Diagnostic Testing
Potential PURL Review Form
PURL Jam Version

Version #12 Sept 20, 2010

PURLs Surveillance System
Family Physicians Inquiries Network

SECTION 1: Identifying Information for Nominated Potential PURL
[to be completed by PURLs Project Manager]

1. Citation	Bianchi DW, Parker RL, Wentworth J, Madankumar R, Saffer C, Das AF, Craig JA, Chudova DI, Devers PL, Jones KW, Oliver K, Rava RP, Sehnert AJ; CARE Study Group. DNA sequencing versus standard prenatal aneuploidy screening. N Engl J Med. 2014 Feb 27;370(9):799-808. doi: 10.1056/NEJMoa1311037. PubMed PMID: 24571752.
2. Hypertext link to PDF of full article	http://www.ncbi.nlm.nih.gov/pubmed/?term=DNA+sequencing+versus+standard+prenatal+aneuploidy+screening.
3. First date published study available to readers	2/27/14
4. PubMed ID	24571752
5. Nominated By	Jim Stevermer Other:
6. Institutional Affiliation of Nominator	University of Missouri Other:
7. Date Nominated	4/12/14
8. Identified Through	Evidence Updates Other:
9. PURLS Editor Reviewing Nominated Potential PURL	Kate Rowland
10. Nomination Decision Date	4/24/14
11. Potential PURL Review Form (PPRF) Type	Diagnostic Test
12. Other comments, materials or discussion	
13. Assigned Potential PURL Reviewer	Kohar Jones, MD
14. Reviewer Affiliation	University of Chicago Other:
15. Date Review Due	5/29/14
16. Abstract	BACKGROUND: In high-risk pregnant women, noninvasive prenatal testing with the use of massively parallel sequencing of maternal plasma cell-free DNA (cfDNA testing) accurately detects fetal autosomal aneuploidy. Its performance in low-risk women is unclear. METHODS: At 21 centers in the United States, we collected blood samples from women with singleton pregnancies who were undergoing standard aneuploidy screening (serum biochemical assays with or without nuchal translucency measurement). We performed massively parallel sequencing in a blinded fashion to determine the chromosome dosage for each sample. The primary end point was a comparison of the false positive rates of detection of fetal

trisomies 21 and 18 with the use of standard screening and cfDNA testing. Birth outcomes or karyotypes were the reference standard.
RESULTS:
The primary series included 1914 women (mean age, 29.6 years) with an eligible sample, a singleton fetus without aneuploidy, results from cfDNA testing, and a risk classification based on standard screening. For trisomies 21 and 18, the false positive rates with cfDNA testing were significantly lower than those with standard screening (0.3% vs. 3.6% for trisomy 21, P<0.001; and 0.2% vs. 0.6% for trisomy 18, P=0.03). The use of cfDNA testing detected all cases of aneuploidy (5 for trisomy 21, 2 for trisomy 18, and 1 for trisomy 13; negative predictive value, 100% [95% confidence interval, 99.8 to 100]). The positive predictive values for cfDNA testing versus standard screening were 45.5% versus 4.2% for trisomy 21 and 40.0% versus 8.3% for trisomy 18.
CONCLUSIONS:
In a general obstetrical population, prenatal testing with the use of cfDNA had significantly lower false positive rates and higher positive predictive values for detection of trisomies 21 and 18 than standard screening. (Funded by Illumina; ClinicalTrials.gov number, NCT01663350.).

17. Pending PURL Review Date

SECTION 2: Critical Appraisal of Validity
[to be completed by the Potential PURL Reviewer]

1. Is the spectrum of severity of patients' illness comparable to the patient group typically seen by family physicians and other primary care clinicians?

Yes

2. Is the proportion of patients with the target illness comparable to the patient group typically seen by family physicians and other primary care clinicians?

Yes

3. The nature of the test being studied is clearly specified.

☒ Well covered ☐ Not addressed
☐ Adequately addressed ☐ Not reported
☐ Poorly addressed ☐ Not applicable
Comments:

4. The test is compared with an appropriate gold standard.

☒ Well covered ☐ Not addressed
☐ Adequately addressed ☐ Not reported
☐ Poorly addressed ☐ Not applicable
Comments:

5. Where no gold standard exists, a validated reference standard is used as comparator.

☐ Well covered ☐ Not addressed
☐ Adequately addressed ☐ Not reported
☐ Poorly addressed ☒ Not applicable
Comments:

6. Patients for testing are selected either as a consecutive series or randomly, from a clearly defined study population.

☒ Well covered ☐ Not addressed
☐ Adequately addressed ☐ Not reported
☐ Poorly addressed ☐ Not applicable
Comments:

7. The test and gold standard are measured independently (blind) of each other.

☒ Well covered ☐ Not addressed
☐ Adequately addressed ☐ Not reported
☐ Poorly addressed ☐ Not applicable
Comments:

8. The test and gold standard are applied as close together in time as possible.

☐ Well covered ☐ Not addressed
☐ Adequately addressed ☐ Not reported
☐ Poorly addressed ☒ Not applicable
Comments:

9. Results are reported for all patients that are entered into the study.

☒ Well covered
☐ Adequately addressed
☐ Poorly addressed
☐ Not addressed
☐ Not reported
☐ Not applicable
Comments:

10. A pre-test diagnosis is made and reported.

☐ Well covered
☐ Adequately addressed
☐ Poorly addressed
☐ Not addressed
☐ Not reported
☒ Not applicable
Comments:

11. How many patients are included in this study?

Please indicate number of patients included, with inclusion/exclusion criteria used to select them.

2042 women over 18 with a singleton pregnancy were recruited, trisomy 21 1909, trisomy 18 1905. Investigators required accessibility to pregnancy and delivery records, such as reports from lab screening, fetal US, cytogenetic testing, and newborn physical exams.

12. What is the prevalence (proportion of people with the disease being tested for) in the population from which patients were selected?

trisomy 21 5/1909 (0.3%); trisomy 18 2/1905 (0.1%)--in general in the population, according to Pepid

- Trisomy 18 (Edward's syndrome)- 1/8000 live births
- Trisomy 21 (Down's syndrome)- 1/800 live births

13. What are the main characteristics of the patient population?

Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based

Pregnant women from 21 clinical centers in 14 states in the United States

14. What test is being evaluated in this study?

Consider whether the technology being described is comparable / relevant to the test being considered in the guideline. i.e. make sure the test has not been superseded by later developments.

cell-free DNA testing consisting of massively parallel sequencing of maternal plasma cell-free DNA from 10 mL sample of peripheral venous blood in first, second, or third trimester

15. What is the reference standard with which the test being evaluated is compared?

Indicate whether a gold standard, or if not how this standard was validated.

Standard aneuploidy screening included assays for first or second trimester serum markers with or without ultrasound fetal nuchal translucency measurement (reference standard for screening). Reference standard for diagnosis with newborn physical exams for live births, and karyotype analysis for nonlive births.

16. What is the estimated sensitivity of the test being evaluated? (state 95% CI)

Sensitivity = proportion of results in patients with the disease that are correctly identified by the new test.

trisomy 21 100 (47.8-100)
trisomy 18 100 (15.8-100)

17. What is the estimated specificity of the test being evaluated? (state 95% CI)

Specificity = proportion of results

trisomy 21 99.7 (99.3-99.9)
trisomy 18 99.8 (99.6-100)

in patients without the disease that are correctly identified by the new test	
18. What is the positive predictive value of the test being evaluated? *Positive predictive value = proportion of patients with a positive test result that actually had the disease.*	trisomy 21 45.5 (16.7-76.6) trisomy 18 40.0 (5.3-85.3)
19. What is the negative predictive value of the test being evaluated? *Negative predictive value = proportion of patients with a negative test result that actually did not have the disease.*	trisomy 21 100 (99.8-100) trisomy 18 100 (99.8-100)
20. What are the likelihood ratios for the test being evaluated? *If not quoted in the study, a number of tools are available that simplify calculation of LRs. Please indicate where results are calculated rather than taken from the study.*	
21. How was this study funded? Does the funding source raise issues of conflict of interest or bias? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	Illumina, with study authors employees and patent holders for the company

SECTION 3: Review of Secondary Literature
[to be completed by the Potential PURL Reviewer]

Citation Instructions	For UpTo Date citations, use style modified from http://www.uptodate.com/home/help/faq/using_UTD/index.html#cite & AMA style. Always use Basow DS as editor & current year as publication year. EXAMPLE: Auth I. Title of article. {insert author name if given, & search terms or title.} In: Basow DS, ed. UpToDate [database online]. Waltham, Mass: UpToDate; 2009. Available at: http://www.uptodate.com. {Insert dated modified if given.} Accessed February 12, 2009. {whatever date PPRF reviewer did their search.} For DynaMed, use the following style: Depression: treatment {insert search terms or title}. In: DynaMed [database online]. Available at: http://www.DynamicMedical.com. Last updated February 4, 2009. {Insert dated modified if given.} Accessed June 5, 2009.{search date}
1. DynaMed excerpts	These following statements are bolded, with information on specific trials underneath maternal plasma cell-free fetal DNA screening appears to have high sensitivity and specificity for fetal trisomies 21 and 18 in high-risk women maternal plasma DNA screening for fetal trisomies 21 and 18 may reduce the need for invasive follow-up testing compared to standard aneuploidy screening (level 2 [mid-level] evidence) chromosome-selective sequencing of maternal plasma cell-free DNA may detect trisomy 21 and trisomy 18 first-trimester combination of maternal age, free beta-hCG, pregnancy-associated plasma protein A, and fetal nuchal translucency has 91% sensitivity for trisomy 18 and 85.2% sensitivity for Down syndrome first- and second-trimester screening protocols can detect Down syndrome and non-Down aneuploidies massively parallel sequencing of maternal plasma DNA associated with accurate identification of Turner

syndrome
massively parallel sequencing of maternal plasma DNA associated with accurate identification of Turner syndrome in cases of fetal nuchal cystic hygroma
massively parallel sequencing of maternal plasma DNA associated with accurate identification of trisomy 18 in cases of fetal nuchal cystic hygroma
massively parallel sequencing of maternal plasma DNA associated with accurate identification of trisomy 18 screening using first and second trimester markers may be useful for detecting trisomy 18
first trimester risk algorithm may identify 95% of cases of trisomy 13 and trisomy 18 combined

2. DynaMed citation/access date

Title. Screening and Monitoring During Pregnancy--Chromosomal Abnormalities Author. In: DynaMed [database online]. Available at: www.DynamicMedical.com Last updated: june 24, 2014. Accessed June 26, 2014

3. Bottom line recommendation or summary of evidence from DynaMed (1-2 sentences)

Implicit by structure of article: maternal plasma cfDNA screening standard of care

4. UpToDate excerpts

PRENATAL GENETIC TESTING — Genetic testing is performed for definitive diagnosis when the offspring is at increased risk of a known heritable disease. It can be performed before birth using cells derived from the placenta (from 10 to 14 weeks of gestation), amniotic fluid (from 15 weeks of gestation to term), fetal blood (from about 18 weeks of gestation to term), or fetal tissue (from about 20 weeks of gestation to term), and sometimes from cell-free fetal nucleic acids in maternal blood (from about 9 weeks of gestation) [18]. It can even be performed before implantation, using cells derived from preimplantation blastocysts conceived in vitro.

§ (See "Preimplantation genetic diagnosis".)
§ (See "Chorionic villus sampling".)
§ (See "Diagnostic amniocentesis".)
§ (See "Fetal blood sampling".)
§ (See "Prenatal diagnosis using cell-free nucleic acids in maternal blood".)

The prenatal diagnosis of specific genetic disorders is discussed in individual topic reviews or within the topic review for the specific disease.

Conventional karyotyping is the principal cytogenetic tool used for prenatal diagnosis. DNA microarrays to detect submicroscopic chromosomal abnormalities can be offered as an adjunct in prenatal cases with abnormal anatomical findings and a normal conventional karyotype [19,20]. There are many additional techniques for genetic testing: testing may be DNA-based, cytogenetic, or metabolic, depending upon its purpose (table 4). The best approach depends on the disorder that is being evaluated and should be determined in consultation with a genetic counselor. (See "Genetic counseling and testing".) ...

Genetic testing can be performed before birth using cells derived from the placenta, amniotic fluid, fetal blood, or fetal tissue, and sometimes from cell-free fetal nucleic acids in maternal blood. It can also be performed before implantation, using cells derived from preimplanted blastocysts conceived in vitro. (See 'Prenatal genetic testing' above.)///

From the linked article: Down Syndrome, PreNatal Screening Overview
(written by authors who are all linked to a cfDNA company, last updated March 13 2014)
Disclosures: Geralyn M Messerlian, PhD Grant/Research Support: Natera, Inc; Sequenom; Beckman (prenatal screening [ccfDNA, hCG]). Consultant/Advisory Boards: Sequenom (prenatal screening). Glenn E Palomaki, PhD Grant/Research/Clinical Trial Support: Natera Inc [ccf DNA (panorama test)]. Consultant/Advisory Boards: Cellula, Inc; Beckman Coulter; Perkin Elmer [Down Syndrome screening (screening assays)]. Employment: WIH. Louise Wilkins-Haug, MD, PhD Grant/Research/Clinical Trial Support: Arisoa [Noninvasive prenatal diagnostic testing free fetal DNA (Noninvasive prenatal testing product)]. Vanessa A Barss, MD Employee of UpToDate, Inc. Equity Ownership/Stock Options: Merck; Pfizer; Abbvie.)

Cell-free DNA in maternal blood — Maternal plasma-based tests for cell-free DNA use next generation genomic sequencing to detect trisomy 21, 18, 13, and possibly sex aneuploidy after 10 weeks of gestation. Several commercial laboratories offer DNA test options. Each company has developed its own proprietary technology for assessment of cell-free DNA in maternal blood and calculation of aneuploidy risk, thus sensitivity and specificity vary slightly. All of these are considered laboratory-developed tests (LDTs) and have not been subject to US Food and Drug Administration (FDA) approval. (See "Prenatal

diagnosis using cell-free nucleic acids in maternal blood".)

And finally, from the last linked article: updated May 2014
(written by authors who are all linked to Ariosa, another company that does cfDNA testing--Disclosures: Adam Wolfberg, MD Patent Holder: Mindchild Medical, Inc [fetal monitoring]. Employment: Ariosa Diagnostics, Inc [non-invasive prenatal testing (harmony prenatal test)]. Equity Ownership/Stock Options: Mindchild Medical, Inc; Ariosa Diagnostics, Inc [non-invasive prenatal testing (harmony prenatal test)]. Aaron B Caughey, MD, PhD Equity Ownership/Stock Options: Ariosa [prenatal diagnosis]; Cellscape [prenatal diagnosis]; Mindchild [fetal monitoring]. Louise Wilkins-Haug, MD, PhD Grant/Research/Clinical Trial Support: Arisoa [Noninvasive prenatal diagnostic testing free fetal DNA (Noninvasive prenatal testing product)]. Vanessa A Barss, MD Employee of UpToDate, Inc. Equity Ownership/Stock Options: Merck; Pfizer; Abbvie.)
INTRODUCTION — Current methods of fetal genetic testing typically involve obtaining samples of amniotic fluid, placenta, fetal blood or, rarely, other fetal tissues or fluids. The invasive techniques required for obtaining fetal samples (eg, amniocentesis, chorionic villus biopsy, fetal umbilical vessel venipuncture, fetoscopy-guided biopsy) place the fetus at risk of injury or death. Therefore, development of accurate, safe, rapid, noninvasive tests for prenatal diagnosis is an area of active investigation. …Noninvasive testing for trisomy 21, trisomy 18 and trisomy 13, as well as sex-chromosome aneuploidies is commercially available. Some clinicians are using noninvasive testing as a screening test in high-risk and low-risk patients, particularly those who would otherwise select invasive diagnostic testing.

5. UpToDate citation/access date

Always use Basow DS as editor & current year as publication year.
Title. Basic principles of genetic screening for obstetrics Author. Disclosures: Harry Ostrer, MD Nothing to disclose. Louise Wilkins-Haug, MD, PhD (editor) Grant/Research/Clinical Trial Support: Arisoa [Noninvasive prenatal diagnostic testing free fetal DNA (Noninvasive prenatal testing product)]. Vanessa A Barss, MD Employee of UpToDate, Inc. Equity Ownership/Stock Options: Merck; Pfizer; Abbvie. In: UpToDate [database online]. Available at: http://www.uptodate.com. Last updated: lit review May 2014, updated August 2013. AccessedJune 26 2014

6. Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences)

Maternal plasma cfDNA is the "next generation" test that provides "accurate, safe, rapid, noninvasive tests for prenatal diagnosis." Reads like an advertisement, written by authors who are each linked to a cfDNA testing company. Ariosa does direct-to-consumer advertising on the web.

7. PEPID PCP excerpts www.pepidonline.com username: fpinauthor pw: pepidpcp

Pregnant women should be offered screening and invasive diagnostic testing regardless of age (SOR B)1
No mention made of cfDNA

8. PEPID citation/access data

Author. Ashley Bainbridge, Sherif Labatia Title. Prenatal Genetic Screening In: PEPID [database online]. Available at: http://www.pepidonline.com. Last updated: Nov 2012. AccessedJune 26 2014

9. PEPID content updating

1. Do you recommend that PEPID get updated on this topic?
☒ Yes, there is important evidence or recommendations that are missing
☐ No, this topic is current, accurate and up to date.
If yes, which PEPID Topic, Title(s):
Prenatal screening should mention cfDNA

2. Is there an EBM Inquiry (HelpDesk Answers and Clinical Inquiries) as indicated by the EB icon (EB) that should be updated on the basis of the review?
☐ Yes, there is important evidence or recommendations that are missing
☐ No, this topic is current, accurate and up to date.
If yes, which Evidence Based Inquiry(HelpDesk Answer or Clinical Inquiry), Title(s):
No EBM

10. Other excerpts (USPSTF; other guidelines; etc.)

ACOG prenatal genetic screening guidelines:
o ACOG recommendations
• screening and invasive diagnostic testing should be available to all women presenting for prenatal care before 20 weeks gestation, regardless of maternal age; counsel women on difference between screening and invasive diagnostic testing (ACOG Level B)

- screening with nuchal translucency alone is less effective than combined test of nuchal translucency and biochemical markers (ACOG Level A)
- offer genetic counseling and option of chorionic villus sampling or second trimester amniocentesis to women with increased risk of fetus with aneuploidy on first trimester screening (ACOG Level A)
- offer targeted ultrasound exam, fetal echocardiogram, or both if fetal nuchal translucency ≥ 3.5 mm in first trimester despite negative aneuploidy screen or normal fetal chromosomes (ACOG Level B)
- subsequent second trimester screening after first trimester screening not indicated unless performed as component of integrated, stepwise sequential, or contingent sequential test (ACOG Level C)
- integrated first- and second-trimester screening is more sensitive with lower false-positive rates than first-trimester screening alone (ACOG Level C)

o options for screening all women to identify fetus with Down syndrome include
- fetal ultrasound(also called genetic ultrasound)
- combination of serum and ultrasound testing
- noninvasive maternal plasma fetal DNA analysis

o maternal plasma cell-free fetal DNA screening
- appears to have high sensitivity and specificity for fetal trisomies 21 and 18 in high-risk women (level 2 [mid-level] evidence)
- may reduce the need for invasive follow-up testing compared to standard aneuploidy screening (level 2 [mid-level] evidence)

11. Citations for other excerpts

I copied the ACOG guidelines from Dynamed

12. Bottom line recommendation or summary of evidence from Other Sources (1-2 sentences)

SECTION 4: Conclusions
[to be completed by the Potential PURL Reviewer; Revised by the Pending PURL Reviewer as needed]

1. Validity: How well does the study minimize sources of internal bias and maximize internal validity?

Give one number on a scale of 1 to 7
(1=extremely well; 4=neutral; 7=extremely poorly)
☒1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

2. If 4.1 was coded as 4, 5, 6, or 7, please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?

3. Relevance: Are the results of this study generalizable to and relevant to the health care needs of patients cared for by "full scope" family physicians?

Give one number on a scale of 1 to 7
(1=extremely well; 4=neutral; 7=extremely poorly)
☒1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

4. If 4.3 was coded as 4, 5, 6, or 7, lease provide an explanation.

5. Practice changing potential: If the findings of the study are both valid and relevant, does the practice that would be based on these findings represent a change from current practice?

Give one number on a scale of 1 to 7
(1=definitely a change from current practice; 4=uncertain; 7=definitely not a change from current practice)
☒1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

6. If 4.5 was coded as 1, 2, 3, or 4, please describe the potential new practice recommendation. Please be specific about what should be done, the target patient population and the expected benefit.

7. Applicability to a Family Medical Care Setting:
Is the change in practice recommendation something that could be done in a medical care setting by a family physician (office,

Give one number on a scale of 1 to 7
(1=definitely could be done in a medical care setting; 4=uncertain; 7=definitely could not be done in a medical care setting)
☒1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

hospital, nursing home, etc), such as a prescribing a medication, vitamin or herbal remedy; performing or ordering a diagnostic test; performing or referring for a procedure; advising, educating or counseling a patient; or creating a system for implementing an intervention?
8. If you coded 4.7 as a 4, 5, 6 or 7, please explain. .

9. Immediacy of Implementation: Are there major barriers to immediate implementation? Would the cost or the potential for reimbursement prohibit implementation in most family medicine practices? Are there regulatory issues that prohibit implementation? Is the service, device, drug or other essentials available on the market?
10. If you coded 4.9 as 4, 5, 6, or 7, please explain why.

Give one number on a scale of 1 to 7
(1=definitely could be immediately applied; 4=uncertain; 7=definitely could not be immediately applied)
☒1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

11. Clinical meaningful outcomes or patient oriented outcomes: Are the outcomes measured in the study clinically meaningful or patient oriented?
12. If you coded 4.11 as a 4, 5, 6, or 7, please explain why.

Give one number on a scale of 1 to 7
(1=definitely clinically meaningful or patient oriented; 4=uncertain; 7=definitely not clinically meaningful or patient oriented)
☐1 ☐2 ☐3 ☒4 ☐5 ☐6 ☐7
Current testing is pretty good using standard screening. This is slightly more specific. As the authors note at the end "a consideration of cost-effective ways to incorporate cfDNA testing into general obstetrical practice is beyond the scope of this study. Our findings, however, suggest that cfDNA testing merits serious consideration as a primary screening method for fetal autosomal aneuploidy.

SECTION 4.1: Diving for PURLs
[optional for the potential PURL reviewer -if you wish to be the author on the summary]

1. Study Summary- Please summarize the study in 5-7 sentences

2. Criteria- note yes or no for those which this study meets

RELEVENT - y
VALID - y
CHANGE IN PRACTICE- y
MEDICAL CARE SETTING - y
IMMEDIATELY APPLICABLE - y
CLINICALLY MEANINGFUL - M

3. Bottom Line- one –two sentences noting the bottom line recommendation

It is gold rush time for companies rushing to capitalize on maternal plasma cell free DNA massively parallel sequencing. These laboratory derived tests are not subject to FDA approval. Each has different specificity and sensitivity for different aneuploidies. This study from biotech company Illumina examined the false positive rates for trisomy 18 and 21 in low risk women, seeking to extend the recommendations for cfDNA use to all populations. While cfDNA has a higher positive predictive value than standard prenatal screening, both have 100% sensitivity. There was no overlap in the false positive results between standard and cfDNA screening.

4. Title Proposal

SECTION 5: Editorial Decisions
[to be completed by the FPIN PURLs Editor or Deputy Editor]

1. FPIN PURLs editorial decision (select one)

☐ 1 Pending PURL Review—Schedule for Review
☐ 2 Drop
☐ 3 Pending PURL

3. Follow up issues for Pending PURL Reviewer

3. FPIN PURLS Editor making decision

☐1 Bernard Ewigman
☐2 John Hickner
☐3 Sarah-Anne Schumann
☐4 Kate Rowland

4. Date of decision

5. Brief summary of decision

SECTION 6: Survey Questions for SERMO, PURLs Instant Polls and Other Surveys
[To be completed by the PURLs Survey Coordinator and PURLs Editor]

1. Current Practice Question for Surveys

2. Barriers to Implementation Question for Surveys

3. Likelihood of Change Question for Surveys

4. Other Questions for Surveys

SECTION 7: Variables for Secondary Database Analyses

1. Population: Age, gender, race, ethnicity

2. Diagnoses

3. Drugs or procedures

SECTION 8: Pending PURL Review Assignment
[to be completed by PURLs Project Manager

1. Person Assigned for Pending PURL Review

2. Date Pending PURL Review is due

SECTION 9: Pending PURL Review
[to be completed by the Pending PURL Reviewer]

1. Did you address the follow up issues identified at the PURL Jam (Section 5.2). Add comments as needed.

☐ Yes
☐ No
☐ Not applicable
Comments:

2. Did you review the Sermo poll & Instant Poll results (if available)? Add comments as needed.

☐ Yes
☐ No
☐ Not applicable
Comments:

3. Did you modify Sections 2, 3, or 4? Add comments as needed.

☐ Yes
☐ No
☐ Not applicable
Comments:

SECTION 10: PURL Authoring Template
[to be completed by the assigned PURL Author]

Author Citation Information (Name, Degrees, Affiliation)

1. Practice Changer

2. Illustrative Case

3. Background
Clinical Context
Introduction
Current Practice

4. Study Summary

5. What's New

6. Caveats

7. Challenges to Implementation

8. Acknowledgment Sentence

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If using UHC data:
We acknowledge Sofia Medvedev of University HealthSystem Consortium (UHC) in Oak Brook, IL for analysis of the National Ambulatory Medical Care Survey data.

9. References