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Virtual Focus Groups with Primary Care Physicians and OBGYNs: Attitudes about Proposed Hepatitis C Screening Guidelines DVH 2019

Generic Information Collection under Formative Research and Tool Development OMB #0920-0840

Attachment #7

Discussion Guide

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DISCUSSION GUIDE
Virtual Focus Groups with Primary Care Physicians and OBGYNs:
Attitudes about Proposed Hepatitis C Screening Guidelines
DVH 2019

GUIDING RESEARCH QUESTIONS

- What are physicians' current attitudes on screening patients for hepatitis C?
- What are physicians' reactions to CDC's proposed universal hepatitis C screening recommendation?
- What are physicians' reactions to CDC's proposed prevalence-based hepatitis C screening recommendation?
- What are physicians' reactions to CDC's proposed hepatitis C screening recommendation for women during each pregnancy?
- What are physicians' reactions to CDC's proposed prevalence-based hepatitis C screening recommendation for women during each pregnancy?
- What are physicians' reactions to the rationale behind CDC's proposed screening recommendations?

DISCUSSION GUIDE

I. Background (5 minutes)

- My name is [INSERT]. I'm a researcher and independent moderator with KRC Research.
- Thank you for participating in today's discussion. The discussion will be about 75 minutes. The purpose of our discussion is to learn your opinions and behaviors regarding certain screening tests and guidelines.
- The sole sponsor is CDC. Our discussion is for research purposes only. Because privacy is important, I'm going to take a moment to read our Privacy Policy.
  SHOW CONFIDENTIALITY LANGUAGE ON SCREEN, READ:
  - Your feedback is confidential—neither your name nor information that could be associated with you will be included in the final report.
  - We will use first names only during the conversation.
  - The discussion is being audio recorded so we have an accurate record. All audio files and transcripts will be secured.
  - We ask that you not share any information, participant comments, or the identities of any participants in the focus group discussion with your colleagues, family or friends.
- May I please have a verbal agreement from everyone?
- To get started, let me explain how our discussion will work today:
  - There are no wrong answers. You may have different opinions. That's ok—we want to hear all of your opinions.
  - We will be putting some information on your screen to look at and respond to. Each person only sees their own answers, but I can see everyone's answers.

- Since we are having these groups online, we will need to talk one at a time and let everyone have time to speak.
- If at any time you can't see the screen well or have difficulty hearing, let me know—I have a technician here who can help us with any technical issues.
- I am a researcher and a moderator, but I am not physician or an expert in the field. You all are the experts. If you have a question, I will make note of it but I will not be able to answer your questions.
- We would appreciate your attention for the next 75 minutes, please silence your mobile phones and other devices. If you must step away, feel free to do so and we will loop you back into the conversation when you return.

II. Introductions (10 minutes)

- First Name
- Location (City, State)
- Type of medical practice (size, specialty, patient population, health issues you see most often, and any emerging challenges)
- In thinking about how you stay updated on new clinical developments and guidelines, what digital or online resources do you use most frequently?

III. Hepatitis C Screening/Testing Practices (5 minutes)

SHOW ONLINE VOTING TOOL: *Let's begin by getting your reasons for testing patients for hepatitis C.* Please indicate whether you generally test for hepatitis C if the following factor is present.

In general, I test a patient for hepatitis C if this individual factor is present: Check all that apply.	
• Blood transfusion (before 1992) • Elevated ALTs • Tattoos • History of any drug use • Body piercings • HIV • Pregnancy • Born from 1945-1965 • Multiple sexual partners • History of injection drug use • History of incarceration • Man who has sex with other men	___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

- **SUMMARIZE AND EXPLORE RESPONSES in general.**

- **SUMMARIZE and explore responses specifically to people born from 1945-1965.** Do you typically test Baby Boomers (people born 1945-65)? Why or why not?

- **HANDCOUNT:** Has anyone had patients request to be tested for hepatitis C? What prompted them to request testing?

IV. Hepatitis C Screening and Diagnosis (5 Minutes)

SHOW ONLINE VOTING TOOL: So let's talk about how much hepatitis C you see in your practice. We will use the online screen again. In the last year, can you estimate how many of your patients tested positive for hepatitis C antibodies?

- 0
- 1-2
- 3-4
- 5-9
- 10-14
- 15-19
- 20-24
- More than 25
- Not sure or don't remember

- **SHOW SCREEN, SUMMARIZE.**

- So among your patients who tested positive for hepatitis C antibodies, what was the impetus for testing them?

V. PCPs ONLY: Proposal – Universal Screening (35 minutes)

Current recommendations have not been sufficient for identifying all the people living with hepatitis C. As a result, CDC is considering a few different approaches to increase the number of people identified with hepatitis C. We'll be showing you several different statements beginning with this one.

ON SCREEN:
CDC Recommendation under consideration:

Hepatitis C screening at least once in a lifetime for all adults aged 18 years and older

- What is your reaction to this recommendation? What do you think of testing all adults for hepatitis C?
- Nationally, about 1% of the US adult population is living with hepatitis C. I am now going to show you prevalence of current HCV infection, by the states where you live.

- **SHOW INFORMATION FROM TABLE 2: ONLY SHOW STATES IN WHICH PARTICIPANTS PRACTICE (BASED ON SCREENING)**

Table 2. Estimated Total and Prevalence of Persons With Current HCV Infection, US States and District of Columbia, 2013 to 2016

State	2016 Adult Population, No.[a]	Population Included in NHANES Sampling Frame		With Additional Populations Not Included in NHANES Sampling Frame	
		HCV RNA Positive (95% CI), No.[b]	% (95% CI)[c]	HCV RNA Positive, No.[b]	Total Adult Population 2016, No. (%)
Alabama	3 671 100	26 100 (23 100-29 600)	0.71 (0.63-0.81)	30 700	3 736 700 (0.82)
Alaska	542 500	4700 (3900-5700)	0.86 (0.72-1.05)	5200	548 000 (0.95)
Arizona	5 020 500	55 300 (48 000-64 100)	1.10 (0.96-1.28)	61 500	5 090 500 (1.21)
Arkansas	2 215 500	19 100 (16 800-21 800)	0.86 (0.76-0.99)	21 800	2 258 700 (0.97)
California	29 160 200	288 500 (253 500-331 800)	0.99 (0.87-1.14)	318 900	29 544 700 (1.08)
Colorado	4 057 000	32 500 (28 000-38 400)	0.80 (0.69-0.95)	36 300	4 108 500 (0.88)
Connecticut	2 771 800	16 500 (14 200-19 700)	0.60 (0.51-0.71)	18 300	2 812 700 (0.65)
Delaware	719 400	5600 (4800-6500)	0.78 (0.67-0.90)	6300	730 500 (0.86)
District of Columbia	537 500	12 400 (10 500-14 800)	2.32 (1.95-2.76)	12 700	542 400 (2.34)
Florida	15 620 600	133 200 (117 700-152 100)	0.85 (0.75-0.97)	151 000	15 860 200 (0.95)
Georgia	7 465 900	46 400 (41 300-52 300)	0.62 (0.55-0.70)	56 800	7 597 700 (0.75)
Hawaii	1 094 200	5700 (4700-7000)	0.52 (0.43-0.64)	6700	1 107 400 (0.60)
Idaho	1 187 300	9900 (8400-11 800)	0.84 (0.71-0.99)	11 200	1 203 300 (0.93)
Illinois	9 703 700	47 700 (42 200-54 300)	0.49 (0.44-0.56)	54 900	9 842 400 (0.56)
Indiana	4 915 800	35 400 (30 900-40 700)	0.72 (0.63-0.83)	40 200	5 000 100 (0.80)
Iowa	2 339 900	11 100 (9 500-13 100)	0.47 (0.40-0.56)	12 600	2 379 300 (0.53)
Kansas	2 137 000	12 600 (10 900-14 800)	0.59 (0.51-0.69)	14 600	2 173 600 (0.67)
Kentucky	3 331 500	38 600 (33 600-44 800)	1.16 (1.01-1.34)	42 500	3 390 700 (1.25)
Louisiana	3 445 000	44 900 (40 000-50 400)	1.30 (1.16-1.46)	50 000	3 518 500 (1.42)
Maine	1 058 600	6500 (5400-7800)	0.61 (0.51-0.74)	7000	1 069 400 (0.65)
Maryland	4 547 800	37 300 (32 700-43 100)	0.82 (0.72-0.95)	40 600	4 602 900 (0.88)
Massachusetts	5 283 400	35 800 (30 600-42 500)	0.68 (0.58-0.80)	38 100	5 346 600 (0.71)
Michigan	7 578 400	62 800 (55 800-70 900)	0.83 (0.74-0.94)	69 100	7 676 600 (0.90)
Minnesota	4 115 000	22 300 (19 400-26 000)	0.54 (0.47-0.63)	24 300	4 159 900 (0.58)
Mississippi	2 205 500	19 600 (17 500-22 200)	0.89 (0.79-1.01)	22 900	2 251 700 (1.02)
Missouri	4 575 700	35 200 (31 100-40 200)	0.77 (0.68-0.88)	40 300	4 660 800 (0.86)
Montana	787 100	6800 (5700-8000)	0.86 (0.73-1.02)	7400	798 100 (0.93)
Nebraska	1 391 400	6900 (6000-8200)	0.50 (0.43-0.59)	7900	1 412 800 (0.56)
Nevada	2 148 500	19 300 (16 800-22 400)	0.90 (0.78-1.04)	21 900	2 177 400 (1.00)
New Hampshire	1 046 300	7200 (5900-8900)	0.69 (0.57-0.85)	7700	1 058 000 (0.73)
New Jersey	6 810 300	43 400 (37 900-50 300)	0.64 (0.56-0.74)	47 200	6 890 900 (0.68)
New Mexico	1 557 100	25 000 (21 600-29 100)	1.61 (1.39-1.87)	26 700	1 578 000 (1.69)
New York	15 260 100	107 100 (94 900-121 600)	0.70 (0.62-0.80)	116 000	15 448 400 (0.75)
North Carolina	7 545 400	60 200 (53 600-68 100)	0.80 (0.71-0.90)	66 400	7 640 100 (0.87)
North Dakota	559 100	2200 (1800-2800)	0.39 (0.32-0.50)	2600	568 300 (0.45)
Ohio	8 787 100	81 500 (71 800-93 200)	0.93 (0.82-1.06)	89 600	8 938 500 (1.00)
Oklahoma	2 862 800	48 900 (42 700-56 500)	1.71 (1.49-1.97)	53 300	2 922 700 (1.82)
Oregon	3 086 200	45 700 (39 400-53 700)	1.48 (1.28-1.74)	48 700	3 120 900 (1.56)
Pennsylvania	9 888 700	84 500 (74 300-97 000)	0.86 (0.75-0.98)	93 900	10 055 600 (0.93)
Rhode Island	829 900	9600 (8300-11 400)	1.16 (1.00-1.37)	10 000	841 300 (1.19)
South Carolina	3 689 100	31 900 (28 400-36 100)	0.87 (0.77-0.98)	35 600	3 740 300 (0.95)
South Dakota	628 400	3000 (2500-3700)	0.48 (0.39-0.59)	3700	641 000 (0.57)
Tennessee	4 972 200	63 500 (56 200-72 100)	1.28 (1.13-1.45)	69 100	5 053 700 (1.37)
Texas	19 455 200	178 000 (157 500-203 100)	0.91 (0.81-1.04)	202 500	19 777 300 (1.02)
Utah	2 024 600	11 000 (9300-13 100)	0.54 (0.46-0.65)	12 300	2 042 200 (0.60)
Vermont	499 100	3500 (2900-4200)	0.70 (0.58-0.85)	3700	503 800 (0.73)
Virginia	6 348 500	33 500 (29 400-38 500)	0.53 (0.46-0.61)	39 900	6 436 400 (0.62)
Washington	5 412 700	50 000 (43 100-58 900)	0.92 (0.80-1.09)	54 200	5 468 900 (0.99)
West Virginia	1 439 300	19 500 (16 700-23 000)	1.35 (1.16-1.60)	20 600	1 459 400 (1.41)
Wisconsin	4 384 900	24 000 (21 000-27 700)	0.55 (0.48-0.63)	27 900	4 449 600 (0.63)
Wyoming	437 600	3200 (2600-3900)	0.73 (0.60-0.90)	3700	444 300 (0.82)
Total[d,e]	241 152 600	2 035 100 (1 803 600-2 318 000)	0.84 (0.75-0.96)	2 266 700	244 681 600 (0.93)[f]

Abbreviations: HCV, hepatitis C virus; NHANES, National Health and Nutrition Examination Survey.

[a] Population sizes are estimated as of December 2016 based on American Community Survey 5-year estimates from 2012 to 2016 and include noninstitutionalized adults eligible for NHANES. This estimate includes 1 288 600 active-duty military personnel ineligible for NHANES, which cannot be removed at the state level because population sizes are unavailable by home state of personnel. Therefore, this assumes a mean prevalence value for this group, adding 5000 infections nationally.

[b] Number of infected persons is calculated by multiplying the prevalence percentage estimate by the adult population size before rounding for presentation.

[c] The NHANES prevalence percentage estimates are based on results from 2013 to 2016 NHANES. Population size includes noninstitutionalized adults eligible for NHANES from the 2012 to 2016 American Community Survey.

[d] Values may not sum to total due to rounding.

[e] Results are based on a regression model that incorporates data for the period 1999 to 2016 and generates estimates via simulations. Accordingly, these results do not precisely sum to previous national totals for the 2013 to 2016 period.[11]

[f] Does not sum to previous 2013 to 2016 US total due to the exclusion of persons incarcerated in federal prisons who are not assigned to state-specific populations.[11]

- What are your thoughts about this table? How do these numbers for your state compare with your experience?

Another potential approach is to recommend one-time hepatitis C antibody testing for all adults in settings where the prevalence of HCV infection is higher than 0.1%.

ON SCREEN:
CDC Recommendation under consideration:

Hepatitis C screening at least once in a lifetime for all adults aged 18 years and older, except in settings where the prevalence of HCV infection is less than 0.1%

- What is your reaction to this potential recommendation?
- Can you describe what information you have about the prevalence of hepatitis C infection in your practice?
    - Probe: Is obtaining the prevalence of hepatitis C in your practice something you think you could find out about? Can you explain how you go about collecting or getting that information?
- Let's look at some language around determining prevalence and then we will discuss it.

ON SCREEN:
Determining prevalence in a clinic or other health care setting:

In the absence of existing data for hepatitis C prevalence, health-care providers should initiate voluntary screening until they establish that the diagnostic yield is <1 per 1,000 patients screened, at which point such screening is no longer warranted.

- What are your thoughts on this aspect of the recommendation?
- Is getting this prevalence data feasible in your practice?

In addition to the universal testing recommendation for all adults, CDC would recommend everyone who has ongoing risk for HCV infection should be tested periodically for hepatitis C.

ON SCREEN:
CDC Recommendation under consideration:

Regardless of age or setting prevalence, all persons with risk factors should be tested for hepatitis C, with periodic testing while risk factors persist.

- What is your reaction? Can you describe your practice testing patients with risk factors?
- Probe: How do you go about deciding what interval to test your patients?

VI. PCPs ONLY: Rationale for CDC Hepatitis C Screening Recommendation (10 minutes)444

Now, I want to show you some of the background and rationale for the new proposed screening guidelines. Please review the statements separately and then use the online tool to indicate if each statement is compelling to you as a rationale: 1 means "not at all compelling" and 5 means "very compelling."

	Not at all compelling				Very compelling
Hepatitis C is the most common chronic blood-borne infection in the United States.	1	2	3	4	5
Approximately 10%–15% of adults with chronic HCV infection, will develop progressive liver fibrosis and cirrhosis.	1	2	3	4	5
Hepatitis C is the most common reason for liver transplantation in the United States.	1	2	3	4	5
Incidence of hepatitis C is greatest among persons of reproductive age (20–39 years).	1	2	3	4	5
50% of people with hepatitis C are unaware of their infection	1	2	3	4	5
Simple, well-tolerated oral medication regimens result in virologic cure in most people.	1	2	3	4	5
Treatment results in regression of cirrhosis, decreased risk of cancer, increased survival, and reduced transmission to others.	1	2	3	4	5
Identifying infections may result in stigma.	1	2	3	4	5
Limited risk of harms associated with diagnostic work-up and/or treatment for patients with hepatitis C.	1	2	3	4	5
The rate of acute HCV infection has more than doubled from 2011 through 2016, mostly among people of childbearing age.	1	2	3	4	5
During 2010–2016, of all U.S. adults, 1.0% were viremic	1	2	3	4	5

- What's your overall reaction to these points? Are any of them more or less persuasive than others?
- Are there any points that were confusing or that you wanted more information or elaboration?
- Which, if any, of these points really stood out for you?

VII. OB/GYN ONLY: Proposal -Universal Screening During each Pregnancy (35 minutes)

CDC is considering recommending universal hepatitis C antibody testing for all women during each pregnancy.

ON SCREEN:

CDC Recommendation under consideration:

Hepatitis C screening for all pregnant women during each pregnancy

- What is your reaction to this potential recommendation? What do you think of testing all pregnant women for hepatitis C?

- In 2015, of all live births, 0.38% were delivered by women testing positive for anti-HCV or HCV RNA. Now, I am now going to show a table of hepatitis C in women of childbearing age and infection by state and then we will discuss.

[only states where the participants practice will be shown]

Hepatitis C Virus in Women of Childbearing Age, Pregnant Women

	Birth certificate data				Laboratory data	
State	**Total births**	**Births to HCV-infected women**	**Infection rate per 100**	**Rank**	**Detection rate per 100**	**Rank**
West Virginia	19,783	550	2.78	1	2.40	2
Kentucky	55,868	1,027	1.84	2	1.65	3
Vermont	5,888	78	1.32	3	0.14	33a
Montana	12,558	163	1.30	4	2.82	1a
Tennessee	81,522	1,013	1.24	5	1.12	4
Ohio	138,948	1,632	1.17	6	0.66	5
Maine	12,581	141	1.12	7	0.12	37a
New Hampshire	12,403	136	1.10	8	0.28	18
North Dakota	11,306	121	1.07	9	0.32	15a
Pennsylvania	139,334	1,242	0.89	10	0.38	13
New Mexico	25,764	221	0.86	11	0.16	31
Mass-achusetts	71,130	605	0.85	12	0.42	10
Delaware	11,108	83	0.75	13	0.10	40
Alaska	11,262	79	0.70	14	0.53	6
Missouri	74,931	408	0.54	15	0.31	16
Florida	223,570	1,041	0.47	16	0.46	8
Rhode Island	10,881	50	0.46	17	0.00	51a
Oklahoma	53,023	243	0.46	18	0.51	7a
Indiana	83,864	359	0.43	19	0.45	9
Oregon	45,539	184	0.40	20	0.14	35
South Dakota	12,312	43	0.35	21	0.21	23a
Louisiana	64,550	215	0.33	22	0.35	14
Arkansas	38,804	125	0.32	23	0.23	22
Maryland	73,322	233	0.32	24	0.28	19
Washing-ton	88,745	280	0.32	25	0.10	39
Michigan	113,060	329	0.29	26	0.28	20

North Carolina	120,519	347	0.29	27	0.19	26
South Carolina	57,985	166	0.29	28	0.14	34
Virginia	102,980	291	0.28	29	0.16	30
Alabama	59,550	163	0.27	30	0.20	25
New York	232,941	592	0.25	31	0.10	41
Wisconsin	66,758	141	0.21	32	0.39	12a
Arizona	85,164	176	0.21	33	0.15	32
Nevada	36,193	73	0.20	34	0.10	42
Utah	50,702	100	0.20	35	0.16	29
Wyoming	7,747	15	0.19	36	0.06	48
Minnesota	69,648	132	0.19	37	0.20	24a
Iowa	39,407	69	0.18	38	0.30	17a
Colorado	66,411	110	0.17	39	0.11	38
Idaho	22,782	35	0.15	40	0.07	47
Illinois	157,651	217	0.14	41	0.08	46
Kansas	39,100	52	0.13	42	0.08	45
Mississippi	38,291	50	0.13	43	0.18	28
Georgia	131,027	161	0.12	44	0.09	44
Texas	402,485	444	0.11	45	0.12	36
District of Columbia	9,525	10	0.10	46	0.40	11
Nebraska	26,637	25	0.09	47	0.05	49a
California	489,668	435	0.09	48	0.09	43
Hawaii	18,346	12	0.07	49	0.00	50a
New Jersey	NA	NA	NA	50a	0.25	21
Connecticut	NA	NA	NA	51a	0.18	27
All states	3,823,723	14,417	0.38		0.26	

- What are your thoughts on this table? How do the numbers for your state compare with your experience?

- Another potential approach is to recommend hepatitis C testing for all pregnant women, during each pregnancy, in settings where the prevalence of HCV infection is higher than 0.1%.

ON SCREEN:
CDC Recommendation under consideration:

Hepatitis C screening for all pregnant women during each pregnancy, except in settings where the prevalence of HCV infection among pregnant women is less than 0.1%.

- What is your reaction to this potential recommendation?
- Do you have information about the prevalence of hepatitis C infection in your practice?
    - Probe: Is obtaining the prevalence of hepatitis C something you think you could find out about? Can you explain how you go about collecting or getting that information?
    - If none, how might you go about getting that information?
- We will take a look at the potential language around determining prevalence and then we will discuss.

ON SCREEN:
Determining prevalence in a clinic or other health care setting:

In the absence of existing data for hepatitis C prevalence, health-care providers should initiate voluntary screening until they establish that the diagnostic yield is <1 per 1,000 [pregnant] patients screened, at which point such screening is no longer warranted.

- What are your thoughts on this aspect of the recommendation?
- How could you implement this recommendation in your practice? What would it look like for you?

VIII. OB/GYN ONLY: Rationale for CDC Hepatitis C Screening Recommendation (15 minutes)

Now, I want to show you some of the background and rationale for the new proposed screening guidelines. Please review the statements separately and then use the online tool to indicate if each statement is compelling to you as a rationale: 1 means "not at all compelling" and 5 means "very compelling."

	Not at all compelling				Very compelling
Hepatitis C is the most common chronic blood-borne infection in the United States.	1	2	3	4	5

Approximately 10%–15% of adults with chronic HCV infection, will develop progressive liver fibrosis and cirrhosis.	1	2	3	4	5
Hepatitis C is the most common reason for liver transplantation in the United States.	1	2	3	4	5
Incidence of hepatitis C is greatest among persons of reproductive age (20–39 years).	1	2	3	4	5
Perinatal transmission of hepatitis C occurs in 5.8% of pregnancies.	1	2	3	4	5
50% of people with hepatitis C are unaware of their infection.	1	2	3	4	5
Simple, well-tolerated oral medication regimens result in virologic cure in most people.	1	2	3	4	5
Women can be treated following pregnancy, reducing transmission risk to future children.	1	2	3	4	5
Identifying hepatitis C infected pregnant women also identifies at-risk infants needing testing.	1	2	3	4	5
Treatment results in regression of cirrhosis, decreased risk of cancer, increased survival, and reduced transmission to others.	1	2	3	4	5
Identifying infections may result in stigma.	1	2	3	4	5
Limited risk of harms associated with diagnostic work-up and/or treatment for patients with hepatitis C.	1	2	3	4	5
The rate of acute HCV infection has more than doubled from 2011 through 2016, mostly among people of childbearing age.	1	2	3	4	5
In 2015, of all live births, 0.38% were delivered by women testing positive for anti-HCV or HCV RNA.	1	2	3	4	5
Statistical modeling suggests that pregnant women lived 1.21 years longer and had a 16% lower HCV-attributable mortality with universal testing. Universal prenatal hepatitis C testing increased identification of neonates exposed to hepatitis C at birth from 44% to 92%.	1	2	3	4	5
Universal testing during pregnancy with no treatment reimbursement restrictions was found cost effective at a willingness-to-pay threshold of $50,000 when the prevalence of HCV RNA was at or above 0.03%-0.04%.	1	2	3	4	5

- What's your overall reaction to these points? Are any of them more persuasive than others?
- Are there any that you need more information or elaboration?
- Which, if any of these points really stood out for you?

IX. Wrap Up (5 minutes)

Before we wrap up, is there any feedback you would like to share with CDC about anything we discussed tonight?

Thank you.