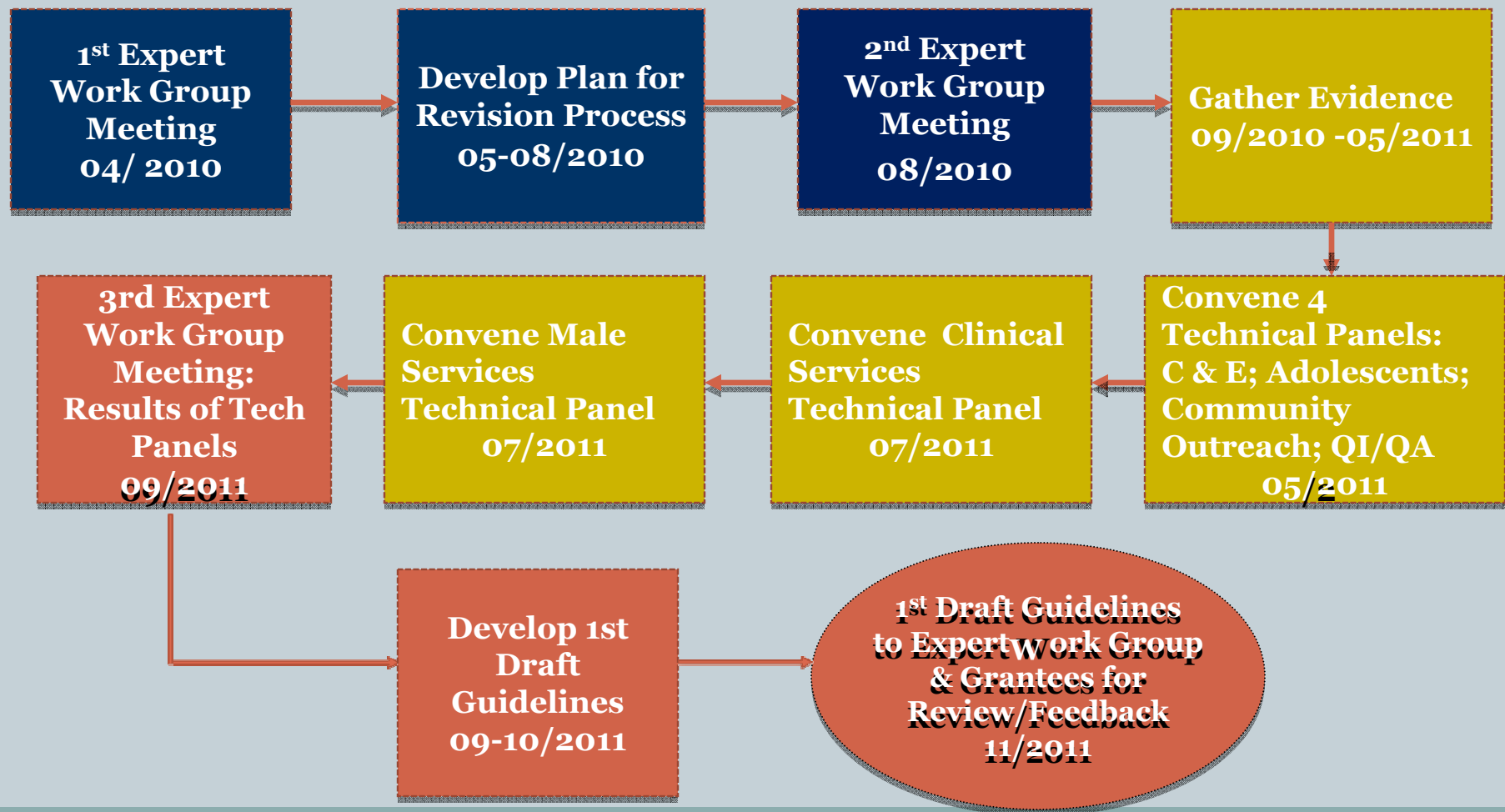
Professional Recommendations on Clinical Care

- Compile information from existing professional organizations (e.g., CDC's Division of STD Prevention, CDC's Breast & Cervical Cancer Program, ACOG, AMA, AAP, etc.)

- Consider women's <u>and</u> men's health

- Answer 3-4 key questions about key screening/treatment tasks:
  - What are the recommendations?
  - Are there any inconsistencies?
  - What makes most sense in the context of a Title X clinic?

The Role of the Technical Panels

- Six Technical Panels will be convened:
  - Counseling & Education – May 2011
  - Community Outreach – May 2011
  - Adolescents – May 2011
  - QA/QI – May 2011
  - Clinical services (women and men) – July 2011

- Members selected for their expertise in the content area

- Their job is to:
  - Consider potential implications for program guidelines
  - Consider future research priorities

Guidance Revision Process: Next Steps

1st Expert Work Group Meeting 04/ 2010 →
Develop Plan for Revision Process 05-08/2010 →
2nd Expert Work Group Meeting 08/2010 →
Gather Evidence 09/2010 -05/2011 →

Convene 4 Technical Panels: C & E; Adolescents; Community Outreach; QI/QA 05/2011 →
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Convene Male Services Technical Panel 07/2011 →
3rd Expert Work Group Meeting: Results of Tech Panels 09/2011 →

Develop 1st Draft Guidelines 09-10/2011 →
1st Draft Guidelines to Expert Work Group & Grantees for Review/Feedback 11/2011

Guidance Revision Process: Phase 2

Grantee Feedback

- OPA welcomes all grantee comments/feedback on the Guidelines drafts

- Grantees have two opportunities for commenting and providing feedback on the draft Guidelines
  - ❑November 2011
  - ❑March 2012

- OPA is developing a Guidelines website for submission and management of grantee comments/feedback

Title X Program Guidelines

Summary:

- This Guidelines revision process is unlike previous updates/revisions
- The end goals:
  - To produce evidence-based or evidence-informed Title X Program Guidelines that also provide a service/contribution to the greater reproductive health community
  - To create a process/mechanism for keeping the Guidelines current (similar to the MEC approach)
  - To use the review of evidence, and the gaps identified, to inform OPA's future research efforts

Questions?