

# MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

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# **Brief Measure Information**

**NQF#:** 3699e

**Corresponding Measures:** 

Measure Title: SINC-Based Contraceptive Care, Non-Postpartum

Measure Steward: University of California, San Francisco

**sp.02. Brief Description of Measure:** Percentage of women who 1) received or had documented use of most or moderately effective contraception and 2) received a long-acting reversible contraceptive method during the calendar year.

To focus the measure on the population of women interested in contraceptive services, the denominator excludes those individuals who did not receive or have documented use of a method if they indicated during the year that they did not want these services, as well as those who are eligible for postpartum contraceptive services during the measurement period.

**1b.01 Developer Rationale:** Supporting patients to prevent pregnancy when they wish to do so has social and health benefits for individuals and their families [1, 2]. Contraception is a highly effective clinical preventive service that can assist women in reaching their reproductive health goals [3, 4]. While most and moderately effective contraceptive methods have a failure rate of 1-23%, not using any method at all has a failure rate of 85% [4]. In order to support patients to achieve their reproductive goals, facilities at which individuals receive care must ensure that contraceptive needs are assessed and met. This includes ensuring that the most effective reversible methods of contraception - intrauterine devices and implants – are available in a timely fashion.

Multiple commentaries have detailed how the use of performance measures related to contraceptive provision can improve health care quality and promote positive reproductive health outcomes [5-7]. The University of California, San Francisco (UCSF) designed the Self-Identified Need for Contraception (SINC) — Based Contraceptive Care, Non-Postpartum electronic clinical quality measure (eCQM, NQF #3699e) to give health care organizations and facilities the opportunity to measure contraceptive provision among clients who want contraceptive services. Specified for use with electronic health record (EHR) system data, NQF #3699e can be calculated in a wider array of health care settings, including systems that do not rely on administrative claims. Below, we describe the rationale for an eCQM of contraceptive use.

The National Quality Forum (NQF) endorsed the first clinical performance measures focused on contraception in October 2016, empowering health care organizations to assess contraceptive services to improve quality of family planning care. Stewarded by the U.S. Health and Human Services (HHS) Office of Population Affairs (OPA) and specified for calculation in administrative claims, the Contraceptive Care measures (NQF #2902,

#2903, and #2904) estimate the percentage of women ages 15-44 years provided a most or moderately effective method of contraception in two populations in this age range: postpartum women and all fecund women. These NQF-endorsed measures also evaluate access to long-acting reversible contraception (LARC), which is a subset of most and moderately effective methods, by focusing on low (i.e., less than 2%, rather than high) rates of use as a proxy for access [5-7].

The contraceptive provision measures provide reliable and valid metrics for health entities to evaluate the proportion of women receiving prescription contraceptive methods, but administrative claims data has limitations affecting measure implementation in different care settings as well as assessment of previous contraceptive services received and client preferences for contraception. The claims-based measures are designed for calculation in service delivery systems with a fee-for-services model, which rely on claims. Thus, entities that use prospective payment systems, such as Federally Qualified Health Centers (FQHCs), which are community-based health care providers that receive federal funds to provide primary care services in underserved areas, cannot easily employ NQF #2902, #2903, and #2904 to evaluate contraceptive services quality. These measures also do not always accurately identify which contraceptive method a woman is using following a visit (particularly LARC methods and sterilization, which are not captured in administrative claims if provided prior to the latest health care visit or during a previous measurement period). Furthermore, client preferences for contraceptive services are not available in administrative data, and the claims-based measures cannot accurately parse which women need or want contraceptive services.

Electronic clinical quality measures (eCQMs) offer a way to measure family planning and reproductive health care quality by utilizing electronic health record (EHR) system data [4]. Unlike administrative claims, EHR systems can capture client need for contraceptive and other health services and are utilized in a wider array of health care settings. Ideally, eCQMs are calculated with data captured in structured form during the process of patient care. NQF #3682e, UCSF's SINC-Based Contraceptive Care eCQM, aims to document contraceptive use and define the postpartum population in need of contraceptive services for the denominator more accurately through encounter-level EHR data. To focus the measure on the population of women interested in contraceptive services, UCSF created the Self-Identified Need for Contraception (SINC) data element. SINC consists of a standardized question and response options in the LOINC code system. It serves as a l exclusion criterion for the #3699e denominator. Before SINC, no measure of patient desire for contraceptive services existed for consistent implementation across EHR systems (note that One Key Question® [8], a proprietary question that assess desire for pregnancy in the next year, does not fulfill this need, in that it assesses future desires, rather than immediate need for services). Developed through our engagement with Reproductive Justice Consultants and industry stakeholders, this screening question asks patients for their desire for contraceptive services on the day of their visit. SINC helps refine the NQF #3682e denominator to exclude those individuals who did not receive or have documented use of a prescription contraceptive method if they indicated no desire for these services [9]. This novel data element helps guard against the possibility of directive or coercive counseling towards contraception that may be an unintentional result of use of a contraceptive use performance measure. This is particularly important given the (ongoing) history of reproductive oppression, contraceptive coercion, and biased counseling in the United States directed at women of color and low-income women [10-18]. A standardized measure of self-identified contraceptive need also provides an -opportunity to hardwire patient-centered workflows into the EHR that can facilitate patients getting their needs met.

Similar to the currently endorsed measures of contraceptive provision that rely on claims data (NQF #2903), #3699e is designed to encourage provision of the full range of methods. We recognize that some patients will prefer to use non-prescription methods that do not qualify as most- or moderately-effective methods, even when provided with full counseling. As a result, we do not have a currently identified benchmark for this measure, and do not expect scores to reach 100%. The goal of the NQF #3699e sub-measure related to IUD and implant provision is to ensure access to these methods, and will be interpreted similarly to NQF #2904, in which the goal is to identify low rates of provision (i.e., below 2%) as an indication of barriers to access. We emphasize that it is important that these contraceptive services are provided in a client-centered manner that treats each person as a unique individual with respect, empathy, and understanding, providing accurate, easy-to-understand information based on the client's self-identified needs, goals, preferences, and values [19].

In summary, the SINC-Based Contraceptive Care, Non-Postpartum eCQM can be used in settings that cannot use the claims-based contraceptive provision measures and provides improved measurement of whether patient's contraceptive needs are being fulfilled. By specifying the denominator as people who self-identify as needing contraceptive services, NQF #3699e shifts focus to people's reproductive health needs as they define them. Implementing NQF #3699e will result in quality improvement initiatives that help health care organizations better meet clients' needs by increasing patient-centered access to contraception in a wider range of settings, a step towards the goal of reproductive autonomy and well-being for all.

**sp.12 Numerator Statement:** Primary measure: Eligible women who received or were documented to be using a most (i.e., sterilization, implants, intrauterine devices or systems [IUD/IUS]) or moderately effective (i.e., injectables, oral pills, patch, or ring) contraceptive method.

Sub-measure: Eligible women provided a long-acting reversible contraceptive method (IUD or implant).

**sp.14. Denominator Statement:** All women, aged 15-44, with a qualifying encounter in the calendar year **sp.16. Denominator Exclusions:** 

- 1. Documentation of anatomical infecundity due to removal of uterus and/or bilateral ovaries, and
- 2. Among those who did not receive or be documented to use a most or moderately effective method in the measurement period, those who indicated they did not want contraceptive services, and
- 3. Those who had prenatal visit between 1/1/XX-1 (year prior to the measurement year) and 9/30/XX (the measurement year) with a live birth date, if documented, or a documented estimated delivery date between 10/1/XX-1 and 9/30/XX, provided they did not have a documented ectopic pregnancy intrauterine fetal demise, early pregnancy loss, or abortion. The inclusion in this measure of those who were documented to have a non-live birth ensures that whether the contraceptive needs of these individuals are met is measured, as the peripartum measure excludes these individuals in order to focus on the peripartum care pathway.

Measure Type: Outcome: Intermediate Clinical Outcome

sp.28. Data Source: Electronic Health Records; Electronic Health Data

sp.07. Level of Analysis: Facility

# Preliminary Analysis: New Measure for Approval for Trial Use

# Criteria 1: Importance to Measure and Report

# 1a. Evidence

**1a. Evidence.** The evidence requirements for a *structure, process or intermediate outcome* measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

# The developer provides the following description for this measure:

• This is a new intermediate clinical outcome measure at the facility level that assesses percentage of women who 1) received or had documented use of most or moderately effective contraception and 2) received a long-acting reversible contraceptive method during the calendar year..

- The developer provides a <u>logic model</u> that depicts several healthcare system evidence-based clinical family planning recommendations of CDC and OPA that affect two intermediate clinical outcomes: provision of contraceptive methods based on client's choice, and client's use of contraception.
- The developer notes that these intermediate outcomes signify a client's decision at the end of a clinical encounter that will influence their probability of having an undesired pregnancy.

The developer provides the following evidence for this measure:

•	Systematic Review of the evidence specific to this measure?	$\boxtimes$	Yes	No
•	Quality, Quantity and Consistency of evidence provided?	$\boxtimes$	Yes	No
•	Evidence graded?	$\boxtimes$	Yes	No

### **Summary:**

- The developer provides both a Clinical Practice Guideline recommendation and the graded systematic reviews that support it as evidence for this measure.
  - o The Clinical Practice Guideline from Morbidity and Mortality Weekly Report (MMWR) states that "providers should work with the client interactively to select an effective and appropriate contraceptive method." Specifically, the guideline notes that providers can educate the client about contraceptive methods that the client can safely use, and help the client consider potential barriers. It also recommends the use of decision aids.
  - The developer links the systematic reviews published by the CDC in the American Journal of Preventive Medicine describing the evidence and their grading. The review contains 132 studies from 9 systematic reviews, graded according to USPSTF criteria, from A (good evidence to consider inclusion) to F (good evidence to support exclusion). The systematic reviews include 41 randomized controlled trials, as well as other types of research studies and national survey data.
  - The developer notes that actions taken by facilities to provide family planning services should:
    - define a core set of family planning services for women and men;
    - describe how to provide contraceptive and other clinical services, serve adolescents, and perform quality improvements;
    - encourage the use of the family planning visits to provide selected preventive health services for women, in accordance with the recommendations for women issued by the Institute of Medicine (IOM) and adopted by HHS; and
    - support offering a full range of Food and Drug Administration (FDA)-approved contraceptive methods as well as counseling that highlights the effectiveness of contraceptive methods overall.
  - o Four additional reviews were provided that were published since the systematic review listed above. They provided updated scientific findings but did not change the conclusions of the original systematic reviews and did not make a substantial shift in how family planning care should be provided.
- The developer provides another systematic review from ACOG in 2017 stating that intrauterine
  devices (IUDs) and contraceptive implants, also called long-acting reversible contraceptives (LARC), are
  effective reversible contraceptive methods that can be provided to a broad range of patients wishing
  to prevent pregnancy, including postpartum women.

- o The recommendations were graded Level A (based on good and consistent scientific evidence), Level B (based on limited or inconsistent scientific evidence), and Level C (based primarily on consensus and expert opinion).
- The developer cites the U.S. Medical Eligibility Criteria (MEC) for Contraceptive Use (2016) which concluded that most women can use most contraceptive methods safely to prevent pregnancy. This criteria was supported by 13 systematic reviews with 108 articles and graded evidence, published by the CDC.
  - The American Academy of Family Physicians has since issued four practice guidelines which support and advocate for the use of U.S. MEC.
- The developer also cites the 2016 U.S. Selected Practice Recommendations for Contraceptive Use, which concluded that most women can start most contraceptive methods at any time, and few examinations or tests, if any, are needed before starting a contraceptive method. The selected practice recommendations also include guidance for management of bleeding irregularities and updated procedures for missed pills and dosing errors with the contraceptive patch and ring.
- The developer provides the 2017 Women's Preventive Services Guidelines as evidence of proper contraceptive care, which should include counseling, initiation, and follow-up. The guidelines were supported by two systematic reviews, one randomized controlled trial (RCT), two observational studies, one 1 clustered randomized trial, and one book chapter. The updates were supported by 34 RCTs identified from a recent systematic review. The developer reports that the strength of evidence is high.
  - Additional information was added in January 2022 since the guidelines were first published. They provided updated research on effective, comprehensive contraceptive care but did not change the conclusions of the original guidelines and did not make a substantial shift in the care that should be provided.
- Evidence from Contraceptive Technology is presented as well. Contraceptive Technology is a primary resource for multiple stakeholders regarding contraceptive failure rates. The developer reports that the book contains 3,136 total studies in book, 103 in the chapter on Efficacy, Safety, and Personal Considerations. Regarding most and moderately effective methods, failure rates per year under typical use are less than 1 percent and 4 to 7 percent, respectively.
- The developer cites Contraceptive Counseling in Clinical Settings: An Updated Systematic Review (2018), which concludes that evidence supports the utility of contraceptive counseling, in general, and specific interventions or aspects of counseling. Promising components of contraceptive counseling were identified. This systematic review consisted of 35 articles and 32 studies graded using the USPSTF system. Twelve of the studies are graded level I (evidence obtained from at least one properly randomized controlled trial) and the remaining are graded II-1 to II-3.
- The developer also cites Committee Opinion No. 710: Counseling Adolescent About Contraception ACOG, which recommends that regardless of a patient's age or previous sexual activity, the obstetrician-gynecologist routinely should address her contraceptive needs, expectations, and concerns including emergency contraception. It also states that OB-GYNs should be aware of statues that relate to minors and be prepared to address misperceptions about contraception. The recommendations also states that the initial encounter and follow-up visits should include continual reassessment of sexual concerns, behavior, relationships, prevention strategies, and testing and treatment for sexually transmitted infections per the CDC guidelines. The potential harm identified emphasized that at no time should an adolescent patient be forced to use a method by someone other than themselves.
- The developer cites *Patient-Centered Contraceptive Counseling (2022)* which recommends that OB-GYNs incorporate a reproductive justice framework into their contraceptive counseling. The

- Committee also recommended that OB-GYNs should also utilize shared decision-making through patient-centered contraceptive counseling.
- The developer cites Committee Opinion No. 642: Increasing Access to Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy (2015) ACOG (Group 10) which recommends that for all women at risk of unintended pregnancy, obstetrician-gynecologists should provide counseling on all contraceptive options, including implants and IUDs, adopt best practices for LARC insertion, advocate for coverage and appropriate payment and reimbursement for every contraceptive method by all payers in all clinically appropriate circumstances, and become familiar with and support local, state (including Medicaid), federal, and private programs that improve affordability of all contraceptive methods.

# **Questions for the Committee:**

• How strong is the evidence for this relationship?

Guidance from	ı the	<b>Evidence</b>	<b>Algorithm</b>
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Preliminary rating for evidence:	⊠ High	☐ Moderate	□ Low	□ Insufficient	
immediate-outcome measure is pro from a systematic review provided HIGH	` '	, , ,	•	, ,	
Not a health outcome (Box 1) -> Sys	stematic revie	ew and grading o	f the body o	of empirical evidence for the	

1b. Gap in Care/Opportunity for Improvement and Disparities

**1b. Performance Gap.** The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- The developer does not have performance scores available for NQF #3699e as they are submitting this eCQM for Approval for Trial Use.
- The developer does provide 2019 Family Planning Annual Report (FPAR) results that showed that overall, 15.9 percent of clients ages 15-19 and 17.2 percent of clients ages 20-44 were provided a LARC method.

#### **Disparities**

• The developer notes that in the Washington State Health Care Authority (WA HCA) sample population for #3699e, data suggests that there are opportunities for improvement to ensure that all race/ethnicity non-postpartum groups have equal access to the full range of contraceptive methods. The specific distribution was not provided.

#### **Questions for the Committee:**

•	Is there a ga	o in care	that warrants	a national	performance	measure?
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Preliminary rating for opportunity for improvement:	☐ High	<b>⊠</b> Moderate	□ Low □
Insufficient			

# **Committee Pre-evaluation Comments:**

#### 1a. Evidence

- Developer noted a number of existing clinical guidelines for support of evidence
- This is a new measure that uses EHR data and may be especially useful in organizations like FQHCs that use a prospective payment system.
- High level of evidence to support this measure

## 1b. Gap in Care/Opportunity for Improvement and Disparities

- Noted variation in performance in use of contraception across different subgroups
- Although performance scores for this measure are not yet available, there is evidence to demonstrate disparities in access to and use of effective contraception based on race and ethnicity.
- Supporting evidence there exists a performance gap

# Criteria 2: Scientific Acceptability of Measure Properties

Complex measure evaluated by Scientific Methods Panel?  $\square$  Yes  $\boxtimes$  No

**Evaluators:** N/A

# 2a. Reliability: Specifications and Testing

**2a1. Specifications** requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented.

- Submitted measure specification follows established technical specifications for eCQMs (QDM, HQMF, and CQL) as indicated Sub-criterion 2a1.
- Submitted measure specification is fully represented and is not hindered by any limitations in the established technical specifications for eCQMs.

**2a2. Reliability testing** demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers.

# **Specifications:**

 eCQMs was specified using the latest industry accepted eCQM technical specifications: health quality measure format (HQMF), Quality Data Model (QDM), Clinical Quality Language (CQL), and value sets vetted through the National Library of Medicine's Value Set Authority Center (VSAC).

#### **Reliability Testing:**

 Because this measure is submitted for Approval for Trial Use, testing information was not provided therefore the Committee does not vote on reliability or validity.

#### **Questions for the Committee regarding reliability:**

• Do you have any concerns that the measure cannot be consistently implemented (i.e., are measure specifications adequate)?

2b. Validity: Validity testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

**2b2. Validity testing** should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality.

**2b2-2b6.** Potential threats to validity should be assessed/addressed.

- Because this measure is submitted for Approval for Trial Use, testing information was not provided therefore the Committee does not vote on reliability or validity.
- The Feasibility Scorecard indicated that the following data elements have issues with accuracy:
  - Procedure, performed: Delivery Live Births
  - o Assessment, performed: Sterilization SNOMED Findings
  - Assessment, performed: Intrauterine Devices SNOMED Findings
  - Assessment, performed: Contraceptive Implant SNOMED Findings
  - Assessment, performed: Injectable Contraceptive SNOMED Findings
  - o Assessment, performed: Oral Contraceptive Pill SNOMED Findings
  - o Assessment, performed: Contraceptive Patch SNOMED Findings
  - Assessment, performed: Contraceptive Ring SNOMED Findings
  - o Assessment, performed: Infecund Not for Contraceptive Reasons SNOMED Findings
  - Assessment, performed: Sterilization LOINC
  - o Assessment, performed: Intrauterine Devices LOINC
  - o Assessment, performed: Contraceptive Implant LOINC
  - Assessment, performed: Injectable Contraceptive LOINC
  - o Assessment, performed: Oral Contraceptive Pill LOINC
  - Assessment, performed: Contraceptive Patch LOINC
  - Assessment, performed: Contraceptive Ring LOINC
  - o Encounter, performed: Home Healthcare Services (grouping)
  - Device, order: Female Sterilization HCPCS Devices
  - Device, order: IUD Devices (grouping)
  - o Device, order: Contraceptive Implant Devices (grouping)
  - Device, order: Contraceptive Patch Devices (grouping)
  - o Device, order: Contraceptive Ring HCPCS Devices
  - Medication, order: Intrauterine Devices RXNORM Medications
  - o Medication, order: Contraceptive Implant RXNORM Medications
  - o Medication, order: Injectable Contraceptive RXNORM Medications
  - Medication, order: Oral Contraceptive Pill RXNORM Medications
  - o Medication, order: Contraceptive Patch RXNORM Medications
  - Medication, order: Contraceptive Ring RXNORM Medications
  - Procedure, performed: Injectable Contraceptive Provision Procedures (grouping)
  - o Procedure, performed: Oral Contraceptive Pill Provision Procedures (grouping)
  - Procedure, performed: Contraceptive Patch SNOMED Provision Procedures
  - o Procedure, performed: Intrauterine Devices SNOMED Surveillance Procedures

- o Procedure, performed: Contraceptive Implant SNOMED Surveillance Procedures
- Assessment, performed: Do you want to talk about contraception or pregnancy prevention during your visit today
- Assessment, performed: No I am already using contraception
- o Assessment, performed: No I am hoping to become pregnant in the near future
- o Assessment, performed: No I am unsure or dont want to use contraception
- Assessment, performed: No I do not want to talk about contraception today because I am here for something else
- Assessment, performed: No This question does not apply to me/I prefer not to answer
- o Assessment, performed: Yes

# Questions for the Committee regarding validity:

• Are the accuracy issues captured in the Feasibility Scorecard substantial enough to impact the validity of these data elements?

# **Committee Pre-evaluation Comments:**

## 2a. Reliability

- 2a1. Reliability-Specifications
  - It would be helpful if the developer can address the missing data at Site 2 and how this issue will be solved moving forward for all sites
  - o A major concern is the need to add a code for Self-Identified Need for Contraception (SINC) to all coding systems currently in use.
  - o N/A
- 2a2. Reliability-Testing
  - o N/A
  - o N/A
  - o N/A

#### 2b. Validity

- N/A
- N/A
- N/A

## 2b2-2b6. Potential threats to validity

- 2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment)
  - o N/A
  - o Exclusions are reasonable.
  - o N/A
- 2b4-7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data)
  - N/A
  - o N/A
  - o N/A

# Criterion 3. Feasibility

- **3. Feasibility** is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.
  - Data for this measure are generated or collected by and used by healthcare personnel during the provision of care and coded by someone other than the person obtaining the original information.
    - o ALL data elements are in defined fields in electronic health records.
  - The submission includes two measure specifications, an HQMF/QDM measure specification and an FHIR measure specification. Both measure specifications follow established technical specifications for eCQMs.
    - The measure specifications and value sets will all be available at no charge on UCSF's Person-Centered Reproductive Health Program (PCRHP) website (https://pcrhp.ucsf.edu/sincbasedeCQMs ). NQF #3682e specifications will also be published in CMS's Measure Authoring Tool (MAT) website https://www.emeasuretool.cms.gov/ registration required) with the title "SINC-Based Contraceptive Care, Non-Postpartum", while the value sets used will be posted in the National Library of Medicine (NLM) Value Set Authority Center (VSAC, https://vsac.nlm.nih.gov/ registration required). Using a simulated data set, the submission demonstrates that the evaluation of 100% of the measure logic can be automated.
    - The Feasibility Scorecard assesses each data element across the following domains:
      - Availability is the data element readily available in a structured format across EHR systems?
      - Accuracy- is the information contained in the data is correct?
      - o Standards is the data element coded using a nationally accepted terminology standard?
      - Workflow is the data element routinely captured and used during care delivery?
    - The developer has identified feasibility issues for the following data elements. For each data element the developer was asked to provide additional context for the issue and a plan for addressing the issue.

## Feasibility Scorecard for Scientific Acceptability of Measure Properties

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
Procedure, performed: Delivery Live Births	Used in denominator exclusions	Use estimated delivery date (EDD) as a proxy for live birth delivery date	Currently, our ambulatory settings do not capture information on live birth delivery dates that occur at inpatient facilities. The eCQM specification allows for use of EDD, which our EHR system contains as a data element.

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
All of the Assessment, performed: SNOMED Findings	Used in numerator	Use ICD-10-CM codes to capture health conditions utilized in the measure (e.g., infecund, non-live births) as well as access, provision, and surveillance of most and moderately effective contraceptive methods	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We use ICD-10-CM to capture this information. AllianceChicago will migrate to a new data platform, Health Catalyst, that will help map some current EHR elements to LOINC, RXNORM, and SNOMED. Once the existing EHR data elements needed for eCQM calculation can be mapped to national terminology standards, Health Catalyst could bridge the gap to more easily assess contraceptive use and provision.

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
All of the Assessment, performed: LOINC	Used in numerator	Use ICD-10-CM codes to capture access, provision, and surveillance of most and moderately effective contraceptive methods	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We use ICD-10-CM to capture this information. AllianceChicago will migrate to a new data platform, Health Catalyst, that will help map some current EHR elements to LOINC, RXNORM, and SNOMED. Once the existing EHR data elements needed for eCQM calculation can be mapped to national terminology standards, Health Catalyst could bridge the gap to more easily assess contraceptive use and provision.
All of the Assessment, performed: SINC LOINC	Used in denominator exclusions	While SINC provides the opportunity to exclude clients from the denominator, it is not necessary to calculate the measure.	The specification does not offer an alternative terminology for this element, which requires LOINC or standardized mapping of similar questions that assess service needs related to contraception, but we can calculate the other denominator exclusions in our EHR to calculate the measure. We are currently considering our options to capture this data element in collaboration with UCSF.

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
Assessment, performed: Infecund Not for Contraceptive Reasons SNOMED Findings	Used in denominator exclusions	Use ICD-10-CM and CPT codes to capture this denominator exclusion condition	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We use ICD-10-CM to capture this information. AllianceChicago will migrate to a new data platform, Health Catalyst, that will help map some current EHR elements to LOINC, RXNORM, and SNOMED. Once the existing EHR data elements needed for eCQM calculation can be mapped to national terminology standards, Health Catalyst could bridge the gap to more easily assess contraceptive use and provision.
Encounter, performed: Home Healthcare Services (grouping)	Used in denominator	Data not captured as it is not a service performed	At current home health care services are not performed at our ambulatory settings.

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
Device, order: Female Sterilization HCPCS Devices	Used in numerator	Use CPT codes to capture the procedures related to female sterilization	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We use CPT to capture this information. AllianceChicago will migrate to a new data platform, Health Catalyst, that will help map some current EHR elements to LOINC, RXNORM, and SNOMED. Once the existing EHR data elements needed for eCQM calculation can be mapped to national terminology standards, Health Catalyst could bridge the gap to more easily assess contraceptive use and provision.

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
Devices (grouping)	Used in numerator	Use CPT codes to capture the procedures related to IUD access and provision	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We use CPT to capture this information. AllianceChicago will migrate to a new data platform, Health Catalyst, that will help map some current EHR elements to LOINC, RXNORM, and SNOMED. Once the existing EHR data elements needed for eCQM calculation can be mapped to national terminology standards, Health Catalyst could bridge the gap to more easily assess contraceptive use and provision.

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
Device, order: Contraceptive Implant Devices (grouping)	Used in numerator	Use CPT codes to capture the procedures related to contraceptive implant access and provision	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We use CPT to capture this information. AllianceChicago will migrate to a new data platform, Health Catalyst, that will help map some current EHR elements to LOINC, RXNORM, and SNOMED. Once the existing EHR data elements needed for eCQM calculation can be mapped to national terminology standards, Health Catalyst could bridge the gap to more easily assess contraceptive use and provision.

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
Device, order: Contraceptive Patch Devices (grouping)	Used in numerator	Use CPT codes to capture the provision of contraceptive patch	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We use CPT to capture this information. AllianceChicago will migrate to a new data platform, Health Catalyst, that will help map some current EHR elements to LOINC, RXNORM, and SNOMED. Once the existing EHR data elements needed for eCQM calculation can be mapped to national terminology standards, Health Catalyst could bridge the gap to more easily assess contraceptive use and provision.

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
Device, order: Contraceptive Ring HCPCS Devices	Used in numerator	Use CPT codes to capture the provision of contraceptive ring	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We use CPT to capture this information. AllianceChicago will migrate to a new data platform, Health Catalyst, that will help map some current EHR elements to LOINC, RXNORM, and SNOMED. Once the existing EHR data elements needed for eCQM calculation can be mapped to national terminology standards, Health Catalyst could bridge the gap to more easily assess contraceptive use and provision.

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
All of the Medication, order: RXNORM Medications	Used in numerator	Use NDC codes to capture the most and moderately effective contraceptive medications	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We use NDC to capture this information. AllianceChicago will migrate to a new data platform, Health Catalyst, that will help map some current EHR elements to LOINC, RXNORM, and SNOMED. Once the existing EHR data elements needed for eCQM calculation can be mapped to national terminology standards, Health Catalyst could bridge the gap to more easily assess contraceptive use and provision.

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
Procedure, performed: Injectable Contraceptive & Oral Contraceptive Pill Provision Procedures	Used in numerator	Use ICD-10-CM and NDC codes to capture provision of injectable contraceptive	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation.  Although not procedure codes, we use ICD-10-CM and NDC codes to capture provision of these moderately effective contraceptive methods.  AllianceChicago will migrate to a new data platform, Health Catalyst, that will help map some current EHR elements to LOINC, RXNORM, and SNOMED. Once the existing EHR data elements needed for eCQM calculation can be mapped to national terminology standards, Health Catalyst could bridge the gap to more easily assess contraceptive use and provision.

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
All of the Procedure, performed: SNOMED Provision Procedures and Surveillane Procedures	Used in numerator	Use CPT codes to capture access, provision, and surveillance of most and moderately effective contraceptive methods	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We use CPT to capture this information. AllianceChicago will migrate to a new data platform, Health Catalyst, that will help map some current EHR elements to LOINC, RXNORM, and SNOMED. Once the existing EHR data elements needed for eCQM calculation can be mapped to national terminology standards, Health Catalyst could bridge the gap to more easily assess contraceptive use and provision.

# **Scorecard for Assessing Feasibility Data Elements**

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
Ethnicity	Supplemental Data Element (SDE) and not required for measure computation	We code ethnicity similar to ONC and utiliize "Hispanic" and "Non-Hispanic" categories. Our system also has a custom list to capture "ethnic background.	This SDE is not required for measure calculation, and our EHR system elements utilize standard categories.

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
Race	Supplemental Data Element (SDE) and not required for measure computation	Our system uses similar race categories as ONC with one exception: we have a "Multiracial" option instead of ONC's "Other".	This SDE is not required for measure calculation, and our EHR system elements utilize standard categories.
Procedure, performed: Delivery Live Births	Used in denominator exclusions	Use estimated delivery date (EDD) as a proxy for live birth delivery date	Currently, our ambulatory settings do not capture information on live birth delivery dates that occur at inpatient facilities. The eCQM specification allows for use of EDD, which our EHR system contains as a data element.
All of the Assessment, performed: SNOMED Findings	Used in numerator	Use ICD-10-CM codes to capture the surveillance of these contraceptive methods	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We plan to gather the same data through ICD-10-CM codes.
Assessment, performed: Infecund Not for Contraceptive Reasons SNOMED Findings	Used in denominator exclusions	Use ICD-10-CM codes to capture this denominator exclusion condition	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We plan to gather the same data through ICD-10 codes.

Data Element	How is the data element used in computation of measure - e.g. numerator, denominator	Explain how the data element is feasible within the context of the measure logic?	What is the plan for readdressing this data element?
All of the Medication, order: RXNORM Medications	Used in numerator	Use NDC codes to capture the medications	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We plan to gather the same data through NDC codes.
All of the Procedure, performed: SNOMED Provision Procedures and Surveillane Procedures	Used in numerator	Use CPT codes to capture the procedures of these contraceptive methods	Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation. We plan to gather the same data through CPT codes.

# **Questions for the Committee:**

- Are the required data elements available in electronic form, e.g., EHR or other electronic sources?
- Is the data collection strategy ready to be put into operational use?
- For data elements assessed to have feasibility issues, does the developer present a credible, nearterm path to electronic collection?

Preliminary rating for feasibility:	☐ High	<b>⊠</b> Moderate	☐ Low	☐ Insufficient

# **Committee Pre-evaluation Comments:**

## 3. Feasibility

- It would be helpful if the measure developer could speak about how they'll address the data elements that have feasibility concerns
- A major concern is the need to add a code for Self-Identified Need for Contraception (SINC) to all coding systems currently in use.
- No concerns

# Criterion 4: Use and Usability

## 4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

**4a. Use** evaluates the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

**4a.1. Accountability and Transparency.** Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

#### Current uses of the measure

Publicly reported?	$\square$ Yes	⊠ No
Current use in an accountability program?	$\square$ Yes	⊠No □ UNCLEAR
Planned use in an accountability program?	☐ Yes	⊠No □ NA

### Accountability program details

- The measure is submitted to NQF for Trial Use.
- The measure developer is testing the measure for pilot implementation in the Innovating Contraceptive Care in Community Health Centers (ICC in CHCs) project.
- The measure is not currently in use in any accountability programs.
- The developer states that the measure is in use in 20 Federally Qualified Health Centers (FQHCs).
- The developer also reports that they plan to work with the Office of Population Affairs for implementation in all Title X facilities and all data elements have been included in the planning for the new version of the Title X reporting system, FPAR 2.0.

**4a.2.** Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

## Feedback on the measure by those being measured or others

- To develop NQF #3699e, the developer solicited a wide range of expert input, including convening three stakeholder panels to discuss how to optimize the measure specifications to capture the desired measure of the extent to which patient's contraceptive needs are being addressed.
- The developer conducted meetings with both HHS Office of Population Affairs (OPA) and the Coalition to Expand Contraceptive Access (CECA), which brought together representatives from CMS, OPA, and the Planned Parenthood Federation of America (PPFA), as well as relevant stakeholders including direct care providers and national membership organizations such as the National Family Planning and Reproductive Health Association (NFPRHA), to discuss measurement of contraceptive provision and care.

#### **Questions for the Committee:**

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use:	⊠ Pass	□No Pass
4b. Usability (4a1. Improveme	nt; 4a2. Bene	efits of measure)

**4b. Usability** evaluates the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

**4b.1 Improvement.** Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

#### Improvement results

• The measure is submitted to NQF for Trial Use and is not in use yet, therefore, there are no improvement results yet.

**4b2. Benefits vs. harms.** Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

## Unexpected findings (positive or negative) during implementation

- The developer did not report any unexpected findings since the measure is not yet in use.
- The developer notes that unintended negative consequences are not anticipated.
- The developer states that there is a concern that the measure may lead to coercive practices in which
  women are not offered a free choice of methods and are pressured to use most or moderately
  effective contraception and therefore the developer incorporated the Self-Identified Need for
  Contraception (SINC) question into #3699e so that those who are not interested in discussing
  prescription contraceptive methods can be excluded from the denominator for measure calculation.
- The developer states that they plan to provide guidance for the LARC-focused sub-measure, which will align with guidance for NQF #2904 and should remove pressure on providers to inappropriately "promote" LARC methods.

#### **Potential harms**

There are no harms identified by the developer.

#### **Questions for the Committee:**

- How can the performance results be used to further the goal of high-quality, efficient healthcare?
- Do the benefits of the measure outweigh any potential unintended consequences?

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Preliminary rating for Usability and use:	☐ High	⊠Moderate	□ Low	☐ Insufficient

# **Committee Pre-evaluation Comments:**

#### 4a. Use

• It was unclear how those being measured will be informed about their performance on this measure

- The developer plans to test this measure in a new initiative, Innovating Contraceptive Care in Community Health Centers (ICC in CHCs). This project should provide real-world input and experience with the feasibility of this measure.
- New proposed measure to be trialed

#### 4a. Usability

- No concerns.
- The developer recommends using this measure in conjunction with the Person-Centered Contraceptive Counseling (PCCC) measure (NQF #3543).
- No results yet, but believe results could show opportunities and gaps in performance, leading to improvement work.

# **Criterion 5: Related and Competing Measures**

## **Related measures**

- NQF #2903 Contraceptive Care Most & Moderately Effective Methods
- NQF #2904 Contraceptive Care Access to LARC
- NQF #3543 Person-Centered Contraceptive Counseling (PCCC) measure

#### Harmonization

• The developer reported that these measures have been harmonized to the extent possible.

# **Committee Pre-evaluation Comments:**

# **5: Related and Competing Measures**

- A number of related measures; all are harmonized with this measure
- No concerns
- Not that I'm aware of.

# Public and NQF Member Comments (Submitted as of June 15, 2022)

# **Member Expression of Support**

• No public comments received.

# **Developer Submission**

# Criteria 1: Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Measure and Report: Evidence section. For example:

#### 2021 Submission:

Updated evidence information here.

#### 2018 Submission:

Evidence from the previous submission here.

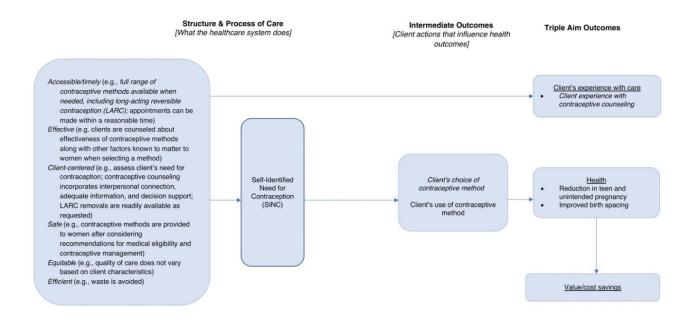
## 1a.01. Provide a logic model.

Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

#### [Response Begins]

The diagram in Figure 1 below describes the relationship between the structures and processes of quality contraceptive care, including patient- (or client-) centered care, and improved outcomes, including the intermediate clinical outcome of relevance for this application: contraceptive use. This logic model was developed in 2017 by the U.S. Department of Health and Human Services (HHS), Office of Population Affairs (OPA), in collaboration with the University of California San Francisco (UCSF) Person-Centered Reproductive Health Program, measure steward for the NQF-endorsed Person-Centered Contraceptive Counseling (PCCC) measure (NQF #3543) and steward for this proposed measure. The diagram was created in the context of describing OPA's work and has since been modified to reflect new developments in thinking about the measurement of contraceptive provision (specifically, using the Self-Identified Need for Contraception measure (SINC) to identify those in need of contraceptive care).

Figure 1: Office of Population Affairs conceptual framework for clinical performance measures for contraceptive care [2]



OPA's conceptual framework for contraceptive care incorporates essential components of the Institute of Medicine's (now the National Academy of Medicine) six dimensions of quality care, Donabedian's quality of care model *structure* and *process* categories, and the Institute for Healthcare Improvement's concept of the "Triple Aim". Several evidence-based clinical family planning recommendations of CDC and OPA serve as examples of health systems' structure and process components in contraceptive care [1]. These components affect two intermediate clinical outcomes: provision of contraceptive methods based on client's choice, and client's use of contraception. The intermediate outcomes signify a client's decision at the end of a clinical encounter that will influence their probability of having an undesired pregnancy. The structure and process also directly affect the client's experience with care. Health outcomes are influenced through the intermediate outcomes of client behavior; and cost-savings result in reductions in undesired pregnancy and improvements in birth spacing [2].

#### References

[1] Gavin, L., Moskosky, S., Carter, M., Curtis, K., Glass, E., Godfrey, E., Marcell, A., Mautone-Smith, N., Pazol, K., Tepper, N., Zapata, L., & Centers for Disease Control and Prevention (CDC) (2014). Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. *MMWR. Recommendations and reports : Morbidity and mortality weekly report. Recommendations and reports*, 63(RR-04), 1–54.

[2] Gavin, L. E., Ahrens, K. A., Dehlendorf, C., Frederiksen, B. N., Decker, E., & Moskosky, S. (2017). Future directions in performance measures for contraceptive care: a proposed framework. *Contraception*, *96*(3), 138–144. https://doi.org/10.1016/j.contraception.2017.06.001

#### [Response Ends]

# 1a.02. Select the type of source for the systematic review of the body of evidence that supports the performance measure.

A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data.

### [Response Begins]

Clinical Practice Guideline recommendation (with evidence review)

Other systematic review and grading of the body of evidence (e.g., Cochrane Collaboration, AHRQ Evidence Practice Center)

### [Response Ends]

If the evidence is not based on a systematic review, skip to the end of the section and do not complete the repeatable question group below. If you wish to include more than one systematic review, add additional tables by clicking "Add" after the final question in the group.

#### **Evidence - Systematic Reviews Table (Repeatable)**

Group 1 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

## [Response Begins]

# **Clinical Practice Guideline recommendation**

- Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs.
- Gavin L, Moskosky S, Carter M, Curtis K, Glass E, Godfrey E, Marcell A, Mautone-Smith N, Pazol K, Tepper N, Zapata L; Centers for Disease Control and Prevention (CDC)
- 2014 Apr 25
- Gavin L, Moskosky S, Carter M, Curtis K, Glass E, Godfrey E, Marcell A, Mautone-Smith N, Pazol K, Tepper N, Zapata L; Centers for Disease Control and Prevention (CDC). Providing quality family planning services:
   Recommendations of CDC and the U.S. Office of Population Affairs. MMWR Recomm Rep. 2014 Apr 25;63(RR-04):1-54. PMID: 24759690.
- https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

#### [Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

### [Response Begins]

"Providers should work with the client interactively to select an effective and appropriate contraceptive method. Specifically, providers should educate the client about contraceptive methods that the client can safely use, and help the client consider potential barriers to using the method(s) under consideration. Use of decision aids (e.g., computerized programs that help a client to identify a range of methods that might be appropriate for the client based on her physical characteristics such as health conditions or preferences about side effects) before or while waiting for the appointment can facilitate and maximize the utility of the time spent on this step.

Providers should inform clients about all contraceptive methods that can be used safely."

Source: CDC/OPA (2014). Providing Quality Family Planning Services (QFP), page 8 and Appendix B Generally, the QFP recommendations outline how to provide family planning services by:

- defining a core set of family planning services for women and men,
- describing how to provide contraceptive and other clinical services, serve adolescents, and perform quality improvements, and
- encouraging the use of the family planning visit to provide selected preventive health services for women, in accordance with the recommendations for women issued by the Institute of Medicine (IOM) and adopted by HHS
- support offering a full range of Food and Drug Administration (FDA)-approved contraceptive methods as well as counseling that highlights the effectiveness of contraceptive methods overall

#### [Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

#### [Response Begins]

Of 132 studies, 41 are graded level I and the rest are graded II-1 to II-3 using the USPSTF system. The authors described their method to assess the internal and external validity of included studies below:

"The quality, or internal validity, of each individual study was assessed to consider the risk that the findings may be confounded by a systematic bias. We used the schema developed by the USPSTF for describing a study's level of risk for bias. A rating of risk for bias was determined through the presence or absence of several characteristics that are known to protect a study from the confounding influence of bias. We developed criteria by which the risk for bias of individual studies could be evaluated, based on recommendations from several sources, including the USPSTF; the Grading of Recommendations Assessment, Development and Evaluation (GRADE); and Community Guide for Preventive Services."

Further details can be found in Appendix A of QFP (p. 30-32). In addition, CDC published its methodology for the systematic reviews describing the evidence and their grading in the following paper:

Tregear, S. J., Gavin, L. E., & Williams, J. R. (2015). Systematic Review Evidence Methodology: Providing Quality Family Planning Services. *American journal of preventive medicine*, 49(2 Suppl 1), S23–S30. https://doi.org/10.1016/j.amepre.2015.03.033

The SRs contained in the body of evidence are provided in a supplement of *American Journal of Preventive Medicine*: American Journal of Preventive Medicine, Volume 49, Issue 2, Supplement 1, Pages S1-S123 (August 2015). Available online at:

https://www.ajpmonline.org/issue/S0749-3797(15)X0002-X

#### [Response Ends]

## 1a.06. Provide all other grades and definitions from the evidence grading system.

#### [Response Begins]

**USPSTF** 

- I Evidence obtained from at least one properly randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II–2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies and case reports, or reports of expert committees

#### GRADE

The implications of a strong recommendation are:

- For patients—most people in your situation would want the recommended course of action and only a small proportion would not; request discussion if the intervention is not offered
- For clinicians—most patients should receive the recommended course of action
- For policy makers—the recommendation can be adopted as a policy in most situations.

The implications of a weak recommendation are:

- For patients—most people in your situation would want the recommended course of action, but many would not
- For clinicians—you should recognize that different choices will be appropriate for different patients and that you must help each patient to arrive at a management decision consistent with her or his values and preferences
- For policy makers—policy making will require substantial debate and involvement of many stakeholders.

# [Response Ends]

# 1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

### [Response Begins]

A multistage process was used to develop the recommendations that drew on established procedures for developing clinical guidelines. First, an Expert Work Group was formed comprising family planning clinical providers, program

administrators, and representatives from relevant federal agencies and professional medical associations to help define the scope of the recommendations. Next, literature about three priority topics (i.e., counseling and education, serving adolescents, and quality improvement) was reviewed by using the USPSTF methodology for conducting systematic reviews. The results were presented to three technical panels comprising subject matter experts (one panel for each priority topic) who considered the quality of the evidence and made suggestions for what recommendations might be supported on the basis of the evidence. In a separate process, existing clinical recommendations on women's and men's preventive services were compiled from more than 35 federal and professional medical associations, and these results were presented to two technical panels of subject matter experts, one that addressed women's clinical services and one that addressed men's clinical services. The panels provided individual feedback about which clinical preventive services should be offered in a family planning setting and which clinical recommendations should receive the highest consideration.

CDC and OPA used the input from the subject matter experts to develop a set of core recommendations and asked the Expert Work Group to review them. The members of the Expert Work Group were more familiar with the family planning service delivery context than the members of the Technical Panel and thus could better comment on the feasibility and appropriateness of the recommendations, as well as the supporting evidence. The Expert Work Group considered the core recommendations by using the

following criteria: 1) the quality of the evidence; 2) the positive and negative consequences of implementing the recommendations on health outcomes, costs or cost-savings, and implementation challenges; and 3) the relative importance of these consequences, (e.g., the likelihood that implementation of the recommendation will have a substantial effect on health outcomes might be considered more than the logistical challenges of implementing it). In certain cases, when the evidence from the literature reviews was inconclusive or incomplete, recommendations were made on the basis of expert opinion. Finally, CDC and OPA staff considered the individual feedback from Expert Work Group members when finalizing the core recommendations and writing the recommendations document.

Summary can be found in Appendix B of the 2014 QFP (p. 35-44).

#### [Response Ends]

### 1a.08. Provide all other grades and definitions from the recommendation grading system.

# [Response Begins]

- A: There is good evidence to support the recommendation that the condition be considered specifically in a preconception care evaluation.
- B: There is fair evidence to support the recommendation that the condition be considered specifically in a preconception care evaluation
- C: There is insufficient evidence to recommend for or against the inclusion of the condition in a preconception care evaluation, but recommendation to include or exclude may be made on other grounds.
- D: There is fair evidence to support the recommendation that the condition be excluded in a preconception care evaluation.
- E: There is good evidence to support the recommendation that the condition be excluded in a preconception care evaluation.

#### [Response Ends]

#### 1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

#### [Response Begins]

Quantity: Summaries of the evidence used to prepare these recommendations are published in 9 separate systematic reviews in the original 2014 version of the guideline, and a total of 132 studies are included in the 9 systematic reviews.

Quality: CDC and the Office of Population Affairs developed QFP recommendations by conducting an extensive review of published evidence, seeking expert opinion, and synthesizing existing clinical recommendations from CDC, agencies such as the U.S. Preventive Services Task Force (USPSTF), and professional medical associations such as the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics.

Types of studies included in the systematic reviews included: randomized controlled trials (41 studies), non-randomized controlled trials, national survey data, prospective cohorts, case-control cohort, cross-sectional studies, pre-post studies, ecological evaluation, and descriptive studies.

Summary can be found in Appendix B of the 2014 QFP (p. 35-44). In addition, CDC published its methodology for the systematic reviews describing the evidence and their grading in the following paper:

Tregear, S. J., Gavin, L. E., & Williams, J. R. (2015). Systematic Review Evidence Methodology: Providing Quality Family Planning Services. *American journal of preventive medicine*, 49(2 Suppl 1), S23–S30. https://doi.org/10.1016/j.amepre.2015.03.033

#### [Response Ends]

#### 1a.10. Provide the estimates of benefit, and consistency across studies.

#### [Response Begins]

QFP provides guidelines to provide family planning services, including the provision of contraception, to help women plan and space births, prevent unintended pregnancies, and reduce the number of abortions.

[Response Ends]

#### 1a.11. Indicate what, if any, harms were identified in the study.

#### [Response Begins]

The harms were not listed in these guidelines. However, CDC clinical recommendations on contraceptive safety address this question. CDC's "US Medical Eligibility Criteria for Contraceptive Use" (USMEC) describe what contraceptive methods are safe for women with a range of characteristics (e.g., age, postpartum) and medical conditions (e.g., infectious, or chronic diseases). The citation for the USMEC recommendations is:

Curtis, K. M., Tepper, N. K., Jatlaoui, T. C., Berry-Bibee, E., Horton, L. G., Zapata, L. B., Simmons, K. B., Pagano, H. P., Jamieson, D. J., & Whiteman, M. K. (2016). U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. *MMWR. Recommendations and reports: Morbidity and mortality weekly report. Recommendations and reports*, 65(3), 1–103. https://doi.org/10.15585/mmwr.rr6503a1

#### [Response Ends]

# 1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

#### [Response Begins]

Gavin L, Pazol K, Ahrens K. Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2017. MMWR Morb Mortal Wkly Rep 2017;66:1383–1385. DOI: <a href="http://dx.doi.org/10.15585/mmwr.mm6650a4External">http://dx.doi.org/10.15585/mmwr.mm6650a4External</a>

Gavin L, Pazol K. Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2015. MMWR Morb Mortal Wkly Rep 2016;65:231–234. DOI: <a href="http://dx.doi.org/10.15585/mmwr.mm6509a3">http://dx.doi.org/10.15585/mmwr.mm6509a3</a>

These two reviews revised and updated the 2014 version based on new scientific findings. They did not make a substantial shift in how family planning care should be provided.

The American Academy of Family Physicians issued a clinical practice guideline recommendation in support of and advocating use for use of QFP, which did not change conclusions of original SR. This AAFP guideline is available online at: <a href="https://www.aafp.org/afp/2015/0501/p625.html">https://www.aafp.org/afp/2015/0501/p625.html</a>

In 2018, OPA updated and expanded several systematic reviews on the following topics addressed in the 2014 QFP: counseling and education (three updated and one new systematic review), serving adolescents (one updated and one new systematic review), and community education and engagement (one paper updating two previous systematic

reviews). These articles did not change conclusions of the original SR and were published in a theme issue of *American Journal of Preventative Medicine*:

American Journal of Preventative Medicine, Volume 55, Issue 5, Pages 677-690, (November 01, 2018). Available online at:

https://www.ajpmonline.org/issue/S0749-3797(17)X0016-0#

### [Response Ends]

Group 2 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

# [Response Begins]

- Long-Acting Reversible Contraception: Implants and Intrauterine Devices
- American College of Obstetricians and Gynecologists (ACOG)
- 2017 November, reaffirmed in 2021
- Long-acting reversible contraception: implants and intrauterine devices. Practice Bulletin No. 186. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017; 130:e251-69
- https://doi.org/10.1097/AOG.0000000000002400

## [Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

#### [Response Begins]

In summary, intrauterine devices (IUDs) and contraceptive implants, also called long-acting reversible contraceptives (LARC), are the most effective reversible contraceptive methods that can be provided to a broad range of patients wishing to prevent pregnancy, including postpartum women.

Below is the Summary of Recommendations, by grade:

## "The following recommendations are based on good and consistent scientific evidence (Level A):

Insertion of an IUD immediately after first-trimester uterine aspiration should be offered routinely as a safe and effective contraceptive option.

Insertion of the contraceptive implant on the same day as first-trimester or second-trimester induced or spontaneous abortion should be offered routinely as a safe and effective contraceptive option.

Routine antibiotic prophylaxis is not recommended before IUD insertion.

## The following recommendations are based on limited or inconsistent scientific evidence (Level B):

Intrauterine devices and the contraceptive implant should be offered routinely as safe and effective contraceptive options for nulliparous women and adolescents.

Insertion of an IUD or an implant may occur at any time during the menstrual cycle as long as pregnancy may be reasonably excluded.

Insertion of an IUD immediately after confirmed completion of first-trimester medication-induced abortion should be offered routinely as a safe and effective contraceptive option.

Women who have not undergone routine screening for STIs or who are identified to be at increased risk of STIs based on patient history should receive CDC-recommended STI screening at the time of a single visit for IUD insertion. Intrauterine device insertion should not be delayed while awaiting test results. Treatment for a positive test result may occur without removal of the IUD.

Intrauterine devices may be offered to women with a history of ectopic pregnancies.

#### The following recommendations are based primarily on consensus and expert opinion (Level C):

Long-acting reversible contraceptives have few contraindications and should be offered routinely as safe and effective contraceptive options for most women.

The copper IUD should be offered routinely to women who request emergency contraception and are eligible for IUD placement.

To improve LARC method satisfaction and continuation, patient counseling should include information on expected bleeding changes and reassurance that these changes are not harmful.

Endometrial biopsy, colposcopy, cervical ablation or excision, and endocervical sampling may all be performed with an IUD in place.

Actinomyces on cytology is considered an incidental finding. In the absence of symptoms, no antimicrobial treatment is needed, and the IUD may be left in place.

There is no compelling evidence for the removal of an IUD or implant before its expiration date in menopausal women." (p. e262)

#### [Response Ends]

# 1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

#### [Response Begins]

Grades assigned to the evidence followed the method outlined by the U.S. Preventive Services Task Force (USPSTF). The evidence associated with the recommendations included 132 graded studies.

The evidence was graded as follows:

30 studies were graded I (Evidence obtained from at least one properly designed randomized controlled trial.)

13 studies were graded II-2 (Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.)

43 studies were graded II-3 (Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.)

46 studies were graded III (Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.)

#### [Response Ends]

#### 1a.06. Provide all other grades and definitions from the evidence grading system.

## [Response Begins]

Studies were reviewed and evaluated for quality according to the method outlined by the USPSTF. All grades in the USPSTF grading system for research studies were assigned to the analyses comprising the evidence, except for the following grade:

II-1 Evidence obtained from well-designed controlled trials without randomization.

#### [Response Ends]

#### 1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

### [Response Begins]

The USPSTF grading system for recommendations was used to assign grades. A total of 17 recommendations were provided in this clinical practice guideline recommendation with evidence review.

3 recommendations were assigned the grade Level A (Recommendations are based on good and consistent scientific evidence)

7 recommendations were assigned the grade Level B (Recommendations are based on limited or inconsistent scientific evidence)

7 recommendations were assigned the grade Level C (Recommendations are based primarily on consensus and expert opinion)

#### [Response Ends]

#### 1a.08. Provide all other grades and definitions from the recommendation grading system.

#### [Response Begins]

Not applicable. All grades are included in the box above.

[Response Ends]

#### 1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

#### [Response Begins]

This SR counted 151 studies in its body of evidence. About one-third of these studies were randomized controlled trials, case-control studies, or cohort studies.

30 randomized controlled trials

13 cohort or case-control analytic studies

43 studies from multiple time series with or without intervention, uncontrolled experiments

46 descriptive studies, expert committee reports, expert opinions based on clinical experience

15 systematic reviews

2 cost-benefit studies

2 meta-analyses

#### [Response Ends]

#### 1a.10. Provide the estimates of benefit, and consistency across studies.

#### [Response Begins]

ACOG's review indicated that LARC methods are safe, highly effective forms of contraception for most women, including subpopulations of women like adolescent females, nulliparous women, and women post-abortion. An increase in LARC use may have partially contributed to the decline in the rate of unintended pregnancies in the United States from 51% to 45% between 2008-2011. Citing Trussell's 2011 review of contraceptive failure rates, this review reported that the LARC methods have a typical failure rate less than 1%.

ACOG found good and consistent evidence that LARC methods can be inserted immediately after induced or spontaneous abortion, providing safe and effective contraception to prevent pregnancy. One RCT reported that among women receiving immediate insertion post-abortion, six-month IUD use rates were higher than in the delayed-insertion group (92.3% vs. 76.6%; p<0.001) with no difference for expulsion risk between groups. No pregnancies occurred in the immediate insertion group. For post-abortion implant insertion, one RCT found that risk of medication abortion failure was low and similar between the immediate placement (i.e., same day as mifepristone administration) and after medication-induced abortion (3.9% vs. 3.8%). Another prospective cohort study indicated that continuation rates were similar among women with immediate and delayed post-abortion implant placement (82% for immediate and interval placement).

ACOG determined that adequate scientific evidence exists that IUDs and implants should be offered to adolescents and nulliparous women routinely as safe and effective contraceptive options with a prevent pregnancy. One retrospective cohort study in IUD users reported that serious complications (i.e, ectopic pregnancy, pelvic inflammatory disease) were rare regardless of age or IUD type. Although adolescent women (ages 15-19) were more likely to have a claim for

menstrual bleeding changes or normal pregnancy than women ages 25-44, early discontinuation rates were similar in both groups (13% vs. 11%).

#### [Response Ends]

#### 1a.11. Indicate what, if any, harms were identified in the study.

#### [Response Begins]

ACOG described the following harms for LARC methods in this review.

#### Harms identified with IUDs

In two studies (prospective and retrospective cohorts), users of copper and levonorgestrel-releasing (LNG) IUDs had similar mean weight gain. Commonly reported adverse effects with the copper IUD are heavy menstrual bleeding and pain. Some LNG IUD users reported the following hormone-related side effects: headaches, nausea, breast tenderness, mood changes, and ovarian cyst formation.

Expulsion, method failure, and perforation are complications with IUDs that appear to rarely occur. A large, prospective, noninterventional 2015 study surveilling over 61,000 women for seven years reported 1.4 per 1000 LNG IUD insertions and 1.1 per 1000 copper IUD insertions.

#### Harms identified with Implants

Changes in menstrual bleeding patterns is a common side effect of implant use. One randomized, multicenter comparative study noted that the median number of bleeding/spotting days decreased from the first 90 days to the last year of the study period (Implanon: 33.5 to 19-21.5 days; Norplant: 34.5 to 18.0-23.0). The mean overall incidence decreased during the study (Implanon: 66.0% to 27.3%; Norplant: 69.0% to 21.7%).

Additional adverse events reported by implant users are gastrointestinal difficulties, headaches, breast pain, vaginitis, acne, and weight gain.

Another RCT reported that 1-year cumulative discontinuation rates due to menstrual bleeding disturbances was 2.1% for implants, but weight gain was cited as the main reason for 7% of users to discontinue the implant. About 83% of participants in this study continued using the implant for the project duration.

One integrated analysis of international clinical trials reported that complications were rare during implant insertion and removal (1.0% for insertion, 1.7% for removal). Women experiencing insertion complications reported pain, slight bleeding, hematoma formation, deep or incorrect insertion and unrecognized insertion. Complications with removal include breakage of the implant and failure to palpate or locate the implant due to deep insertion.

#### [Response Ends]

1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

# [Response Begins]

This clinical guidance was reaffirmed in 2021 without changing the SR's conclusions.

# [Response Ends]

Group 3 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

## [Response Begins]

- US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016.
- CDC
- 2016
- Curtis KM, Tepper NK, Jatlaoui TC, et al. U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. MMWR Recomm Rep 2016;65(No. RR-3):1–104. DOI: <a href="http://dx.doi.org/10.15585/mmwr.rr6503a1">http://dx.doi.org/10.15585/mmwr.rr6503a1</a>

http://dx.doi.org/10.15585/mmwr.rr6503a1

#### [Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

#### [Response Begins]

The United States Medical Eligibility Criteria for Contraceptive Use, 2016 (US MEC) includes recommendations for using specific contraceptive methods by women and men who have certain characteristics or medical conditions. The recommendations in this report are intended to assist health care providers when they counsel women, men, and couples about contraceptive method choice. This report serves as an update to the 2010 US MEC, which was adapted from the fourth edition of World Health Organization's *Medical Eligibility Criteria for Contraceptive Use* (WHO MEC).

The SR concludes that most women, including those with certain characteristics (e.g., adolescents, postpartum) and medical conditions (e.g., infectious or chronic diseases), can use most contraceptive methods safely to prevent pregnancy. Recommendations related to IUDs and implants are reported in this review. Women who have health conditions associated with increased risk for adverse health events as a result of pregnancy should consider long-acting, highly effective contraception.

The 2016 US MEC recommendations are summarized in the following tables: <a href="https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria">https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria</a> 508tagged.pdf

Safety of contraceptive methods is a component of the structure and process of the health care system, which affects the provision of contraceptive methods, including LARC. The recommendations aim to eliminate unneeded medical barriers to accessing and using contraception.

#### [Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

#### [Response Begins]

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed for reporting systematic reviews.

The level of evidence from the systematic reviews for each evidence summary are provided based on the U.S. Preventive Services Task Force (USPSTF) system, which includes ratings for study design (I: randomized controlled trials; II-1: controlled trials without randomization; II-2: observational studies; and II-3: multiple time series or descriptive studies), ratings for internal validity (good, fair, or poor), and categorization of the evidence as direct or indirect for the specific review topic.

Evidence in this guideline ranges from I to II-3, good to poor, direct to indirect, depending on the condition and contraceptive method evaluated.

For the 2016 US MEC update, CDC published 13 systematic reviews describing the evidence and their grading related to new recommendations not previously included in the 2010 US MEC. These reviews are provided in a supplement of *Contraception*: Contraception, Volume 96, Issue 6, Pages 579-760 (December 2016). Available online at: <a href="https://www.sciencedirect.com/journal/contraception/vol/94/issue/6">https://www.sciencedirect.com/journal/contraception/vol/94/issue/6</a>

#### [Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

The following grade from the USPSTF system was not assigned to evidence in this SR:

III: Opinions of respected authorities, based on clinical experience, descriptive studies and case reports, or reports of expert committees.

#### [Response Ends]

# 1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

#### [Response Begins]

Appendices B – J provide summaries of classifications for whether women with certain medical conditions or characteristics can use contraceptive methods. The following methods are included: IUDs, progestin-only contraceptives (including etonogestrel implants), combined hormonal contraceptives, barrier contraceptive methods, fertility awareness-based methods, lactational amenorrhea method, coitus interruptus, female and male sterilization, and emergency contraceptive pills.

The four categories utilized to classify the use of contraceptive methods, including LARC methods, for women with certain medical conditions or characteristics are as follows:

- U.S. MEC 1 = A condition for which there is no restriction for the use of the contraceptive method.
- U.S. MEC 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- U.S. MEC 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
- U.S. MEC 4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

Depending on the contraceptive methods and conditions, the grading ranges from U.S. MEC 1 – 4.

The recommendations were developed as part of a multi-stage process. First, CDC reviewed the existing recommendations in the US MEC 2010 for new evidence identified through the WHO/CDC CIRE system that might result in a changed recommendation. CDC then held an initial expert panel meeting to obtain input and draft a list of topics to consider for the update, including new recommendations. Next CDC staff and other invited authors conducted independent systematic reviews for topics under consideration. These reviews were conducted to identify direct evidence about the safety of contraceptive methods use by women with selected conditions. At a second expert meeting, participants were asked to provide their input using the scientific evidence presented from the systematic reviews to develop potential recommendations. Feedback also was received from three external reviewers, composed of health care providers and researchers who had not participated in the update meetings. These reviewers were asked to provide comments on the accuracy, feasibility, and clarity of the recommendations. During the second expert meeting, areas of research that need additional investigation also were considered. Afterwards CDC chose and documented the recommendations in this report, taking into account the perspectives offered by expert meeting participants.

#### [Response Ends]

#### 1a.08. Provide all other grades and definitions from the recommendation grading system.

#### [Response Begins]

Not applicable. All grades are included in the box above.

[Response Ends]

#### 1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

#### [Response Begins]

Quantity – Summaries of the evidence used to prepare the new recommendations issued in 2016 are published in 13 separate systematic reviews. These summaries included a total of 108 articles.

Quality – The 108 articles described the following types of studies: randomized controlled trials, non-randomized controlled trials, prospective and retrospective cohort studies, case-control studies, pharmacokinetic studies, cross-sectional studies, and pooled analyses.

#### [Response Ends]

#### 1a.10. Provide the estimates of benefit, and consistency across studies.

# [Response Begins]

A broad range of contraceptive methods are safe for women with a range of characteristics (e.g., age, postpartum) and medical conditions (e.g., infectious, or chronic diseases). The goal of these recommendations is to remove unnecessary medical barriers to accessing and using contraception.

#### [Response Ends]

# 1a.11. Indicate what, if any, harms were identified in the study.

# [Response Begins]

Some harms were noted in the clarification column in each appendix. However, the individual studies comprising the body of evidence may have specifically identified potential adverse events related to contraceptive method use among women with certain health conditions and characteristics.

CDC published 13 systematic reviews describing the evidence and their grading for this update in a supplement of *Contraception*: Contraception, Volume 96, Issue 6, Pages 579-760 (December 2016). Available online at: https://www.sciencedirect.com/journal/contraception/vol/94/issue/6

#### [Response Ends]

1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

#### [Response Begins]

American Academy of Family Physicians issued the following practice guidelines which support and advocate for the use of US MEC:

https://www.aafp.org/afp/2017/0115/afp20170115p125.pdf

https://www.aafp.org/afp/2016/1201/afp20161201p942.pdf

https://www.aafp.org/afp/2015/0501/afp20150501p625.pdf

https://www.aafp.org/afp/2012/0215/afp20120215p403.pdf

These new guidelines did not change the SR's conclusions.

#### [Response Ends]

Group 4 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

# [Response Begins]

- U.S. Selected Practice Recommendations for Contraceptive Use
- Curtis KM, Jatlaoui TC, Tepper NK, et al.
- 2016
- Curtis KM, Jatlaoui TC, Tepper NK, et al. U.S. Selected Practice Recommendations for Contraceptive Use, 2016.
   MMWR Recomm Rep 2016;65(No. RR-4):1–66. DOI: <a href="http://dx.doi.org/10.15585/mmwr.rr6504a1">http://dx.doi.org/10.15585/mmwr.rr6504a1</a>
- http://dx.doi.org/10.15585/mmwr.rr6504a1

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

#### [Response Begins]

Most women can start most contraceptive methods at any time, and few examinations or tests, if any, are needed before starting a contraceptive method. Routine follow-up for most women includes assessment of her satisfaction with the contraceptive method, concerns about method use, and changes in health status or medications that could affect medical eligibility for continued use of the method.

[Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

#### [Response Begins]

Evidence in this guideline ranges from I to II-3, good to poor, direct to indirect, depending on the contraceptive methods provision and related services.

The level of evidence from the systematic reviews for each evidence summary are provided based on the U.S. Preventive Services Task Force (USPSTF) system, which includes ratings for study design (I: randomized controlled trials; II-1: controlled trials without randomization; II-2: observational studies; and II-3: multiple time series or descriptive studies), ratings for internal validity (good, fair, or poor), and categorization of the evidence as direct or indirect for the specific review question.

Evidence considered for use in SPR was considered in a multi-tiered approach. For the 2013 version of SPR, CDC initiated a process to adapt WHO SPR for the United States. This adaptation process included four steps: 1) determining the scope of and process for the adaptation, including an October 2010 meeting in which individual feedback was solicited from a small group of partners and experts; 2) preparing the systematic reviews of the evidence during October 2010—September 2011 to be used for the adaptation, including peer review; 3) convening a larger meeting of experts in October 2011 to examine the evidence and receive input on the recommendations; and 4) finalizing recommendations by CDC.

Additional evidence was similarly garnered and considered for the 2016 update to SPR.

#### [Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

#### [Response Begins]

USPSTF

I Evidence obtained from at least one properly randomized controlled trial.

II–1 Evidence obtained from well-designed controlled trials without randomization.

II–2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II–3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies and case reports, or reports of expert committees

# [Response Ends]

1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

#### [Response Begins]

Appendix A of SPR provides a summary of classifications for hormonal contraceptive methods and intrauterine devices by condition, pregnancy, and age. (<a href="https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf">https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf</a>), pages -53-61

Depending on the contraceptive methods and conditions, the grading ranges from U.S. MEC 1-4.

Categories of medical eligibility criteria for contraceptive use:

U.S. MEC 1 = A condition for which there is no restriction for the use of the contraceptive method.

- U.S. MEC 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- U.S. MEC 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
- U.S. MEC 4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

#### [Response Ends]

#### 1a.08. Provide all other grades and definitions from the recommendation grading system.

# [Response Begins]

Not applicable. All grades are included in the box above.

[Response Ends]

#### 1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

#### [Response Begins]

Quantity - 353 Studies

Quality – study types included systematic reviews, meta-analyses, randomized controlled trials, clinical trials, diagnostic accuracy studies, and case series.

#### [Response Ends]

# 1a.10. Provide the estimates of benefit, and consistency across studies.

# [Response Begins]

Most women can start most contraceptive methods at any time, and few examinations or tests, if any, are needed before starting a contraceptive method.

[Response Ends]

# 1a.11. Indicate what, if any, harms were identified in the study.

# [Response Begins]

Because changes in bleeding patterns are one of the major reasons for discontinuation of contraception, recommendations are provided for the management of bleeding irregularities with various contraceptive methods. In addition, because women and health care providers can be confused about the procedures for missed pills and dosing errors with the contraceptive patch and ring, the instructions are streamlined for easier use.

[Response Ends]

# 1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

# [Response Begins]

Not applicable.

[Response Ends]

Group 5 - Evidence - Systematic Reviews Table

#### 1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

#### [Response Begins]

- Women's Preventive Services Guidelines
- Health Resources and Services Administration (HRSA) and ACOG
- 2019 December 17 (Contraception recommendation updated in January 2022)
- Health Resources and Services Administration. (2019, December). Women's Preventive Services
  Guidelines. U.S. Department of Health and Human Services, Health Resources and Services
  Administration. https://www.hrsa.gov/womens-guidelines/index.html
- https://www.womenspreventivehealth.org/recommendations/contraception/

#### [Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

#### [Response Begins]

The Women's Preventive Services Initiative recommends that adolescent and adult women have access to the full range of contraceptives and contraceptive care to prevent unintended pregnancy and improve birth outcomes. Contraceptive care includes screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period). Contraceptive care also includes follow-up care (e.g., management, evaluation, and changes, including the removal continuation, and discontinuation of contraceptives).

The WPSI recommends that the full range of female-controlled U.S. Food and Drug Administration (FDA)-approved, - granted, or -cleared contraceptives, effective family planning practices, and sterilization procedures be available as part of contraceptive care. The full range of contraceptive methods currently includes those listed in the FDA's Birth Control Guide (<a href="https://www.fda.gov/media/150299/download">https://www.fda.gov/media/150299/download</a>): (1) sterilization surgery for women, (2) implantable rods, (3) copper intrauterine devices, (4) intrauterine devices with progestin (all durations and doses), (5) injectable contraceptives, (6) oral contraceptives (combined pill), (7) oral contraceptives (progestin only), (8) oral contraceptives (extended or continuous use), (9) the contraceptive patch, (10) vaginal contraceptive rings, (11) diaphragms, (12) contraceptive sponges, (13) cervical caps, (14) condoms, (15) spermicides, (16) emergency contraception (levonorgestrel), and (17) emergency contraception (ulipristal acetate), and additional contraceptives approved, granted, or cleared by the FDA.

# [Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

#### [Response Begins]

While grades of evidence are not presented in the guideline, below is how the recommendations were developed: The WPSI has contracted with physician scientists with extensive experience in systematic review methodology and clinical guideline development from the Pacific Northwest Evidence-based Practice Center (EPC) at Oregon Health & Science University to conduct reviews and updates of the evidence for each topic under consideration. Focused updates of evidence reviewed for the nine topics considered for revision include overviews of recent systematic reviews for the U.S. Preventive Services Task Force (USPSTF) published since the last recommendations were issued by the Institute of Medicine (IOM) Committee in 2011, as well as systematic reviews and key studies published since the most recent systematic reviews for the USPSTF.

A research librarian conducted searches in Ovid MEDLINE, Cochrane Central Register of Controlled Trials, and Cochrane Database of Systematic Reviews through July 2016 for all topics.

A best evidence approach was applied when reviewing abstracts and selecting studies to include for the updates that involves using the most relevant studies with the strongest methodologies. For well-woman visits and contraceptive methods and counseling, there are no USPSTF reviews or recommendations, therefore, other systematic reviews and studies published since the 2011 IOM recommendations for these topics were included.

Randomized controlled trials and large (>100) prospective cohort studies were included if they provided relevant information for each topic. Other study designs, such as case-control and modeling studies, were included when evidence was lacking or when they demonstrated new findings. Studies conducted in settings applicable to the United States were

targeted. The focus of each review was on gaps identified in the 2011 IOM recommendations and any new evidence that could change or additionally inform the recommendations where evidence was not previously available. Selection criteria specific to each topic were developed to address issues specific to the WPSI.

Applicability is defined as the extent to which the effects observed in published studies are likely to reflect the expected results when a specific intervention is applied to the population of interest under "real-world" conditions. It is an indicator of the extent to which research included in a review might be useful for informing clinical decisions in specific situations. Factors important for understanding the applicability of studies were considered including differences in the interventions and comparators, populations, and settings.

No new or revised statistical meta-analyses were conducted. Studies were qualitatively synthesized according to interventions, populations, and outcomes measured. Studies and their findings were summarized in a narrative, descriptive format to provide an overview of the new evidence for each topic.

MSC members interact with the EPC to identify topics and scope. Updates to previous recommendations were evaluated using established methodology.

In 2019, HRSA published updated guidelines online, and updated its Contraception recommendation in 2022.

#### [Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

[Response Begins]

Not applicable.

[Response Ends]

1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

#### [Response Begins]

While grades of recommendations are not presented in the guideline, below is how the recommendations were developed:

- In addition to current systematic reviews and randomized controlled trials, other supporting evidence is considered including organization guidelines and policies, epidemiologic data, and other relevant sources.
- Physician investigators from the EPC attend in-person and teleconference MSC meetings to assist with interpretation of evidence, including addressing queries about individual studies included in the literature search. Investigators work closely with the MSC, and each of the subcommittees, to provide expert perspective on the quality and strength of the supporting evidence.
- In addition, like the 2011 IOM Panel, the MSC panel considered multiple levels of evidence when developing the recommendations and permitted recommendations to be based on varying levels of evidence, expert consensus, or standard best practices.

#### [Response Ends]

1a.08. Provide all other grades and definitions from the recommendation grading system.

# [Response Begins]

Preventive services recommended by the committee followed the criteria of the 2011 IOM Panel:

- The condition to be prevented affects a broad population
- The condition to be prevented has a large potential impact on health and well being
- The quality and strength of evidence is supportive.

# [Response Ends]

1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

#### [Response Begins]

2 systematic reviews

1 randomized controlled trial

- 2 observational studies
- 1 clustered randomized trial
- 1 book chapter

#### [Response Ends]

#### 1a.10. Provide the estimates of benefit, and consistency across studies.

#### [Response Begins]

The effectiveness of the full range of FDA-approved contraceptive methods for preventing or delaying pregnancy is well established. Effective comprehensive contraceptive care includes counseling, initiation, and follow-up. Contraceptive counseling and access to contraceptive methods is associated with increased contraceptive use and decreased unintended pregnancy rates. Long-acting reversible contraceptive (LARC) methods are the most effective reversible contraceptive option for most women, including nulliparous women and adolescents who are sexually active. Counseling on LARC methods is associated with lower pregnancy rates and lower rates of abortion and repeat abortion. Providing an increased supply of oral contraceptives at initiation is associated with higher continuation rates and lower unintended pregnancy rates.

# [Response Ends]

#### 1a.11. Indicate what, if any, harms were identified in the study.

# [Response Begins]

The harms related to contraceptive method use were not listed in these guidelines. However, CDC clinical recommendations on contraceptive safety explicitly address this question. CDC's "US Medical Eligibility Criteria for Contraceptive Use" (USMEC) describe what contraceptive methods are safe for women with a range of characteristics (e.g., age, postpartum) and medical conditions (e.g., infectious, or chronic diseases). The citation for the USMEC recommendations is:

Curtis, K. M., Tepper, N. K., Jatlaoui, T. C., Berry-Bibee, E., Horton, L. G., Zapata, L. B., Simmons, K. B., Pagano, H. P., Jamieson, D. J., & Whiteman, M. K. (2016). U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. MMWR. Recommendations and reports: Morbidity and mortality weekly report. Recommendations and reports, 65(3), 1–103. https://doi.org/10.15585/mmwr.rr6503a1

#### [Response Ends]

# 1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

#### [Response Begins]

For the 2022 update, 34 randomized controlled trials (RCTs) relevant to the WPSI Contraception Recommendation were identified from a recent systematic review of studies published since 2000. Trials evaluated the effectiveness of contraceptive counseling and provision interventions to increase contraceptive use. Comparisons included enhanced counseling, additional support services, or provision of contraceptives versus usual care or alternative interventions, such as educational materials without counseling. Most studies evaluated use of LARC or effective types of contraception from 3 to 12 months after the intervention as outcomes. Although the definition of effective types varied across studies, LARC and hormonal contraceptives were most frequently reported. Despite the inherent clinical heterogeneity of the trials, results consistently indicated increased contraceptive use with interventions regardless of clinical intention. This included counseling and provision for general populations of adolescents and women, advanced provision of emergency contraception, counseling and provision delivered immediately postpartum or at the time of abortion, and provision directly by pharmacists.

Based on the number, quality, and size of studies; consistency of results between studies; and directness of evidence, the strength of evidence is high for counseling and provision interventions to increase use for general populations. Future research should further evaluate effective approaches to counseling and provision of contraceptives that prioritize individual's goals and preferences and reduce barriers to care. Gaps remain in determining best practices and approaches to contraceptive care, particularly for populations at risk for disparities.

The 2022 update resulted in very minor wording revisions to the WPSI Contraception recommendations, but the conclusions did not change.

#### [Response Ends]

Group 6 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

#### [Response Begins]

- Contraceptive Technology. 21st Ed
- Hatcher RA, Nelson AL, Trussell J, Cwiak C, Cason P, Policar MS, Edelman A, Aiken ARA, Marrazzo J, Kowal D, eds.
- 2018
- Hatcher RA, Nelson AL, Trussell J, Cwiak C, Cason P, Policar MS, Edelman A, Aiken ARA, Marrazzo J, Kowal D, eds. Contraceptive technology. 21st ed. New York, NY: Ayer Company Publishers, INC., 2018.
- http://www.contraceptivetechnology.org/the-book/

#### [Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

# [Response Begins]

- Use of the top-tier reversible contraceptives the intrauterine devices (IUDs) and the contraceptive implant –
  entails the lowest risk of pregnancy.
- Correct and consistent use of most contraceptive methods results in a low risk of pregnancy
- Most contraceptives pose little risk to most users' health, although personal risk factors should influence personal choice.

#### [Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

#### [Response Begins]

Grade not assigned, but Contraceptive Technology serves as the primary source of information about contraceptive failure rates and is cited by the World Health Organization, CDC, and leading health professional associations in the US and other countries.

#### [Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

#### [Response Begins]

Not applicable.

[Response Ends]

1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

# [Response Begins]

Grade not assigned, but Contraceptive Technology serves as the primary source of information about contraceptive failure rates and is cited by the World Health Organization, CDC, health care service delivery organizations, and leading health professional associations in the US and other countries.

#### [Response Ends]

1a.08. Provide all other grades and definitions from the recommendation grading system.

#### [Response Begins]

Not applicable.

[Response Ends]

#### 1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

#### [Response Begins]

Quantity – 3,136 total studies in book, 103 in the chapter on Efficacy, Safety, and Personal Considerations (p. 95-129) Quality – Contraceptive Technology serves as the primary source of information about contraceptive failure rates and is cited by the World Health Organization, CDC, and leading professional associations in the US and other countries. Two sources of data are used to estimate contraceptive failure. The first is published research comprised of results from clinical trials and surveys. The second source is CDC's National Survey of Family Growth (NSFG) is used to estimate typical use rates using data from a nationally representative sample of users.

#### [Response Ends]

#### 1a.10. Provide the estimates of benefit, and consistency across studies.

#### [Response Begins]

Key findings of this review are estimated failure rates for a wide range of contraceptive methods under "perfect" and "typical" use. The most recent findings, published in 2018 are that the most effective methods, (LARC and sterilization) have a failure rate less than 1% per year under typical use; the moderately effective methods (shot/Depo, pills/patch/ring (PPR)) have a typical failure fate of 4-7%. PPR typical use failure rates have slightly (6 to 7%) increased from 2011 to 2018 while shot typical use failure rate has dropped from 6% to 4%. Diaphragm typical use failure rates have increased since the 2011 study and are no longer considered moderately effective.

#### [Response Ends]

# 1a.11. Indicate what, if any, harms were identified in the study.

# [Response Begins]

Authors state that, "In general, contraceptives pose few serious health risks to users. Moreover, the use of contraceptive methods is generally far safer than pregnancy." (p. 111). The authors state that the absolute level of risk for death is very low for most people and that other major health risks from contraceptive use are uncommon and are most likely to occur in individuals with underlying medical conditions (p. 111).

# [Response Ends]

1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

# [Response Begins]

Not applicable.

[Response Ends]

Group 7 - Evidence - Systematic Reviews Table

# 1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

- Contraceptive Counseling in Clinical Settings: An Updated Systematic Review
- Lauren B Zapata, Karen Pazol, Christine Dehlendorf, Kathryn M. Curtis, Nikita M. Malcolm, Rachel B. Rosmarin, Brittni N. Frederiksen
- 2018 November 1
- Lauren B. Zapata, Karen Pazol, Christine Dehlendorf, Kathryn M. Curtis, Nikita M. Malcolm, Rachel B. Rosmarin, Brittni N. Frederiksen, Contraceptive Counseling in Clinical Settings: An Updated Systematic Review, American Journal of Preventive Medicine, Volume 55, Issue 5, 2018, Pages 677-690.

https://doi.org/10.1016/j.amepre.2018.07.006

#### [Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

#### [Response Begins]

Overall, evidence supports the utility of contraceptive counseling, in general, and specific interventions or aspects of counseling. Promising components of contraceptive counseling were identified.

[Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

#### [Response Begins]

Evidence in this guideline ranges from I to II-3, low to high risk of bias, depending on the age group of study participants (e.g., adolescents, young adults, adults, and mixed populations) and outcome type (e.g., long-, medium-, and short-term outcomes and client experiences).

This SR is reported according to the PRISMA checklist. The strength and quality of the evidence in this SR are graded using on the U.S. Preventive Services Task Force (USPSTF) system, which includes ratings for study design (I: randomized controlled trials; II-1: controlled trials without randomization; II-2: observational studies; and II-3: multiple time series or descriptive studies) and risk of bias (low, moderate, high).

The studies included in the SR were graded as follows:

I: 12 studies (2 high risk, 10 moderate risk)

II-1: 3 studies (2 high risk, 1 moderate risk)

II-2: 11 studies (9 high risk, 2 moderate risk)

II-3: 6 studies (6 high risk)

Six key questions (KQs) were developed, and an analytic framework was utilized to describe the relationships between the population of interest; the intervention of interest; and the outcomes of interest.

## [Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

# [Response Begins]

Not applicable. All grades and definitions are included in the box above.

[Response Ends]

1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

#### [Response Begins]

Not applicable.

[Response Ends]

1a.08. Provide all other grades and definitions from the recommendation grading system.

#### [Response Begins]

Not applicable.

[Response Ends]

1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

Quantity - 35 articles; 32 studies

Quality - 14 RCTs, 2 non-randomized trials, 5 cohort studies, 5 cross-sectional studies, and 6 pre-post studies

#### [Response Ends]

#### 1a.10. Provide the estimates of benefit, and consistency across studies.

#### [Response Begins]

Overall, findings support the provision of contraceptive counseling, compared with no counseling, on contraceptive use behaviors.

Six of nine studies among adolescents and young adults and 16 of 23 studies among adults or mixed populations found a statistically significant positive impact of counseling on at least one outcome of interest.

Promising components of contraceptive counseling include an emphasis on the quality of interaction between counselor and client (e.g., developing rapport); personalizing discussions to meet clients' individual needs; and addressing psychosocial determine of contraceptive use behaviors (e.g., perceived benefits and barriers, outcome expectations. New components that resulted in some statistically significant positive effects include an emphasis on shared decision making, asking about the patient's reproductive life plan/pregnancy intentions, and discussion of contraceptive methods by level of effectiveness.

#### [Response Ends]

#### 1a.11. Indicate what, if any, harms were identified in the study.

#### [Response Begins]

While the article did not identify any harms of contraceptive counseling, authors stated that following would strengthen the evidence base: improved documentation of counseling content and processes, increased attention to the relationships between client experiences and behavioral outcomes and examining the comparative effectiveness of different counseling approaches to identify those that are most effective.

#### [Response Ends]

1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

#### [Response Begins]

Not applicable.

# [Response Ends]

Group 8 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

# [Response Begins]

- Committee Opinion No. 710: Counseling Adolescents About Contraception
- ACOG
- 2017, reaffirmed 2021
- Committee Opinion No. 710 Summary: Counseling Adolescents About Contraception. (2017). Obstetrics and gynecology, 130(2), 486–487. https://doi.org/10.1097/AOG.000000000002228
- https://doi.org/10.1097/AOG.0000000000002228

#### [Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

- Regardless of a patient's age or previous sexual activity, the obstetrician-gynecologist routinely should address her contraceptive needs, expectations, and concerns.
- Statutes on the rights of minors to consent to health care services vary by state, and obstetrician-gynecologists should be familiar with the regulations that apply to their practice.
- Emergency contraception routinely should be included in discussions about contraception, including access issues. The American College of Obstetricians and Gynecologists recommends that obstetrician-gynecologists write advance prescriptions for oral emergency contraception for their patients.
- Long-acting reversible contraceptive (LARC) methods have higher efficacy, higher continuation rates, and higher satisfaction rates compared with short-acting contraceptives. Because LARC methods are safe, they are excellent contraceptive choices for adolescents.
- Obstetrician-gynecologists should be aware of and be prepared to address the most common misperceptions about contraceptive methods in a way that is age appropriate and compatible with the patient's health literacy.
- The initial encounter and follow-up visits should include continual reassessment of sexual concerns, behavior, relationships, prevention strategies, and testing and treatment for sexually transmitted infections (STIs) per the Centers for Disease Control and Prevention's (CDC) guidelines.

# [Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

[Response Begins] Not applicable. [Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

[Response Begins] Not applicable. [Response Ends]

1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

[Response Begins] Not applicable. [Response Ends]

1a.08. Provide all other grades and definitions from the recommendation grading system.

[Response Begins] Not applicable. [Response Ends]

1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

[Response Begins] Not applicable. [Response Ends]

1a.10. Provide the estimates of benefit, and consistency across studies.

Modern contraceptives are very effective when used correctly and, thus, effective counseling regarding contraceptive options and provision of resources to increase access are key components of adolescent health care. Regardless of a patient's age or previous sexual activity, the obstetrician-gynecologist routinely should address her contraceptive needs, expectations, and concerns. Obstetrician-gynecologists should be aware of and be prepared to address the most common misperceptions about contraceptive methods in a way that is age appropriate and compatible with the patient's health literacy.

# [Response Ends]

#### 1a.11. Indicate what, if any, harms were identified in the study.

#### [Response Begins]

At no time should an adolescent patient be forced to use a method chosen by someone other than herself, including a parent, guardian, partner, or health care provider.

#### [Response Ends]

1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

#### [Response Begins]

This clinical guidance was reaffirmed in 2021 without changing the SR's conclusions. [Response Ends]

Group 9 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

#### [Response Begins]

- Patient-Centered Contraceptive Counseling
- American College of Obstetricians and Gynecologists (ACOG)
- 2022 January 20
- American College of Obstetricians and Gynecologists' Committee on Health Care for Underserved Women, Contraceptive Equity Expert Work Group, and Committee on Ethics (2022). Patient-Centered Contraceptive Counseling: ACOG Committee Statement Number 1. Obstetrics and gynecology, 139(2), 350–353. <a href="https://doi.org/10.1097/AOG.00000000000004659">https://doi.org/10.1097/AOG.00000000000004659</a>
- https://doi.org/10.1097/AOG.00000000000004659

# [Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

#### [Response Begins]

Based on the principles outlined in this Committee Statement, the American College of Obstetricians and Gynecologists makes the following recommendations and conclusions:

- Obstetrician—gynecologists (ob-gyns) should intentionally incorporate the reproductive justice framework into contraceptive counseling by:
  - acknowledging historical and ongoing reproductive mistreatment of people of color and other marginalized individuals whose reproductive desires have been devalued;
  - recognizing that counselor bias, unconscious or otherwise, can affect care and working to minimize the effect of bias on counseling and care provision; and
  - prioritizing patients' values, preferences, and lived experiences in the selection or discontinuation of a contraceptive method.

 Ob-gyns should adhere to the recommended ethical approach of shared decision making through patientcentered contraceptive counseling.

#### [Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

# [Response Begins]

Not applicable.

[Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

# [Response Begins]

Not applicable.

[Response Ends]

1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

# [Response Begins]

Not applicable.

[Response Ends]

1a.08. Provide all other grades and definitions from the recommendation grading system.

#### [Response Begins]

Not applicable.

[Response Ends]

1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

# [Response Begins]

Not applicable.

[Response Ends]

1a.10. Provide the estimates of benefit, and consistency across studies.

#### [Response Begins]

Contraception can be a fundamental part of an individual's health and wellness. Therefore, contraceptive counseling is an important interaction between patients and obstetrician—gynecologists and other health care practitioners. Counseling is an opportunity to solicit an individual's values, preferences, and insight into what matters most to them as it relates to contraception.

Intentional application of a patient-centered reproductive justice framework and use of a shared decision making model is the recommended approach for providing supportive contraceptive counseling and care to help patients to achieve their reproductive goals.

# [Response Ends]

1a.11. Indicate what, if any, harms were identified in the study.

However, contraceptive counseling may be subject to undue influence, such as a counselor's personal biases (implicit or explicit), pressure or coercion from a counselor or partner, or even the ideology of the institution at which someone is seeking contraceptive access.

[Response Ends]

1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

# [Response Begins]

Not applicable.

[Response Ends]

Group 10 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

# [Response Begins]

- Committee Opinion No. 642: Increasing Access to Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy.
- ACOG
- 2015, reaffirmed 2018
- Committee Opinion No. 642: Increasing Access to Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy. (2015). Obstetrics and gynecology, 126(4), e44–e48. https://doi.org/10.1097/AOG.00000000001106
- https://doi.org/10.1097/AOG.000000000001106

#### [Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

# [Response Begins]

- For all women at risk of unintended pregnancy, obstetrician-gynecologists should provide counseling on all contraceptive options, including implants and IUDs.
- Adopt best practices for LARC insertion.
- Advocate for coverage and appropriate payment and reimbursement for every contraceptive method by all payers in all clinically appropriate circumstances.
- Become familiar with and support local, state (including Medicaid), federal, and private programs that improve
  affordability of all contraceptive methods.

# [Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

#### [Response Begins]

Not applicable.

[Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

#### [Response Begins]

Not applicable.

1a.07. Provide the grade assigned to the recommendation, with definition of the grade. [Response Begins] Not applicable. [Response Ends] 1a.08. Provide all other grades and definitions from the recommendation grading system. [Response Begins] Not applicable. [Response Ends] 1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence. [Response Begins] Not applicable. [Response Ends] 1a.10. Provide the estimates of benefit, and consistency across studies. [Response Begins] Obstetrician-gynecologists may contribute to increasing access to contraceptive implants and intrauterine devices. Obstetrician-gynecologists should counsel about implants and intrauterine devices for all appropriate candidates, including nulliparous women and adolescents. Obstetrician-gynecologists should adopt best practices for long-acting reversible contraception insertion. Obstetrician-gynecologists are encouraged to advocate for coverage and appropriate payment and reimbursement for every contraceptive method by all payers in all clinically appropriate circumstances. [Response Ends] 1a.11. Indicate what, if any, harms were identified in the study. [Response Begins] Not applicable. [Response Ends] 1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review. [Response Begins] Not applicable. [Response Ends] 1a.13. If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, describe the evidence on which you are basing the performance measure. [Response Begins] [Response Ends]

1a.14. Briefly synthesize the evidence that supports the measure.

[Response Begins] [Response Ends]

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#### 1a.15. Detail the process used to identify the evidence.

[Response Begins] [Response Ends]

# 1a.16. Provide the citation(s) for the evidence.

[Response Begins] [Response Ends]

#### 1b.01. Briefly explain the rationale for this measure.

Explain how the measure will improve the quality of care, and list the benefits or improvements in quality envisioned by use of this measure.

#### [Response Begins]

Supporting patients to prevent pregnancy when they wish to do so has social and health benefits for individuals and their families [1, 2]. Contraception is a highly effective clinical preventive service that can assist women in reaching their reproductive health goals [3, 4]. While most and moderately effective contraceptive methods have a failure rate of 1-23%, not using any method at all has a failure rate of 85% [4]. In order to support patients to achieve their reproductive goals, facilities at which individuals receive care must ensure that contraceptive needs are assessed and met. This includes ensuring that the most effective reversible methods of contraception - intrauterine devices and implants – are available in a timely fashion.

Multiple commentaries have detailed how the use of performance measures related to contraceptive provision can improve health care quality and promote positive reproductive health outcomes [5-7]. The University of California, San Francisco (UCSF) designed the Self-Identified Need for Contraception (SINC) — Based Contraceptive Care, Non-Postpartum electronic clinical quality measure (eCQM, NQF #3699e) to give health care organizations and facilities the opportunity to measure contraceptive provision among clients who want contraceptive services. Specified for use with electronic health record (EHR) system data, NQF #3699e can be calculated in a wider array of health care settings, including systems that do not rely on administrative claims. Below, we describe the rationale for an eCQM of contraceptive use.

The National Quality Forum (NQF) endorsed the first clinical performance measures focused on contraception in October 2016, empowering health care organizations to assess contraceptive services to improve quality of family planning care. Stewarded by the U.S. Health and Human Services (HHS) Office of Population Affairs (OPA) and specified for calculation in administrative claims, the Contraceptive Care measures (NQF #2902, #2903, and #2904) estimate the percentage of women ages 15-44 years provided a most or moderately effective method of contraception in two populations in this age range: postpartum women and all fecund women. These NQF-endorsed measures also evaluate access to long-acting reversible contraception (LARC), which is a subset of most and moderately effective methods, by focusing on low (i.e., less than 2%, rather than high) rates of use as a proxy for access [5-7].

The contraceptive provision measures provide reliable and valid metrics for health entities to evaluate the proportion of women receiving prescription contraceptive methods, but administrative claims data has limitations affecting measure implementation in different care settings as well as assessment of previous contraceptive services received and client preferences for contraception. The claims-based measures are designed for calculation in service delivery systems with a fee-for-services model, which rely on claims. Thus, entities that use prospective payment systems, such as Federally Qualified Health Centers (FQHCs), which are community-based health care providers that receive federal funds to provide primary care services in underserved areas, cannot easily employ NQF #2902, #2903, and #2904 to evaluate contraceptive services quality. These measures also do not always accurately identify which contraceptive method a woman is using following a visit (particularly LARC methods and sterilization, which are not captured in administrative claims if provided prior to the latest health care visit or during a previous measurement period). Furthermore, client preferences for contraceptive services are not available in administrative data, and the claims-based measures cannot accurately parse which women need or want contraceptive services.

Electronic clinical quality measures (eCQMs) offer a way to measure family planning and reproductive health care quality by utilizing electronic health record (EHR) system data [4]. Unlike administrative claims, EHR systems can capture client need for contraceptive and other health services and are utilized in a wider array of health care settings. Ideally, eCQMs are calculated with data captured in structured form during the process of patient care. NQF #3682e, UCSF's SINC-Based Contraceptive Care, eCQM, aims to document contraceptive use and define the postpartum population in need of contraceptive services for the denominator more accurately through encounter-level EHR data. To focus the measure on

the population of women interested in contraceptive services, UCSF created the Self-Identified Need for Contraception (SINC) data element.

SINC consists of a standardized question and response options in the LOINC code system. It serves as a l exclusion criterion for the #3699e denominator. Before SINC, no measure of patient desire for contraceptive services existed for consistent implementation across EHR systems (note that One Key Question® [8], a proprietary question that assess desire for pregnancy in the next year, does not fulfill this need, in that it assesses future desires, rather than immediate need for services). Developed through our engagement with Reproductive Justice Consultants and industry stakeholders, this screening question asks patients for their desire for contraceptive services on the day of their visit. SINC helps refine the NQF #3682e denominator to exclude those individuals who did not receive or have documented use of a prescription contraceptive method if they indicated no desire for these services [9]. This novel data element helps guard against the possibility of directive or coercive counseling towards contraception that may be an unintentional result of use of a contraceptive use performance measure. This is particularly important given the (ongoing) history of reproductive oppression, contraceptive coercion, and biased counseling in the United States directed at women of color and lowincome women [10-18]. A standardized measure of self-identified contraceptive need also provides an -opportunity to hardwire patient-centered workflows into the EHR that can facilitate patients getting their needs met. Similar to the currently endorsed measures of contraceptive provision that rely on claims data (NQF #2903), #3699e is designed to encourage provision of the full range of methods. We recognize that some patients will prefer to use nonprescription methods that do not qualify as most- or moderately-effective methods, even when provided with full counseling. As a result, we do not have a currently identified benchmark for this measure, and do not expect scores to reach 100%. The goal of the NQF #3699e sub-measure related to IUD and implant provision is to ensure access to these methods, and will be interpreted similarly to NQF #2904, in which the goal is to identify low rates of provision (i.e., below 2%) as an indication of barriers to access. We emphasize that it is important that these contraceptive services are provided in a client-centered manner that treats each person as a unique individual with respect, empathy, and understanding, providing accurate, easy-to-understand information based on the client's self-identified needs, goals, preferences, and values [19].

In summary, the SINC-Based Contraceptive Care, Non-Postpartum eCQM can be used in settings that cannot use the claims-based contraceptive provision measures and provides improved measurement of whether patient's contraceptive needs are being fulfilled. By specifying the denominator as people who self-identify as needing contraceptive services, NQF #3699e shifts focus to people's reproductive health needs as they define them. Implementing NQF #3699e will result in quality improvement initiatives that help health care organizations better meet clients' needs by increasing patient-centered access to contraception in a wider range of settings, a step towards the goal of reproductive autonomy and well-being for all.

# References

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#### [Response Ends]

# 1b.02. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Include mean, std dev, min, max, interquartile range, and scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

#### [Response Begins]

At this time, we do not have performance scores available for NQF #3699e as we are submitting this eCQM for Approval for Trial Use. We plan to calculate performance scores for #3699e during our pilot project, Innovating Contraceptive Care in Community Health Centers (ICC in CHCs), for which data collection will begin in Summer 2022. [Response Ends]

1b.03. If no or limited performance data on the measure as specified is reported above, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement. Include citations.

#### [Response Begins]

Evidence for gap in performance in contraceptive provision in the non-postpartum population comes both from the scientific literature and from use of the existing NQF-endorsed contraceptive measures (NQF #2903 and #2904) that rely on administrative claims data in the Center for Medicaid & Medicare Services (CMS) Health Care Quality Measures Adult and Child Core Sets and the Title X Family Planning Program. Our NQF #3699e primary measure corresponds to NQF #2903 and assesses provision of most and moderately effective contraception, while the NQF #3699e sub-measure estimates provision of long-acting reversible contraception (LARC) methods, like NQF #2904 [1].

Existing research demonstrates that patients experience barriers to receiving their desired contraceptive method. One source of data comes from the Title X program. Administered by the U.S. Department of Health and Human Services (HHS) Office of Population Affairs (OPA), the Title X Family Planning program is the only federal grant program dedicated solely to providing low-income individuals with comprehensive family planning and related preventive health services. In the context of conducting a Performance Measure Learning Collaborative (PMLC) aiming to improve the quality of their family planning services, Title X utilized modified versions of NQF #2903 and #2904 to assess one aspect of quality of care in 12 sites. Prior to the PMLC, the percentage of clients using a most or moderately effective method percentage ranged from 46% to 92% at participating sites. Ten of twelve PMLC sites (83%) experienced an increase in among those seeking care, indicating that through quality improvement targeting gaps in care provision, more women's needs were able to be met [2]. Similarly, an analysis of the Women's Healthcare Experiences and Preferences Study reported that approximately 36% of respondents reported not using their preferred method and wanted to be using a more effective form of contraception [3].

While the existing NQF-endorsed contraceptive provision measures use different measurement sources and strategies to evaluate contraceptive access, they are similar in providing an assessment of the quality of care related to access to methods. Results from these measures indicate the need for quality improvement related to contraceptive provision. Specifically, the CMS Health Care Quality Measures Adult and Child Core Sets included NQF #2903 and #2904, which are similar to the primary and sub-measures of #3699e. Adopted for measurement year 2018, CMS first published #2903 and #2904 measure scores for measurement year 2019 for <a href="both">both</a> the child (ages 15-20) and adult (ages 21-44) age groups because more than 25 states reported these metrics in their Medicaid and Children's Health Insurance Program (CHIP) populations. The state-specific measure scores are available on the CMS's website for State Medicaid and CHIP Profiles [4].

The FFY 2020 CMS Child Core Set median measure score for most and moderately effective methods was approximately 30% for ages 15-20 (Bottom Quartile: 21.2%; Top Quartile: 32.6%), while the median LARC provision score was 4.3% (Bottom Quartile: 3.3%; Top Quartile: 5.8%). The FFY 2020 CMS Adult Core set media for #2903 was 24.5% (Bottom Quartile: 23.0%; Top Quartile: 28.6%), while the median LARC provision score was 5.1% (Bottom Quartile: 3.6%; Top Quartile: 6.1%) [5].

The Title X program also collects contraceptive provision measures scores across its sites in the Title X Family Planning Annual Report (FPAR). These scores demonstrate that even in a program committed to the provision of family planning services, considerable room for improvement exists in its delivery of contraceptive services (Of note, the FPAR data documents sterilization or LARC insertion in a year preceding the measurement year and whether the client was seeking pregnancy, which are data elements not available in the #2903 and #2904 specifications). The 2019 results showed that overall, 65.7% of clients ages 15-19 and 59.5% of clients ages 20-44 were provided a most or moderately effective method of contraception; this FPAR measure is like the NQF #3699e primary measure. Variation by Title X grantee existed (e.g., from 0 to 89.4% for adolescent clients, and from 0 to 82.9 % among adult clients). See 2018 and 2019 FPAR results below [6-7].

*	FPAR 2018	*	FPAR 2019	*
*	Women ages	Women ages	Women ages	Women ages
	15-19	20-44	15-19	20-44
Mean performance score	67.9%	61.3%	65.7%	59.5%
Standard deviation	0.17	0.15	0.19	0.16
Percentiles	*	*	*	*
25 <sup>th</sup>	62.1%	53.8%	58.7%	55.4%
50 <sup>th</sup>	74.0%	63.8%	72.2%	63.2%
75 <sup>th</sup>	79.0%	70.1%	78.7%	70.3%
Min	0.0%	0.0%	0.0%	0.0%
Max	92.3%	88.2%	89.4%	82.9%

<sup>\*</sup> This cell is intentionally left blank.

From 2016-2019, the percentage of all Title X family planning users provided a most or moderately effective method of contraception by year remained quite stable, with a very slight decrease in the percentage of women using most or moderately effective methods in 2018 and 2019 [6-9].

2016: 62%

2017: 62%

2018: 60%

2019: 59%

The 2019 FPAR results showed that overall, 15.9% of clients ages 15-19 and 17.2% of clients ages 20-44 were provided a LARC method; this FPAR measure is like the sub-measure for NQF #3699e. Variation by Title X grantee existed (*e.g.*, from 0 to 43.2% for adolescent clients, and from 0 to 33.9% among adult clients) [6-7].

*	FPAR 2018	*	FPAR 2019	*
*	Women ages	Women ages	Women ages	Women ages
	15-19	20-44	15-19	20-44
Mean performance score	16.2%	17.3%	15.9%	17.2%
Standard deviation	0.10	0.07	0.09	0.08
Percentiles	*	*	*	*
25 <sup>th</sup>	9.2%	12.7%	9.7%	12.4%
50 <sup>th</sup>	14.7%	18.1%	15.2%	17.9%
75 <sup>th</sup>	22.7%	22.2%	22.0%	22.5%
Min	0.0%	0.0%	0.0%	0.0%
Max	62.5%	39.6%	43.2%	33.9%
Number of measured entities	99	99	100	100
Number of women included	563,474	2,642,038	429,112	2,059,301
Grantees with rates < 2%	4	2	5	4
% grantees with rates <2%	4.3%	2.0%	5.1%	4.0%

<sup>\*</sup> This cell is intentionally left blank.

From 2016 through 2019, the percentage of all Title X family planning users provided a LARC method of contraception remained stable during this period [6-9]:

2016: 14% 2017: 16% 2018: 16% 2019: 16%

#### References

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1b.04. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

#### [Response Begins]

At this time, we do not have performance scores available for NQF #3699e as we are submitting this eCQM for Approval for Trial Use. We plan to calculate performance scores by various client attributes for #3699e during our pilot project, Innovating Contraceptive Care in Community Health Centers (ICC in CHCs).

[Response Ends]

1b.05. If no or limited data on disparities from the measure as specified is reported above, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in above.

#### [Response Begins]

Data on disparities comes from both the existing peer-reviewed literature as well as from use of the existing NQF-endorsed contraceptive measures (NQF #2903 and #2904) that rely on administrative claims data. With respect to the peer-reviewed literature, analyses of the nationally representative National Survey of Family Growth (NSFG) have documented differences by race/ethnicity in contraceptive use, with Black women being significantly less likely to use a most or moderately effective contraceptive method than white women [1]. An analysis of the NSFG with respect to LARC use specifically, however, found that there were no differences by income and race [2].

Our NQF #3699e primary measure corresponds to NQF #2903 and assesses provision of most and moderately effective contraception, while the NQF #3699e sub-measure estimates provision of long-acting reversible contraception (LARC) methods, like NQF #2904 [3]. Thus, the existing NQF-endorsed claims-based contraceptive measures also provide information about disparities.

The HHS Office of Population Affairs (OPA) presented NQF #2903 and #2904 calculated in the Washington State Health Care Authority (WA HCA) population to support its Spring 2021 endorsement applications. For 2014-2018, WA HCA reported NQF #2903 measure scores for female clients ages 15-44 by age group and race/ethnicity. The percentages of women that were provided most and moderately effective methods by race/ethnicity remained stable over these five years [4]. In 2018, the WA HCA #2903 measure scores for ages 15-20 differed by race/ethnicity reported (note that race/ethnicity categories other than "Hispanic" report ethnicity as "Not Hispanic" or "Unknown") [4]:

Hispanic: 24.4 White: 37.2 Asian: 19.4 Black: 24.5

American Indian/Alaska Native: 33.7 Hawaiian/Pacific Islander: 18.9 More than One Race: 34.9 Other/Unknown: 23.7

The 2018 WA HCA #2903 measure scores for ages 21-44 also varied by race/ethnicity [3]:

Hispanic: 33.1 White: 27.0 Asian: 26.0 Black: 26.1

American Indian/Alaska Native: 24.6 Hawaiian/Pacific Islander: 23.6 More than One Race: 29.9 Other/Unknown: 26.9

For 2014-2018, WA HCA reported NQF #2904 measure scores for female clients ages 15-44 by age group and race/ethnicity. Among adults ages 21-44, all race/ethnicity groups had LARC provision rates greater than 2% during this

five-year period. Except for 2014, LARC provision rates in clients ages 15-20 were also more than 2% for all race/ethnicity groups [3].

In 2018, the NQF #2904 measure scores for ages 15-20 were as follows (note that race/ethnicity categories other than "Hispanic" report ethnicity as "Not Hispanic" or "Unknown") [3]:

Hispanic: 5.2 White: 7.0 Asian: 3.1 Black: 4.5

American Indian/Alaska Native: 7.3 Hawaiian/Pacific Islander: 4.2 More than One Race: 6.9 Other/Unknown: 4.0

The 2018 LARC provision rates for ages 21-44 by race/ethnicity reported were [3]:

Hispanic: 8.8 White: 5.9 Asian: 5.8 Black: 6.4

American Indian/Alaska Native: 5.7 Hawaiian/Pacific Islander: 5.3 More than One Race: 6.5 Other/Unknown: 5.9

For the primary measure of NQF #3699e, these results suggest that there are opportunities for improvement to ensure that all race/ethnicity non-postpartum groups in WA HCA have equal access to the full range of contraceptive methods in. These differences by socio-demographic characteristics are likely explained in part by modifiable clinical and programmatic considerations. Although providers may see some local variations by socio-demographic characteristics, we believe that these differences will be reduced if contraceptive services are offered in a client-centered manner, as defined by CDC and OPA's family planning services recommendations [5].

For the NQF #3699e sub-measure, the LARC provision percentages available suggest that all race/ethnicity groups in WA HCA appear to have access to LARC methods. In alignment with OPA, UCSF emphasizes that the measure should be used only to monitor access to LARC; and that it could be harmful to set a high benchmark for this measure, because doing so may incentivize coercive practices [6-8]. Contraceptive services must be offered in a client-centered manner, as recommended by CDC and OPA [5].

# References

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from <a href="https://opa.hhs.gov/evaluation-research/title-x-services-research/contraceptive-care-measures/long-acting-reversible">https://opa.hhs.gov/evaluation-research/title-x-services-research/contraceptive-care-measures/long-acting-reversible</a>.

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# Criteria 2: Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.

#### sp.01. Provide the measure title.

Measure titles should be concise yet convey who and what is being measured (see What Good Looks Like).

# [Response Begins]

SINC-Based Contraceptive Care, Non-Postpartum

[Response Ends]

#### sp.02. Provide a brief description of the measure.

Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).

# [Response Begins]

Percentage of women who 1) received or had documented use of most or moderately effective contraception and 2) received a long-acting reversible contraceptive method during the calendar year.

To focus the measure on the population of women interested in contraceptive services, the denominator excludes those individuals who did not receive or have documented use of a method if they indicated during the year that they did not want these services, as well as those who are eligible for postpartum contraceptive services during the measurement period.

#### [Response Ends]

# sp.04. Check all the clinical condition/topic areas that apply to your measure, below.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

• Surgery: General

# [Response Begins]

Reproductive Health: Family planning and contraception

[Response Ends]

# sp.05. Check all the non-condition specific measure domain areas that apply to your measure, below.

# [Response Begins]

Access to Care
Disparities Sensitive
Person-and Family-Centered Care: Person-and Family-Centered Care
Primary Prevention
[Response Ends]

# sp.06. Select one or more target population categories.

Select only those target populations which can be stratified in the reporting of the measure's result.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

• Populations at Risk: Populations at Risk

#### [Response Begins]

Adults (Age >= 18) Children (Age < 18)

Women

[Response Ends]

#### sp.07. Select the levels of analysis that apply to your measure.

Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

Clinician: ClinicianPopulation: Population

# [Response Begins]

Facility

[Response Ends]

sp.08. Indicate the care settings that apply to your measure.

Check ONLY the settings for which the measure is SPECIFIED and TESTED.

[Response Begins]

**Outpatient Services** 

[Response Ends]

sp.09. Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials.

Do not enter a URL linking to a home page or to general information. If no URL is available, indicate "none available".

#### [Response Begins]

https://pcrhp.ucsf.edu/sincbasedeCQMs

[Response Ends]

#### sp.10. Indicate whether Health Quality Measure Format (HQMF) specifications are attached.

Attach the zipped output from the eCQM authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications).

#### [Response Begins]

HQMF specifications are attached.

[Response Ends]

Attachment: 3699e\_3699e\_MAT\_package\_2022-01-05-final\_(1).zip

sp.11. Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.

Attach an excel or csv file; if this poses an issue, <u>contact staff</u>. Provide descriptors for any codes. Use one file with multiple worksheets, if needed.

#### [Response Begins]

Available in attached Excel or csv file

#### [Response Ends]

Attachment: 3699e NPP Valuesets 3699e01192022.xlsx

#### sp.12. State the numerator.

Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome).

DO NOT include the rationale for the measure.

#### [Response Begins]

Primary measure: Eligible women who received or were documented to be using a most (i.e., sterilization, implants, intrauterine devices or systems (IUD/IUS) or moderately effective (i.e., injectables, oral pills, patch, or ring) contraceptive method.

Sub-measure: Eligible women provided a long-acting reversible contraceptive method (IUD or implant).

#### [Response Ends]

#### sp.13. Provide details needed to calculate the numerator.

All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

#### [Response Begins]

Receipt or documented use of a most or moderately effective method (primary measure) or receipt of a contraceptive implant or intrauterine device (sub-measure) is documented using HCPCS, RXNORM, ICD10, CPT, LOINC and SNOMED codes (OIDs contained in following tabs from Value Set excel document, provided in sp.11: Contraceptive Patch, Contraceptive Implant, Contraceptive Ring, Injectable Contraceptive, IUD, and OCP)
[Response Ends]

#### sp.14. State the denominator.

Brief, narrative description of the target population being measured.

#### [Response Begins]

All women, aged 15-44, with a qualifying encounter in the calendar year [Response Ends]

#### sp.15. Provide details needed to calculate the denominator.

All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

#### [Response Begins]

Definition of a qualifying encounter during the calendar year (from 1/1/XX to 12/31/XX) as per CPT, HCPCs and SNOMED codes, using the following:

- 1. Office visits (OID 2.16.840.1.113883.3.464.1003.101.12.1001)
- 2. Home health (OID 2.16.840.1.113883.3.464.1003.101.12.1016)

- 3. Preventative visits initial and established for 0-17, respectively (OID 2.16.840.1.113883.3.464.1003.101.12.1022, OID 2.16.840.1.113883.3.464.1003.101.12.1024)
- 4. Preventative visits initial and established for 18+, respectively: (OID 2.16.840.1.113883.3.464.1003.101.12.1023; OID 2.16.840.1.113883.3.464.1003.101.12.1025)

# [Response Ends]

# sp.16. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

#### [Response Begins]

- 1. Documentation of anatomical infecundity due to removal of uterus and/or bilateral ovaries, and
- 2. Among those who did not receive or be documented to use a most or moderately effective method in the measurement period, those who indicated they did not want contraceptive services, and
- 3. Those who had prenatal visit between 1/1/XX-1 (year prior to the measurement year) and 9/30/XX (the measurement year) with a live birth date, if documented, or a documented estimated delivery date between 10/1/XX-1 and 9/30/XX, provided they did not have a documented ectopic pregnancy intrauterine fetal demise, early pregnancy loss, or abortion. The inclusion in this measure of those who were documented to have a non-live birth ensures that whether or not the contraceptive needs of these individuals are met is measured, as the peripartum measure excludes these individuals in order to focus on the peripartum care pathway.

#### [Response Ends]

#### sp.17. Provide details needed to calculate the denominator exclusions.

All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

#### [Response Begins]

- 1. Infecundity
  - 1. Infecund Not for Contraceptive Reasons ICD10 CM (OID 2.16.840.1.113762.1.4.1166.97)
  - 2. Infecund Not for Contraceptive Reasons, Procedures CPT (OID 2.16.840.1.113762.1.4.1166.15)
- 2. Documentation of "No" responses to the self-identified need for contraception (SINC) question in the measurement period
  - 1. SINC LOINC (OID 2.16.840.1.113762.1.4.1166.115)
- 3. Eligible for postpartum contraception
  - 1. Definition of a prenatal care visit 1/1/XX-1 and 12/31/XX as per CPT, HPs and SNOMED codes Prenatal care bundle visits (OID 2.16.840.1.113762.1.4.1166.205); Prenatal care specific visits (OID 2.16.840.1.113762.1.4.1166.114)
  - 2. Documentation of a live birth date between 10/1/XX-1 and 9/30/XX as per CPT, SNOMED and ICD10 codes Delivery of Live Birth (OID 2.16.840.1.113883.3.464.1003.111.12.1015)
  - 3. Documentation of an EDD between 10/1/XX-1 and 9/30/XX, as per LOINC codes Estimated Delivery Date (OID 2.16.840.1.113762.1.4.1221.131)
  - 4. With the exception of, if they had documentation of a non-live birth between 10/1/XX-1 and 9/30/XX as per CPT, SNOMED and ICD10 codes Nonlive Births and Procedures and Diagnoses, respectively (OID 2.16.840.1.113762.1.4.1166.137, OID 2.16.840.1.113762.1.4.1166.136). These cases are to be added back in.

#### [Response Ends]

# sp.18. Provide all information required to stratify the measure results, if necessary.

Include the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate. Note: lists of

individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format in the Data Dictionary field.

#### [Response Begins]

N/a - no stratification

[Response Ends]

# sp.19. Select the risk adjustment type.

Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section.

# [Response Begins]

No risk adjustment or risk stratification

[Response Ends]

# sp.20. Select the most relevant type of score.

Attachment: If available, please provide a sample report.

# [Response Begins]

Rate/proportion

[Response Ends]

#### sp.21. Select the appropriate interpretation of the measure score.

Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score

#### [Response Begins]

Better quality = Higher score

[Response Ends]

#### sp.22. Diagram or describe the calculation of the measure score as an ordered sequence of steps.

Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.

#### [Response Begins]

Step 1. Identify all women aged 15-44 years of age who had a qualifying encounter at the specified facility

Step 2. Define the denominator by excluding women who:

- Are not at risk for pregnancy due to removal of uterus and/or bilateral ovaries;
- Indicated that they did not wish to discuss contraception and did not receive or have documented use of a most or moderately effective contraceptive method during the calendar year
- Had a prenatal visit with a documented delivery/live birth data between 3 months prior and 9 months into the
  measurement period, or if no delivery/live birth data documented, had an EDD between 3 months prior and 9
  months into the measurement period and did not have documentation of a non-live birth (e.g. still birth,
  miscarriage, or ectopic)

Step 3. Define the numerator by using codes to identify women in the denominator who were provided or continued use of a 1) provision or use of a most or moderately effective method (primary measure) and 2) provision of a long-acting reversible method of contraception (LARC), i.e., IUD or implant (sub-measure).

Step 4a: Calculate the primary measure rates by dividing numerator 1 by the denominator

Step 4b: Calculate the sub-measure by dividing numerator 2 by the denominator

# [Response Ends]

sp.25. If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.

#### [Response Begins]

N/a - not based on sample

[Response Ends]

# sp.28. Select only the data sources for which the measure is specified.

#### [Response Begins]

Electronic Health Data Electronic Health Records [Response Ends]

# sp.29. Identify the specific data source or data collection instrument.

For example, provide the name of the database, clinical registry, collection instrument, etc., and describe how data are collected.

# [Response Begins]

This measure uses data from the Electronic Health Record, as documented using standardized coding languages, collected during clinical encounters and exported for analysis.

[Response Ends]

# sp.30. Provide the data collection instrument.

# [Response Begins]

No data collection instrument provided

# Criteria 3: Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3.01. Check all methods below that are used to generate the data elements needed to compute the measure score.

# [Response Begins]

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

Coded by someone other than person obtaining original information (e.g., DRG, ICD-10 codes on claims) [Response Ends]

3.02. Detail to what extent the specified data elements are available electronically in defined fields.

In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields.

#### [Response Begins]

ALL data elements are in defined fields in electronic health records (EHRs)

[Response Ends]

3.03. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using data elements not from electronic sources.

[Response Begins]

Not applicable.

[Response Ends]

3.05. Complete and attach the NQF Feasibility Score Card.

[Response Begins]

[Response Ends]

Attachment: 3699e\_Measure3699e\_feasibility\_scorecard\_combined\_(2).xlsx

3.06. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

#### [Response Begins]

Two data partners completed the feasibility assessments for NQF #3699e to provide feedback on the measure and its calculation (see the file named "Measure3699e\_feasibility\_scorecard\_combined.xlsx"). The partners described the availability and accuracy of the measure data elements in their electronic health record (EHR) systems, as well as how elements fit into their process of providing care and if the elements utilize national terminology standards. Both partners reported that their EHR systems contained #3699e's data elements, however, neither EHR system employs all code systems included in the eCQM's specifications. Recognizing that different EHR systems use multiple combinations of code systems, this eCQM includes several terminologies to facilitate measure use and calculation, even if one code system is excluded.

NQF #3699e contains a novel data element for users to implement for calculation: the Self-Identified Need for Contraception (SINC). SINC identifies patients who want contraceptive services in a client-centered manner by asking about their needs now and is used to refine the measure denominator. Currently based only in the LOINC code system, SINC requires implementation in EHR systems and incorporation into clinical workflows to ensure identification of client's desire for contraceptive services in a patient-centered way. UCSF plans to apply for SNOMED CT codes for SINC to provide

additional flexibility for entities to incorporate this key data element into their EHRs. With our eCQM testing contractor Far Harbor LLC, UCSF will provide customized technical assistance to its data partners to add SINC to their EHR systems (note that one data partner, OCHIN, has already completed this implementation). Each partner will develop a SINC implementation plan and meet with the UCSF-Far Harbor team to ask questions and address any gaps. We are currently implementing this performance measure in approximately 20 Federally Qualified Health Centers (FQHCs) for our Innovating Contraceptive Care in Community Health Centers (ICC in CHCs) initiative. Through this effort, UCSF will collect information to understand the impact of utilizing this eCQM on FQHCs and its clients through a learning community. These data partners all agree that the COVID-19 pandemic presented challenges to continuing their regular health care service delivery due to staffing shortages. The disruption to FQHCs' workforce has slowed the project's progress, and UCSF has adjusted the project plan to provide additional time for the partners to prepare for launch of quality improvement strategies and #3699e calculation. Comprised of our project team and partner CHCs, the learning community will meet monthly to share accomplishments and discuss issues in data availability and accuracy while using the measure for quality improvement assessment. We aim to learn from our partner organizations and build upon their existing strengths to test NQF #3699e and develop solutions to address challenges to measurement. UCSF plans to create an implementation manual for #3699e to help new measure users to incorporate the measure to improve contraceptive care quality.

This project will then inform efforts to incorporate NQF #3699e into the US Health Resources Services & Administration (HRSA) Uniform Data System (UDS), which evaluates health center performance and care quality nationwide. UCSF has discussed this initiative with HRSA's UDS modernization team to work towards widespread, public reporting of #3699e. We also plan to collaborate with the HHS Office of Population Affairs (OPA) to achieve public reporting of #3699e for all Title X facilities when fully endorsed. All data elements, including SINC, have been included in the blueprint for the new version of the Title X reporting system, Family Planning Annual Report (FPAR) 2.0, to facilitate reporting of this measure across the Title X grantee network.

# [Response Ends]

Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

3.07. Detail any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm),

Attach the fee schedule here, if applicable.

# [Response Begins]

Not applicable. The measure specifications and value sets will all be available at no charge on UCSF's Person-Centered Reproductive Health Program (PCRHP) website (<a href="https://pcrhp.ucsf.edu/sincbasedeCQMs">https://pcrhp.ucsf.edu/sincbasedeCQMs</a>). NQF #3699e specifications will also be published in CMS's Measure Authoring Tool (MAT) website <a href="https://www.emeasuretool.cms.gov/">https://www.emeasuretool.cms.gov/</a> - registration required) with the title "SINC-Based Contraceptive Care, Non-Postpartum", while the value sets used will be posted in the National Library of Medicine (NLM) Value Set Authority Center (VSAC, <a href="https://vsac.nlm.nih.gov/">https://vsac.nlm.nih.gov/</a> - registration required). [Response Ends]

# Criteria 4: Use and Usability

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making.

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement, in addition to demonstrating performance improvement.

#### 4a.01. Check all current uses. For each current use checked, please provide:

Name of program and sponsor

URL

**Purpose** 

Geographic area and number and percentage of accountable entities and patients included

Level of measurement and setting

[Response Begins]

Not in use

[Not in use Please Explain]

We are submitting for trial use - for more information, please see our response in 4a.03

[Response Ends]

# 4a.02. Check all planned uses.

# [Response Begins]

Public reporting

Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

Quality Improvement (internal to the specific organization)

[Response Ends]

4a.03. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.

For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?

# [Response Begins]

As we are applying for endorsement trial use, NQF #3699e has not yet been widely disseminated, and therefore is not ready for use in accountability programs or for public reporting. We note that our timeline of developing and implementing this measure has been influenced by the desire to optimize the measures alignment with principles of Reproductive Justice and reproductive autonomy. Specifically, UCSF has collaborated for the past two years with stakeholders, including those from family planning, primary care, and Reproductive Justice organizations to develop an eCQM denominator that accounts for clients' desire for contraception. Through our work on the Person-Centered Contraceptive Counseling (PCCC) measure (NQF #3543), a patient-reported outcome performance measure (PRO-PM) of contraceptive counseling, as well as broader engagement with issues of health equity and patient-centeredness and contraceptive care, we identified the need for the Self-Identified Need for Contraception (SINC) data element to assess whether clients want to discuss contraception during their health care visit (rather than including all women of

reproductive age in the denominator). Currently based in the LOINC code system, SINC requires implementation in EHR systems and incorporation into clinical workflows to ensure identification of clients' desire for contraceptive services in a patient-centered way.

UCSF has multiple collaborations underway to implement the measure and SINC in Federally Qualified Health Centers (FQHCs) and the Title X family planning services network of the HHS Office of Population Affairs (OPA). These pilot projects will help us to test and refine the measure specifications and develop an implementation guide for organizations wanting to utilize the SINC-Based eCQMs of Contraception. Lessons learned from these early implementations will help UCSF to support eCQM users for public reporting of #3699e.

#### [Response Ends]

4a.04. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.

A credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.

#### [Response Begins]

We plan to launch a one-year pilot in September 2022, Innovating Contraceptive Care in Community Health Centers (ICC in CHCs). This project will convene a learning collaborative to improve patient-centered contraception services in Federally Qualified Health Centers (FQHCs) through use of point-of-care and systems quality improvement (QI) strategies. Approximately 20 participating CHCs will operationalize use of #3699e alongside the Person-Centered Contraceptive Counseling (PCCC) measure (NQF #3543) to evaluate contraceptive care quality. Along with our eCQM testing contractor Far Harbor LLC, we will work closely with our CHC data partners to implement SINC, NQF #3543, and NQF #3699e in their clinical workflows and EHR systems. UCSF will also collaborate with CHCs to ensure that the partners' systems contain all data elements required to calculate #3699e. By September 2023, UCSF plans to collect sufficient data from its partners to conduct the required reliability and validity testing to apply for full NQF endorsement of #3699e.

ICC in CHCs will also lay the foundation for the eCQM to be adopted into accountability programs, such as the US Health

Resources & Services Administration (HRSA) Uniform Data System (UDS) and the CMS Adult and Child Core Sets. UCSF has already begun the process of engaging with stakeholders, including UDS and CMS, to coordinate our efforts. In partnership with HHS Office of Population Affairs (OPA), we aim to also calculate SINC-Based eCQMs of Contraception within the Title X grantee network through Family Planning Annual Report (FPAR) 2.0. Currently in development, FPAR 2.0 is an interoperable, standards-based reporting system that will collect a set of defined data elements from all Title X service sites, including elements needed for #3699e, #3682e, and #3543. FPAR 2.0 will enable participants to improve the way they send and receive health-related data for analysis and annual reports. OPA has defined the FPAR 2.0 set of data elements to support the interoperability standards and is working to map each data element and response option to standardized value sets, utilizing LOINC, SNOMED CT, and RxNorm code systems. Title X grantees will collaborate with new stakeholders and technical experts to pilot and test FPAR 2.0 across the Title X network with the goal of utilization at all service sites [1].

#### References

[1] Office of Population Affairs. (n.d.). Family Planning Annual Report (FPAR) 2.0. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health. Retrieved April 6, 2022 from <a href="https://opa.hhs.gov/research-evaluation/title-x-services-research/family-planning-annual-report/fpar2">https://opa.hhs.gov/research-evaluation/title-x-services-research/family-planning-annual-report/fpar2</a>

# [Response Ends]

4a.05. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

Detail how many and which types of measured entities and/or others were included. If only a sample of measured entities were included, describe the full population and how the sample was selected.

For our pilot implementation, Innovating Contraceptive Care in Community Health Centers (ICC in CHCs), UCSF will deliver feedback through different mechanisms to approximately 20 Federally Qualified Health Centers (FQHCs). The measure specifications for NQF #3699e and #3682e will be available to users through CMS Measure Authoring Tool (MAT) website (<a href="https://www.emeasuretool.cms.gov/">https://www.emeasuretool.cms.gov/</a> - registration required) and UCSF's SINC-Based eCQMs of Contraception website (<a href="https://pcrhp.ucsf.edu/sincbasedeCQMs">https://pcrhp.ucsf.edu/sincbasedeCQMs</a>). Value sets to define #3699e and #3682e are listed in the eCQM MAT specifications and housed in the National Library of Medicine Value Set Authority Center online system (<a href="https://vsac.nlm.nih.gov/">https://vsac.nlm.nih.gov/</a> - registration required). UCSF and its eCQM testing contractor Far Harbor LLC will collaborate with participating CHCs to calculate #3543 through paper or web-based surveys and #3699e using EHR data. The UCSF-Far Harbor team will provide technical assistance for eCQM calculation through coaching meetings for each individual partner. We aim to share performance results with participating CHCs through reports and data briefs that include charts, graphs, and narrative describing the measure scores and changes after initiation of quality improvement (QI) strategies if possible. UCSF will also help with interpretation of eCQM scores and their implications for QI through individual partner meetings. Following completion of the ICC in CHCs project, we will leverage the findings of this process to develop generalizable guidelines for reporting and interpreting the SINC-Based eCQMs.

[Response Ends]

4a.06. Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

#### [Response Begins]

As described, UCSF will develop and refine the process for providing NQF #3699e results and the frequency of #3699e calculation after the September 2022 launch of our pilot project with Federally Qualified Health Centers (FQHCs), Innovating Contraceptive Care in Community Health Centers (ICC in CHCs). Currently, we are preparing our data partners for the start of this initiative and answering their questions on SINC implementation and the data elements for #3699e and #3543.

To provide measure results and customized technical assistance to partners, UCSF plans to engage participants in individual coaching meetings monthly or as needed. We will develop reports specific to each partner and instructional briefs to help with #3699e calculation, utilization, and interpretation of results. The eCQM specifications and value sets will also be published on UCSF's website (<a href="https://pcrhp.ucsf.edu/sincbasedeCQMs">https://pcrhp.ucsf.edu/sincbasedeCQMs</a>) in addition to CMS' Measure Authoring Tool (<a href="https://www.emeasuretool.cms.gov/">https://www.emeasuretool.cms.gov/</a>) and NLM's Value Set Authority Center (<a href="https://vsac.nlm.nih.gov/">https://vsac.nlm.nih.gov/</a>). USCF can also help eCQM users to find these online technical resources to aid their evaluation of their QI efforts. Together with our eCQM testing contractor Far Harbor LLC, we can also offer just-in-time technical assistance and respond to requests for help outside of individual coaching meetings.

#### [Response Ends]

4a.07. Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.

# [Response Begins]

To develop NQF #3699e, UCSF solicited a wide range of expert input, including convening three stakeholder panels to discuss how to optimize the measure specifications to capture the desired measure of the extent to which patient's contraceptive needs are being addressed. In addition, we had a series of meetings with Dr. Joia Crear-Perry from National Birth Equity Collaborative and Dr. Jamila Perritt from Physicians for Reproductive Health to provide a Reproductive Justice and race-equity informed perspective on the measure development. This particularly informed the development and wording of the Self-Identified Need for Contraception (SINC) as a means to refine the denominator of the measure and decrease the potential to incentivize directive counseling towards individuals who are not interested in receiving contraceptive care. The inclusion of SINC in NQF #3699e increases the patient-centeredness of our measure and contributes to patient-centered workflows to identify and meet patients' reproductive health needs. Given the documented disparities in reproductive health counseling experienced by patients of color [1-4], utilization of this data element is also consistent with attention to race equity and health care disparities.

In addition, we had expert workgroup meetings conducted by both HHS Office of Population Affairs (OPA) and the Coalition to Expand Contraceptive Access (CECA), which brought together representatives from CMS, OPA, and the Planned Parenthood Federation of America (PPFA), as well as relevant stakeholders including direct care providers and national membership organizations such as the National Family Planning and Reproductive Health Association (NFPRHA),

to discuss measurement of contraceptive provision and care. In these meetings, we received widespread support for the development of our measure, including around the necessity to refine the denominator.

With respect to measured entities, as described, we have not yet calculated and reported the measures, so are unable to provide information about feedback on implementation. We did provide information about the feasibility of implementing NQF #3699e in the feasibility scorecards included in this application. As noted in these documents, implementation and documentation of the SINC screening question for refinement of the denominator of this eCQM presents the most substantial issue with respect to #3699e implementation. To date, our interaction with facilities has indicated that with appropriate guidance and support this is feasible to accomplish. We plan to continue to collect feedback about the process of implementing the SINC element, as well as the process of calculating the measure overall, throughout our Innovating Contraceptive Care in Community Health Centers (ICC in CHCs) project. We will use input received to continue to refine our processes and technical assistance for our partners and eCQM users.

#### References

- [1] Downing, R. A., LaVeist, T. A., & Bullock, H. E. (2007). Intersections of ethnicity and social class in provider advice regarding reproductive health. *American journal of public health*, *97*(10), 1803–1807. https://doi.org/10.2105/AJPH.2006.092585
- [2] Becker, D., & Tsui, A. O. (2008). Reproductive health service preferences and perceptions of quality among low-income women: racial, ethnic and language group differences. Perspectives on sexual and reproductive health, 40(4), 202–211. https://doi.org/10.1363/4020208
- [3] Borrero, S., Schwarz, E. B., Creinin, M., & Ibrahim, S. (2009). The impact of race and ethnicity on receipt of family planning services in the United States. *Journal of women's health (2002), 18*(1), 91–96. https://doi.org/10.1089/jwh.2008.0976
- [4] Dehlendorf, C., Ruskin, R., Grumbach, K., Vittinghoff, E., Bibbins-Domingo, K., Schillinger, D., & Steinauer, J. (2010). Recommendations for intrauterine contraception: a randomized trial of the effects of patients' race/ethnicity and socioeconomic status. *American journal of obstetrics and gynecology*, 203(4), 319.e1–319.e3198. https://doi.org/10.1016/j.ajog.2010.05.009

# [Response Ends]

#### 4a.08. Summarize the feedback obtained from those being measured.

# [Response Begins]

As part of our work with the Federally Qualified Health Centers (FQHCs) in our one-year pilot, Innovating Contraceptive Care in Community Health Centers (ICC in CHCs), we plan to systematically collect data about the process and experience of implementation of the measure and its reporting. ICC in CHCs will include the following process measures:

- 1. Pre-survey and post-survey of healthcare staff to assess impact on experience of contraceptive care
- 2. Organizational assessment (as a contextual variable to understand results)
- 3. Key informant interviews both of direct care providers and administrative and quality improvement staff to understand the experience of measure calculation and implementation
- 4. Learning collaborative observations, to obtain information about the experience of receiving and acting on measurement scores

UCSF will calculate these process measures and share results with our CHC data partners through learning collaborative meetings and summary reports. Our subsequent application for full NQF endorsement will include this information. To obtain feedback from a broad range of reproductive and sexual health professionals, UCSF will annually convene an expert work group meeting to engage new and existing users of the SINC-Based eCQMs and to understand its use in real world applications. In addition, we will participate in OPA's annual EWG, which consists of both measured entities and broader stakeholders, to obtain ongoing feedback on use of the measure in the real world. This workgroup represents several organizations and is engaged in helping to maintain, refine, and test the existing NQF-endorsed measures related to contraceptive care (NQF #2902, #2903, #2904) and the patient-reported outcome performance measure. [Response Ends]

# 4a.09. Summarize the feedback obtained from other users.

#### [Response Begins]

As described above, UCSF has obtained extensive input from a broad range of stakeholders in the process of specifying and initiating implementation of this measure. This has included reproductive justice consults, and diverse stakeholders in the context of Technical Expert Panels convened by the Coalition to Expand Contraceptive Access (CECA), the National

Contraceptive Quality Measures Workgroup, and the HHS Office of Population Affairs (OPA) Expert Workgroup for Contraceptive Care Performance Measures. This engagement informed development of NQF #3699e, including providing input on how to incorporate client choice more directly into an eCQM of contraceptive provision and use by capturing the extent to which patient's contraceptive needs are addressed in the measure specifications. Moving forward, CECA and the Planned Parenthood Federation of America (PPFA) will jointly convene the National Contraceptive Quality Measures Workgroup to conduct quarterly meetings to bring together researchers, clinical experts, policy advocates, federal partners, community leaders, and others with relevant knowledge and perspectives to share information and lessons learned on contraceptive quality measures implementation and policy, and we will continue to obtain input on our measure. In addition, OPA will continue to convene an annual Expert Work Group (EWG) for Contraceptive Care Performance Measures. Comprised of both measured entities and other stakeholders, the EWG will provide ongoing support and input into UCSF's eCQM implementation and refinement.

#### References

[1] Dehlendorf, C., Akers, A. Y., Borrero, S., Callegari, L. S., Cadena, D., Gomez, A. M., Hart, J., Jimenez, L., Kuppermann, M., Levy, B., Lu, M. C., Malin, K., Simpson, M., Verbiest, S., Yeung, M., & Crear-Perry, J. (2021). Evolving the Preconception Health Framework: A Call for Reproductive and Sexual Health Equity. *Obstetrics and gynecology, 137*(2), 234–239. https://doi.org/10.1097/AOG.000000000000004255

#### [Response Ends]

4a.10. Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

#### [Response Begins]

Through our participation in the Coalition to Expand Contraceptive Access (CECA) Technical Expert Panels, National Contraceptive Quality Measures Workgroup, and HHS Office of Population Affairs (OPA) Expert Work Group, UCSF solicited and received input on how to incorporate client choice more directly into an eCQM of contraceptive provision and use. These discussions focused on capturing the extent to which patient's contraceptive needs are addressed in an eCQM. UCSF also collaborated with Dr. Joia Crear-Perry from National Birth Equity Collaborative (NBEC) and Dr. Jamila Perritt from Physicians for Reproductive Health (PRH) over a series of meetings to incorporate a Reproductive Justice and race-equity informed perspective in eCQM development. Our partnership with NBEC and PRH informed the design of the data element Self-Identified Need for Contraception (SINC) to refine the NQF #3699e denominator and prevent directive counseling towards individuals not interested in receiving contraceptive care. SINC transforms the contraceptive eCQM into a patient-centered measure and contributes to patient-centered workflows, both of which identify and meet patients' reproductive health needs. Given the documented disparities in reproductive health counseling experienced by patients of color [1-4], utilizing SINC in NQF #3699e also ensures that an eCQM of contraception focuses on improving race equity and health care disparities experienced by clients of color during contraceptive care.

The feedback obtained from these workgroups contributed to UCSF finalizing the following substantive decisions regarding our eCQM specifications:

- Incorporation of the SINC data element to account for client choice in the eCQM denominator. We developed SINC in the context of routine care, and considered the use of One Key Question® (OKQ®) as an alternative. OKQ® asks patients whether they wish to get pregnant in the next year and has been proposed as a means of identifying clients in need of contraceptive services by excluding those desiring pregnancy [5]. However, through discussion with stakeholders, we determined OKQ® was not optimal because it does not identify patients who desire contraception and/or pregnancy prevention at the current time (which is not incompatible with desiring pregnancy in a year).
- Definition of the postpartum period to 90 days after live birth delivery for an exclusion criterion aligned with the American College of Obstetrician & Gynecologists (ACOG) postpartum care guidelines [6]. A 90-day window also provides a greater amount of time to meet a patient's contraceptive needs in the postpartum period. As NQF #3699e excludes the postpartum population (i.e., those included in NQF #3682e), this expansion of the postpartum period needed to be integrated into the specifications.
- Utilization of both live birth delivery date and estimated delivery date (EDD) as exclusion criteria for NQF #3699e. Because delivery date is not always available in the electronic health record of the site of prenatal care, NQF #3699e also uses EDD as entered into the prenatal care record to exclude postpartum clients from the eCQM denominator.

# References

- [1] Downing, R. A., LaVeist, T. A., & Bullock, H. E. (2007). Intersections of ethnicity and social class in provider advice regarding reproductive health. *American journal of public health*, *97*(10), 1803–
- 1807. https://doi.org/10.2105/AJPH.2006.092585
- [2] Becker, D., & Tsui, A. O. (2008). Reproductive health service preferences and perceptions of quality among low-income women: racial, ethnic and language group differences. Perspectives on sexual and reproductive health, 40(4), 202–211. https://doi.org/10.1363/4020208
- [3] Borrero, S., Schwarz, E. B., Creinin, M., & Ibrahim, S. (2009). The impact of race and ethnicity on receipt of family planning services in the United States. *Journal of women's health (2002), 18*(1), 91–
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- [5] Power to Decide. (2020 September). *One Key Question® Overview*. Retrieved April 7, 2022 from https://powertodecide.org/sites/default/files/2021-09/One%20Key%20Question Overview.pdf
- [6] ACOG Committee Opinion No. 736: Optimizing Postpartum Care. (2018). *Obstetrics and gynecology, 131*(5), e140–e150. https://doi.org/10.1097/AOG.0000000000002633

# [Response Ends]

4b.01. You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included). If no improvement was demonstrated, provide an explanation. If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

#### [Response Begins]

NQF #3699e is currently planned for use in performance improvement through our pilot project in approximately 20 Federally Qualified Health Centers (FQHCs), Innovating Contraceptive Care in Community Health Centers (ICC in CHCs). Future uses of this measure for performance improvement will include public reporting of #3699e measure scores through HRSA UDS from FQHCs and use in quality improvement (QI) in health facilities. With respect to QI, we anticipate that baseline measurement can help identify entities that have opportunities for improvement in meeting patients' needs for contraceptive care. Care entities can then detect gaps in the reproductive health care pathway, including failure to recognize patients desiring contraceptive care and failure to provide care to clients who want it. Facilities can then implement QI mechanisms to address these gaps. Subsequent calculation of #3699e during the QI implementation can evaluate the impact of the QI interventions.

#### [Response Ends]

4b.02. Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.

#### [Response Begins]

We do not yet have experience with implementation of the measure, so cannot report on unexpected findings to date. We will continue to monitor for such results throughout measure implementation, including in our pilot, Innovating Contraceptive Care in Community Health Centers (ICC in CHCs). We do not anticipate any unintended negative consequences in the future implementation of the measure. A potential concern that remains is that the measure may lead to coercive practices in which women are not offered a free choice of methods and are pressured to use most or moderately effective contraception [1-3]. This concern motivated the development and incorporation of the Self-Identified Need for Contraception (SINC) question into #3699e, in that those who are not interested in discussing prescription contraceptive methods can be excluded from the denominator for measure calculation. Further, we plan to provide guidance for the LARC-focused sub-measure, which will align with guidance for NQF #2904. Specifically, the goal of the NQF #3699e sub-measure is to ensure access to LARC methods in the postpartum period by monitoring very low rates of provision (e.g., below 2%). This measure therefore will not have a benchmark encouraging high rates of use, and

that utilization in pay-for-performance or similar programs will be explicitly defined as inappropriate. If the sub-measure is implemented as intended (*i.e.*, to assess lack of access), this should remove pressure on providers to inappropriately "promote" LARC methods in the non-postpartum population. We will also continue to monitor for unintended impacts on patient-centeredness using the NQF endorsed measure #3543, which assesses patient experience of contraceptive counseling.

Our website provides specific guidance on how the SINC-Based eCQMs should be used (https://pcrhp.ucsf.edu/sincbasedeCQMs).

# References

- [1] Dehlendorf, C., Bellanca, H., & Policar, M. (2015). Performance measures for contraceptive care: what are we actually trying to measure?. *Contraception*, *91*(6), 433–437. <a href="https://doi.org/10.1016/j.contraception.2015.02.002">https://doi.org/10.1016/j.contraception.2015.02.002</a>
- [2] Gold, R.B. (2014). Guarding Against Coercion While Ensuring Access: A Delicate Balance. *Guttmacher Policy Review,* 17(3), 8-14.
- [3] Sonfield, A. (2017). Why family planning policy and practice must guarantee a true choice of contraceptive methods. *Guttmacher Policy Review, 20,* 103–107.

# [Response Ends]

# 4b.03. Explain any unexpected benefits realized from implementation of this measure.

#### [Response Begins]

Not applicable. At this time, we do not have performance scores available for NQF #3699e as we are submitting this eCQM for Approval for Trial Use.

# Criteria 5: Related and Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

If you are updating a maintenance measure submission for the first time in MIMS, please note that the previous related and competing data appearing in question 5.03 may need to be entered in to 5.01 and 5.02, if the measures are NQF endorsed. Please review and update questions 5.01, 5.02, and 5.03 accordingly.

5.01. Search and select all NQF-endorsed related measures (conceptually, either same measure focus or target population).

(Can search and select measures.)

# [Response Begins]

2903: Contraceptive Care – Most & Moderately Effective Methods 3543: Person-Centered Contraceptive Counseling (PCCC) measure 2904: Contraceptive Care - Access to LARC

[Response Ends]

5.02. Search and select all NQF-endorsed competing measures (conceptually, the measures have both the same measure focus or target population).

(Can search and select measures.)

[Response Begins]

[Response Ends]

5.03. If there are related or competing measures to this measure, but they are not NQF-endorsed, please indicate the measure title and steward.

#### [Response Begins]

We are also concurrently submitting the following related eCQM for Approval for Trial Use:

Title: SINC-Based Contraceptive Care, Postpartum (NQF #3682e)

Steward: UCSF

NQF #3682e complements NQF #3699e because it assesses contraceptive provision in the postpartum population, which is excluded from #3699e. Utilizing #3699e and #3682e together can provide a comprehensive picture of contraceptive provision among clients who desire these services, regardless of whether they recently had a live birth delivery.

#### [Response Ends]

5.04. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.

[Response Begins]

Yes

[Response Ends]

5.05. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

[Response Begins]

N/A

5.06. Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.

Provide analyses when possible.

# [Response Begins]

NQF #3699e has no other NQF-endorsed competing measures. UCSF is submitting one other measure (NQF #3682e) for Approval for Trial Use, which is complementary to this application. NQF #3682e focuses on use of most and moderately effective contraceptive methods and LARC methods in clients of reproductive age that had a live birth delivery in the measurement period.

While NQF #2903 and #2904 use claims data, the proposed measure employs data elements from electronic health record (EHR) systems, which allows for utilization in entities that do not rely on claims for reimbursement (e.g., prospective payment systems). The EHR data also allow testing and validating the measures at the facility level, which is largely unavailable in administrative claims. eCQMs specified for calculation at this level can then aid implementation of quality improvement initiatives for contraceptive services.

NQF #3699e allows for better identification of the population of interest with the use of the Self-Identified Need for Contraception (SINC) element. The SINC data element refines the denominator to exclude individuals who do not want contraceptive services and ensures that #3699e has a patient-centered focus. SINC is also designed to facilitate utilization. Currently based in the LOINC code system, the SINC data element can be implemented across EHR systems since it relies on standard terminology utilized in this data source. It consists of one question with five response options to be administered to patients at least annually. UCSF also plans to develop a SNOMED CT data element complementary to the LOINC-based SINC to increase implementation in various health systems.

UCSF also wishes to acknowledge our measure with conceptual overlap to this eCQM: the Person-Centered Contraceptive Counseling (PCCC) measure (NQF #3543). We developed #3543 to enable health facilities and systems to assess patient experience with contraceptive services, and to serve as a 'balancing measure' to support proper utilization of all contraceptive provision measures [1-3].

Endorsed in November 2020 by NQF's Consensus Standards Approval Committee as NQF #3543, the PCCC measure is a four-item patient-reported outcome performance measure (PRO-PM) designed to specifically evaluate the patient-centeredness of contraceptive counseling at the individual clinician/provider and facility levels of analysis [4]. The PCCC's target population intersects with this measure's target population (*e.g.*, ages 15-45 and assigned female at birth), but the PCCC is visit-specific. It is given to patients who have been identified as having received contraceptive counseling during their visit. Our project to implement the eCQMs of contraception, Innovating Contraceptive Care in Community Health Centers (ICC in CHCs), will test #3699e as its own measure and in tandem use with NQF #3543.

After implementing NQF #3543, organizations can observe any fluctuations in PCCC scores that occur with variations in contraceptive provision scores specified for administrative claims and EHR systems. PCCC scores used with NQF #3699e allow groups to ensure that any increase in contraceptive provision does not come at the cost of patient experience. Use of #3543 with #3699e and other contraceptive provision measures can result in a more complete understanding of contraceptive services quality and help health entities to provide both access to a range of contraceptive methods and patient-centered counseling without coercion.

#### References

- [1] Dehlendorf, C., Bellanca, H., & Policar, M. (2015). Performance measures for contraceptive care: what are we actually trying to measure?. Contraception, 91(6), 433–437. <a href="https://doi.org/10.1016/j.contraception.2015.02.002">https://doi.org/10.1016/j.contraception.2015.02.002</a>
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- [4] University of California San Francisco. *The Person-Centered Contraceptive Counseling Measure*. Retrieved March 31 2022 from <a href="https://pcccmeasure.ucsf.edu/">https://pcccmeasure.ucsf.edu/</a>