

Attachment A3. 60-Day Federal Register Notice Comments and Agency Responses,
National Quitline Data Warehouse (NQDW) (OMB 0920-0856)

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Introduction

A 60-day Federal Register Notice was published for *National Quitline Data Warehouse (NYTS) 2022-2024* (OMB Control No. 0920-0856) for July 7, 2021 to September 7, 2021 (Docket No. CDC-2021-0058, Document No. 2021-14441, Vol. 86, No. 127, pages 35797-35798 (2 pages)). The CDC received three substantive comments from the National LGBT Cancer Network, the North American Quitline Consortium, and the Truth Initiative during this period.

CDC has provided responses and plans for action for the comments.

National LGBT Cancer Network

Date submitted: September 4, 2021

Submitter: scout@cancer-network.org

The National LGBT Cancer Network would like to submit a comment on the proposed measurement changes for the National Quitline Data Warehouse.

First, let it be known that the National LGBT Cancer Network is CDC-funded to run one of the eight tobacco and cancer disparity networks, the one on LGBTQ persons. In this capacity we serve as subject matter experts on the topics of LGBTQ tobacco and cancer impacts. A large part of our work is to provide technical assistance on these points to state or federal governmental entities. The author of these specific comments, Dr. Scout, has worked in this capacity for over a dozen years. Over these years, Dr. Scout has also been a subject matter expert on measurement strategies for the sexual orientation and gender identity (SOGI) populations, including testing measures for MN state quitlines, working with National Jewish Quitline and the North American Quitline Consortium to further enhance measures, as a co-chair of the Williams Institute Gender Identity in US Surveillance (GenIUSS) workgroup and more recently as a presenter on SOGI data collection at the Behavioral Risk Factor Surveillance System annual meeting. Our organization has led or co-signed numerous recent letters related to SOGI + intersex data collection, including those to the White House, National Association of Insurance Commissioners, U.S. Senate, U.S. Census Household Pulse Survey, and the HHS Assistant Secretary of Health. We are also members of the Federal LGBTQ Health Policy Roundtable, and as such work closely with a large group of federal organizations to best convey best strategies for policy changes to federal entities.

We strongly support the addition of better measurement strategies for LGBTQ populations in the National Quitline Data Warehouse. As was clearly outlined in the 2011 Institute of Medicine report on LGBT health and newer research continues to support, the disproportionate impact of tobacco on the LGBTQ populations is profound. By most recent MMWR report, we have tobacco use rates 45% higher than the general population. In order to eliminate this disparity, we must measure and monitor access to the quitlines by this population.

In following information coming out of the current convening of the National Academies of Science, Engineering, and Medicine workgroup on SOGI measurement, we would however recommend some minor changes to the question wording.

Ask about gender identity first.

The CDC's recommendation and the recommendation of leading LGBTQ+ researchers and analysts is that gender identity be asked first, before sex assigned at birth. Asking gender identity first reflects the importance of gender in the lived experiences of all people, both transgender and cisgender.

Allow respondents to select all that apply for gender identity, and include a free-text answer option for gender identity.

The option to mark more than one answer choice has not been universally implemented on federal, national-scale U.S. data collections; however, some recent federal and academic data collections, including the National Institutes of Health (NIH) All of Us Research Program and the PRIDE Study, have included this feature. Studies and reviews of gender identity questions have found that, for some gender minority individuals, “male” and “female” are not mutually exclusive from “transgender” or “another gender identity.” A recent study using focus groups and cognitive interviews among sexual and gender minority participants identified the need to allow participants to select more than one answer choice with a “select all that apply” prompt. The ability to select all that apply and inclusion of the answer choice of “Another gender identity (specify)” both clarifies the question is asking about gender identity and provides a write-in option for those who do not find a suitable choice among those provided. These question features are also in line with recently published statistical data collection standards published by the New Zealand government. (If you would like to see more citations to support this, please reference a letter submitted to CMS at this link: https://docs.google.com/document/d/1xHfWIFF2iYG2w0_CsNfcY9vhgWAGaGSlaV6UdSRT6QE/edit.)

Specifically, we recommend the following design for the “two-step” question:

Gender:

What is your gender? Please select all that apply.

1. Male
2. Female
3. Transgender
4. Another gender (please specify): _____

Sex assigned at birth:

What sex were you assigned at birth, on your original birth certificate?

1. Male
2. Female
3. Something else (please specify): _____
4. Prefer not to say

Additionally, in keeping with NIH precedent, we would also strongly urge you to consider measuring intersex status as well on quitline intake. Information on best measures for this can be found at this link: <https://interactadvocates.org/intersex-data-collection/>.

Thank you for the commitment to these improvements. Thank you for your comment. CDC understands the importance of adding better measurement strategies for LGBTQ populations in the National Quitline Data Warehouse (NQDW) and appreciates this helpful guidance from those working directly with LGBTQ

populations. In response to this comment and given the evidence provided, CDC proposes to change the NQDW questionnaire as suggested by the National LGBT Cancer Network. Implementation of this change is contingent on OMB terms of approval. CDC understands that changing these questions would mean they are no longer aligned with those suggested by current OMB guidance, so we look forward to OMB's advice on this matter.

CDC's RESPONSE: Thank you for your comment. CDC understands the importance of adding better measurement strategies for LGBTQ populations in the National Quitline Data Warehouse (NQDW) and appreciates this helpful guidance from those working directly with LGBTQ populations. In response to this comments and given the evidence provided, CDC proposes to change the NQDW questionnaire to ask gender identity as recommended by the National LGBT Cancer Network. CDC also will take ask asking intersex status into consideration. Implementation of changes is contingent on OMB terms of approval.

North American Quitline Consortium

Date submitted: September 7, 2021

Submitter: Linda A. Bailey

Thank you for the opportunity to comment on FR Docket No. CDC-2021-0058, the National Quitline Data Warehouse (NQDW). As President and CEO of the North American Quitline Consortium (NAQC), my comments represent the perspective of a non-profit organization that is comprised of the 53 states and territories that fund quitlines, the service providers that operate quitlines, researchers and national partners. NAQC began its work in Spring of 2004 as a special program within the American Legacy Foundation. Two years later, with the support of the quitline community, I incorporated NAQC as an Arizona non-profit organization that had developed a business plan, the Minimal Data Set (MDS) which includes intake and follow-up questionnaires, an annual survey, best practices programs, and a board of directors. Some of these accomplishments have been documented in peer-reviewed articles (see references 1-7). Since 2004, NAQC's work has focused on best practices to improve the quality and utilization of quitline services in the U.S. and Canada.

The Federal Register Notice identifies five topics of special interest to OMB:

1. Whether the proposed collection of information is necessary for the proper performance of the functions of the agency;
2. The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Ways to enhance the quality, utility and clarity of the information to be collected;
4. How to minimize the burden of the collection of information on those who are to respond; and
5. Assessment of the costs of collecting the information.

NAQC's response to each topic is provided below.

1. Whether the proposed collection of information is necessary for the proper performance of the functions of the agency

NAQC would like to begin its response with some context on the Minimal Data Set (MDS) and Annual Survey of Quitlines, fundamental data collection tools that were developed by NAQC and used by CDC to develop the NQDW. As stated on page 3 of the FRN Publication Request for Information Collections, "the MDS was developed collaboratively by quitlines and stakeholders including professional organizations and CDC, to serve as a core set of information" on quitlines. It is concerning that the FRN does not mention the MDS was led by NAQC and that in addition to developing the data set and gaining consensus from state, provincial and territorial quitlines in the U.S. and Canada, we also gained voluntary implementation of the MDS within 6 months of publication by all quitlines. University-based researchers played a key role in

identifying a need for a standard data set that would help identify critical factors for improving the quality and outcomes of quitline services, and in creating the MDS (especially Drs. Sharon Campbell, Shu-Hong Zhu and Debbie Ossip; see references 1-2). The MDS has been adopted as a standard and useful tool by quitlines and networks of quitlines beyond the U.S. and NAQC, in Europe and Asia. NAQC has played an important role in updating the MDS as quitline services evolve, identifying new required and optional questions, and assessing fidelity of quitlines to the questions and response categories over the years. In addition, through its annual survey of quitlines, NAQC has shared aggregate findings from state and territorial quitlines with the quitline community on an annual basis for the past 15 years. The MDS and annual survey provide critical data for NAQC's best practices programs.

In 2010-2011, CDC began using the MDS in response to legislative reporting requirements for new funding streams, as described in the FRN. Through the new funding streams, CDC contributes about 16% of the total national budget for quitline services (states contribute about 84% of the budget with substantial variations in the percentage from state to state). This supplemental federal funding is important for delivery of state quitline services to tobacco users who want to quit.

Since CDC began using the MDS, NAQC has worked with the agency to keep the formal MDS and CDC's reporting requirements for state quitlines aligned as much as possible. As a non-profit organization, NAQC has been able to update the intake and follow-up questionnaires on a shorter timeframe than a federal agency is able to do. For example, NAQC developed standard optional questions on COVID-19 in spring 2020 and about half of the state quitlines were able to add the questions to intake questionnaires by summer 2020. This expedited development (led by NAQC, researchers and a few quitlines) and implementation (by state quitlines) has allowed us to understand the impact of COVID-19 on tobacco users. NAQC also has updated its questions on sexual orientation and gender identity several times in the past decade as experts such as Dr. Scout learn more about the best approach to asking these questions. As a federal agency, CDC has had resources to go beyond a services survey to also collect data on individual clients who utilize quitline services. This data should help advance our knowledge and the field; it is not an activity NAQC has the IT expertise or funding to pursue.

Turning now to the question of whether the proposed collection of information is necessary for the proper performance of the functions of the agency, NAQC comments:

- The proposed collection of intake questionnaire electronic data files (4 per year) and the seven-month follow-up electronic data file (1 per year) are necessary.
- The proposed quitline services surveys (2 per year) are not necessary. We suggest that CDC can use the data NAQC collects for this purpose. NAQC would be willing to add questions that CDC has added to its reporting requirements that currently do not appear on NAQC's annual survey and to collect the data twice a year if needed by CDC.

CDC's RESPONSE: The purpose for CDC collecting the quitline services survey is to assist in evaluating CDC-funded state and territorial quitlines and to provide a resource to states for ongoing program improvement. The data reported to CDC includes services offered by state quitlines, utilization of state quitlines, and de-identified, individual-level information about quitline callers. Information on services offered by state quitlines and statistics on quitline utilization are obtained by CDC to inform the development of tobacco prevention and control objectives for state and local health departments and to improve delivery of services to targeted sub-populations. CDC's stakeholders use NQDW data to emphasize importance of and monitor

tobacco cessation efforts. Policy decision makers use these data to evaluate existing quitline programs and to plan new programs.

Utilization of the NQDW gives the CDC, states, and other stakeholders the ability to

- Track changes in quitline services and utilization over time, nationally and by state
- Improve states' understanding and utilization of state-specific data
- Allow for comparisons between a single state's data and national data
- Provide answers to questions about quitlines that a single state cannot answer alone
- Assist in promoting the development of best practices

It is essential that CDC have direct control and ready access to these data as CDC provides substantial funding to support state quitline activities and is accountable for the outcomes of these activities. CDC uses NQDW funding for accountability of CDC funding, to respond to inquiries by members of Congress and other policymakers, and to respond to time-sensitive internal and external inquiries regarding the use of quitlines by tobacco users.

2. The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used

- After reviewing the estimated annualized burden hours for collection of information, NAQC believes that the estimates can be improved as follows:
- For the estimates on the burden of the intake questionnaires and seven-month follow-up questionnaires, please include not only the participants and callers to the quitline, but also the quitline staff who ask the questions.
- For the submission of intake questionnaire files, seven-month follow-up questionnaire files and quitline services survey, the estimates seem very low. We would like to clarify whether they include the time to compile and validate the information. The time allocation seems to only include the time to key-in or create the data file.

NAQC suggests that CDC should base the estimates on more than a single, very large quitline service provider who serves many states. This provider has more technical capacity than the smaller single-state providers which is likely to underestimate the time needed to submit data files by all quitlines.

CDC's RESPONSE: Over time, CDC has utilized a consistent method to compute burden that accounts time that the states, DC, Guam, and Puerto Rico spend administering intake and follow-up interviews to quitline callers and for the time needed by these entities to compile and submit aggregate files and service summaries to CDC. Further information about calculation of burden is provided in Section A.12.

3. Ways to enhance the quality, utility and clarity of the information to be collected

NAQC was pleased to see updates to CDC's intake questions which align with changes NAQC has made to the MDS over the past few years (see reference 8). We support these changes which are likely

to enhance the quality, utility and clarity of the information collected.

CDC's RESPONSE: Thank you for your comment and support.

NAQC recommends that on questions related to sexual orientation and gender identity (SOGI), CDC should consider enhancing its questions according to comments submitted by Dr. Scout on behalf of the National LGBT Cancer Network. NAQC plans to begin a process to consider similar updates to SOGI questions in 2021/2022.

CDC's RESPONSE: Thank you for your comment. CDC understands the importance of adding better measurement strategies for LGBTQ populations in the National Quitline Data Warehouse (NQDW) and appreciates this helpful guidance from those working directly with LGBTQ populations. In response to this comment and given the evidence provided, CDC proposes to change the NQDW questionnaire as suggested by the National LGBT Cancer Network. Implementation of this change is contingent on OMB terms of approval.

NAQC also would like to note that clarification may be needed to the purpose and focus of the question on active-duty military service. Our understanding of VA benefits on tobacco cessation is that they are only available for tobacco users who receive their health care through the VA. If this is true, a more focused question on health care coverage through the VA may enhance the quality of the question and the utility of responses.

CDC's RESPONSE: Thank you for your comment. Given the high prevalence of tobacco use by active-duty military, CDC is monitoring the use of quitlines and cessation services by this population. Collecting these data will provide information on how to better serve the needs of our active-duty military.

In 2019, NAQC removed the MDS question on how a participant heard about the quitline, based on feedback from university-based evaluators. These experts noted that the question does not elicit valid responses.

CDC's RESPONSE: Thank you for your comment. CDC is collecting this information to assess whether the caller heard about the quitline through CDC's TIPs campaign. This information is used for planning for Tips and to help inform program improvement. [need to look at the question wording, but HCB is interested in knowing this piece of information]

4. How to minimize the burden of the collection of information on those who are to respond

The required data elements and questionnaires are efficient and minimal. To minimize the burden of data collection, NAQC suggests two alternatives:

- Eliminate the quitline services surveys and rely on NAQC's annual survey for this purpose (see Topic 1, second bullet, for additional information); or
- Reduce the quitline services survey to once a year (and ask quitlines to submit data by quarters or 6-month periods).

CDC's RESPONSE: Thank you for your comment. The frequency of data collection is to fulfill reporting requirements in CDC's Quitline NOFO and to assist in evaluating CDC-funded state and territorial quitline activities for ongoing program improvement.

5. Assessment of the costs of collecting the information

We did not see documentation related to the costs of collecting the information but would like to comment on such information if it is available. Should NAQC's comment on eliminating the CDC quitline services surveys be adopted, the cost of collecting information would be decreased as NAQC does not use federal funding to collect its annual survey information.

CDC's RESPONSE: Thank you for your comment. As noted previously, it is essential for CDC to have direct control and access to these data given the substantial funding CDC provides to state quitlines and given that CDC is accountable for the associated outcomes.

Again, thank you for the opportunity to provide comments. I am available to answer any questions you may have.

Truth Initiative

Date submitted: September 7, 2021

Submitter: M. David Dobbins

Truth Initiative® welcomes the opportunity to submit comment regarding the National Quitline Data Warehouse (NQDW). Truth Initiative uses information from the NQDW and believes there is value in collecting data on quitline use.

Truth Initiative is America's largest nonprofit public health organization dedicated to a future where tobacco and nicotine are things of the past. Our mission is clear: achieve a culture where young people reject smoking, vaping and nicotine. We believe each individual has the right to live in a world free from tobacco and nicotine dependence and tobacco-related death and disease. Our proven-effective, nationally recognized truth® public education campaign has prevented millions of young people from becoming smokers, our This is Quitting vaping cessation program has helped over 350,000 young people begin their journey to quit vaping, and our Vaping: Know the Truth school curriculum will be in 2,000 schools by 2022. These programs and others, along with our rigorous scientific research and policy work, are making strides to end the tobacco epidemic.

We recommend revising the NQDW to collect information about services provided by live chat.

Therefore, in the Intake Questionnaire, we recommend revising the question about mode of entry to the quitline to:

Mode of entry to the quitline

- Direct call to the number
- Fax referral
- Email or On-line referral
- EHR referral/ e-Referral
- Text message
- Live chat
- Other referral modes (specify _____)

We also recommend revising the NQDW Quitline Services Survey to collect information about how services to adolescents (ages 13-17) and young adults (ages 18-24) are handled by the quitlines, particularly around e-cigarettes. Following years of successful tobacco control efforts that achieved record low youth smoking, e-cigarettes have driven total youth tobacco use to rates unseen in decades. Current, or past 30-day, use of e-cigarettes among high school students increased from 11.7 percent to 27.5 percent between 2017 and 2019, driving overall tobacco use among high school students to 31.2 percent.¹⁻³ The most recent data from 2020 show that high school students continue to use e-cigarettes at epidemic levels, with nearly 1 in 5 (19.6 percent) vaping in the past 30 days, and that the intensity of use has increased with 38.9 percent of current users reporting vaping on 20 or more days per month.^{2,3} It is important for the CDC to collect information about state quitline services provided to youth because almost a quarter of adolescents users surveyed in Wave 4 of the PATH survey attempted to quit vaping in the year.⁴ E-cigarettes are now the most commonly used tobacco product among youth and, in the U.S., youth and young adults are more likely than adults to use e-cigarettes. A 2018 Truth Initiative study showed that the highest percentage of JUUL users were ages 18-21 years old.⁵ Breaking out young

adults from older adults in your data set would allow for more nuanced understanding of quitline usage and better comparison in academic literature.

Truth Initiative appreciates CDC taking these comments into account as it looks to continue the NQDW information collection for three years. As we stated above, Truth Initiative greatly values data from the NQDW as it is the only survey to collect data about state quitline use. We urge CDC to revise measures to include information about services provided by live chat and how services to adolescents and young adults are handled, particularly around e-cigarettes. Please do not hesitate to contact Maham Akbar, Public Policy Senior Manager at makbar@truthinitiative.org or 202-454-5932, should you need more information or have questions about this submission.

CDC's RESPONSE: Thank you for your comments. CDC will revise mode of entry to the quitline question as suggested. CDC will take under consideration the collection of information on how services to adolescents (ages 13-17) and young adults (ages 18-24) are handled by the quitlines, particularly around e-cigarettes. Several factors must be considered, such as the length of the questionnaire, which increases the cost and burden on respondents and quitline staff, and the method for how to get informed consent for youth participation. Implementation of this change is contingent on OMB terms of approval.