

**A Practical Guide to Measuring Unmet Need for HIV-  
Related Primary Medical Care:  
Using the Unmet Need Framework**

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# Table of Contents

|  | Page      |
|--|-----------|
| <b>I. Introduction</b>   | <b>1</b>  |
| A. Purpose of the Guide  | 1         |
| B. Background  | 1         |
| C. Definitions   | 2         |
| D. The Framework   | 3         |
| <b>II. Understanding the Unmet Need Framework</b>  | <b>3</b>  |
| A. Operational Definitions   | 3         |
| B. Data Inputs and Sources   | 4         |
| C. Setting Up the Framework  | 8         |
| Table 1: Setting Up the Framework  | 8         |
| Table 2: Potential Data Sources and Utility within Framework   | 9         |
| <b>III. The Unmet Need Estimation Process: Six Steps</b>   | <b>12</b> |
| <b>IV. Setting Up and Using the Unmet Need Framework in Different Jurisdictions: Some Examples of Data Sources</b> | <b>14</b> |
| A. Population Size Data Input Examples   | 15        |
| Table 3: Setting Up and Using the Framework in Different Jurisdictions   | 15        |
| B. Care Patterns Data Input Examples   | 15        |
| <b>V. Calculating Unmet Need Estimates</b>   | <b>16</b> |
| Table 4: Unmet Need Calculations: Jurisdiction 1, Example Data Sources   | 17        |
| Table 5: Unmet Need Calculations: Jurisdiction 2, Example Data Sources   | 18        |
| <b>VI. Cost of Implementing the Unmet Need Framework</b>   | <b>18</b> |
| <b>VII. Enhancing the Basic Definition of Unmet Need</b>   | <b>19</b> |
| <b>VIII. Analyzing Unmet Needs of Subpopulations: Adding to the Picture of Who Needs HIV Care</b>                  | <b>20</b> |
| A. Importance of Subpopulation Analysis  | 20        |
| B. Factors Affecting Analysis of Subpopulations  | 21        |
| <b>IX. Complementary Data within the Needs Assessment Process</b>  | <b>22</b> |
| Geo-Mapping Example  | 23        |

# I. Introduction

## A. Purpose of the Guide

This Guide was prepared to help CARE Act grantees and planning bodies, particularly Title I and Title II jurisdictions, estimate the number of individuals in your jurisdiction who know they are HIV-positive but are not receiving regular HIV-related primary medical care. The University of California at San Francisco (UCSF) has developed a practical framework you can use to develop a quantitative estimate of unmet need. This Guide explains the reasons you need to estimate unmet need, describes the Unmet Need Framework, and provides practical steps and examples to help you use it in your State or eligible metropolitan area (EMA). The first two sections will help you understand the Unmet Need Framework and why it is important. The other sections will guide you through using it to estimate unmet need in your jurisdiction.

## B. Background

The first of the four fundamental principles guiding the HIV/AIDS Bureau (HAB) of the Health Resources and Services Administration (HRSA) is: “to better serve the underserved in response to the HIV/AIDS epidemic’s growing impact among underserved minority and hard-to-reach populations.”

In keeping with this principle, jurisdictions need to assess the shifting demographics of new HIV/AIDS cases throughout the State, territory, or EMA. This helps in adapting care systems to respond to needs of emerging communities and populations. Jurisdictions also need to pay particular attention to identifying people living with HIV (PLWH) who know their status but are not receiving regular HIV-related primary health care (people who are “not in care”). This is the first step towards ensuring that they obtain primary medical care and supportive services, through CARE Act programs or other sources.

This focus on people living with HIV (PLWH) who know their status but are not in care has a legislative basis. The 2000 Amendments to the CARE Act require each Title I and Title II program to:

- “determine the size and demographics of the population of individuals with HIV disease,” and to
- “determine the needs of such populations, with particular attention to both individuals with HIV disease who know their HIV status and are not receiving HIV-related services” and “disparities in access and services among affected subpopulations and historically underserved communities.”

The Amendments also require HRSA/HAB to prepare State and national estimates of unmet need—the number of individuals who know their status but are not in care—as input to Congress about the need for continued appropriations for HIV/AIDS treatment. More specific information about unmet need (*e.g.*, geographic areas and populations most affected) also guides national planning and resource allocations, including discretionary grant funds for capacity development.

The legislation requires estimation of the number of individuals who know their HIV status, not the total number of individuals who are HIV-positive (true prevalence). While the CARE Act supports outreach and counseling and testing to encourage people who are at risk to get tested, its focus is on ensuring care for those who know they are HIV-positive.

## C. Definitions

HRSA/HAB has developed the following definitions related to unmet need. The most important definitions are summarized in the box. These definitions are used throughout the Guide.

### Definitions Related to Unmet Need

Following are HRSA/HAB definitions:

- **Unmet Need for Health Services** (also referred to as **unmet need**) is the need for HIV-related health services by individuals with HIV who are aware of their HIV status, but are not receiving regular primary health care.
- **Primary medical care** is medical evaluation and clinical care that is consistent with U.S. Public Health Service guidelines for the treatment of HIV/AIDS. Such care must include access to anti-retrovirals and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination antiretroviral therapies
- **Other primary health care** includes HIV-related health services other than primary medical care – oral health care, outpatient mental health care, outpatient substance abuse treatment, nutritional services; and specialty medical care referrals.
- **Non-medical supportive services** are other services that contribute to PLWH accessing and remaining in primary medical care.
- **In care:** A person is considered to be **in care** when s/he is receiving regular primary HIV-related medical care (clinical evaluation and clinical care). This medical care should meet U.S. Public Health Service guidelines for the treatment of HIV/AIDS
- **Service gaps** are *all* service needs for *all* PLWH except primary health services for those who know their status and are not in care. The term **unmet need** is used only to describe the unmet need for HIV-related primary health care.

The Unmet Need Framework has operational definitions for **unmet and met need for HIV primary medical care**. These definitions are used in estimating met and unmet need in your jurisdiction.

- An individual with HIV or AIDS is considered to have an **unmet need for care** (or to be **out of care**) when there is no evidence that s/he received any of the following three components of HIV primary medical care during a defined 12-month time frame: (1) viral load (VL) testing, (2) CD4 count, or (3) provision of anti-retroviral therapy (ART).
- A person is considered to have **met need** (or to be **in care**) when there is evidence of any one or more of these three measures during the specified 12-month time frame.

## D. The Framework

HRSA/HAB supports ongoing efforts to develop methods to assist States and EMAs in assessing unmet need. This framework is the result of one of those initiatives. CARE Act grantees and planning bodies can use the framework to estimate how many PLWH who know their status (HIV+/aware individuals) in a jurisdiction are “in” and “out” of HIV primary medical care. Those who are “out of care” constitute your jurisdiction’s estimate of unmet need.

The framework is logical and straightforward. It requires you to obtain data on (1) the total number of people in your jurisdiction who are HIV+/aware (those diagnosed with HIV or AIDS), and (2) the number of people who are “in care,” using the framework’s operational definitions of “in” and “out” of care. By subtracting those in care from the total number of people who are HIV+/aware, you will obtain an estimate of the number of people who know they are HIV-positive and are not in care – those with an unmet need for primary medical care. In other words, you assume that those individuals you cannot identify as “in care” are “out of care.”

The Unmet Need Framework uses data on the number of people in your jurisdiction who are HIV+/aware and not the total number of people with HIV or AIDS (true HIV prevalence). This is consistent with CARE Act Amendments. In addition, an individual must have an HIV diagnosis before receiving HIV primary medical care,

Because care needs and patterns are generally quite different depending on disease progression, the framework distinguishes between individuals who have been diagnosed with AIDS (PLWA) and those who have not been diagnosed with AIDS (PLWH non-AIDS/aware). You will notice that the PLWA term does not require an additional “aware” or “unaware” designation, since all people diagnosed with AIDS are presumed to be aware of their HIV and AIDS status.

The framework will be useful in creating estimates of unmet need unless a jurisdiction has neither existing data sources nor the resources to collect new data. Review the remainder of this Guide. *If, after reviewing it, you decide that your jurisdiction does not have the expertise needed to evaluate the ability to use and/or collect data (e.g., using locally available epidemiologists or health planners), please request technical assistance through your HRSA/HAB Project Officer.*

## II. Understanding the Unmet Need Framework

### A. Operational Definitions

The Unmet Need Framework starts with basic operational definitions of “unmet” and “met” need for HIV primary medical care. These basic definitions meet minimum HRSA/HAB requirements and provide your jurisdiction with a set of measures you can use in estimating unmet need. These are the definitions:

- **Unmet Need for HIV Primary Medical Care** is defined as no evidence of any of the following three components of HIV primary medical care during a specified 12-month

time frame: (1) viral load (VL) testing, (2) CD4 count, or (3) provision of anti-retroviral therapy (ART).

- **Met Need for HIV Primary Medical Care** is defined as evidence of any one or more of these three measures during a specified 12-month time frame.

If desired, jurisdictions can expand the definition of “met” and “unmet” need. For example, you might want to include additional HIV-related services in your definition. However, the basic definition meets minimum HRSA/HAB requirements for an operational definition of the unmet need for HIV primary medical care. As explained in the definitions box, unmet need is different from “service gaps,” which encompass the supportive services that PLWH may also need

In order to help HRSA/HAB compare or aggregate data across jurisdictions, you should use the basic definition in addition to any expanded definitions when you estimate unmet need using the framework.

## **B. Data Inputs and Sources**

The Unmet Need Framework uses two types of inputs:

- 1. Population Size**
- 2. Care Patterns**

In order to measure unmet need for HIV primary medical care using the basic operational definition, you must first determine the Population Size inputs and Care Patterns inputs for a particular geographic area—whether a State, an EMA, or another area such as a county, region, or Public Health Service Area. Jurisdictions usually have a number of potential sources of data for both Population Size and Care Patterns.

### **1. Population Size**

Population Size is the number of people diagnosed with HIV disease (HIV+/aware) living in the jurisdiction during a particular time period. This includes two separate data inputs:

- a. Number of people Living with AIDS (PLWA)**
- b. Number of People Living with HIV non-AIDS who are aware of their status (PLWH non-AIDS/aware)**

Note that combining (a) and (b) results in the total number of HIV+/aware individuals. You may choose to use totals for the numbers of people living during a particular *year* or numbers of people diagnosed and living as of a particular *date*.

These data come mainly from AIDS and HIV reporting, primarily from the HIV/AIDS Reporting System (HARS) managed by the CDC.

- a. **Number of People Living with AIDS (PLWA):** This information is available in all jurisdictions. Since AIDS cases are reported in all States, jurisdiction-specific AIDS data from HARS are available through local or State surveillance departments.
- b. **Number of People Diagnosed and Living with HIV/non-AIDS (PLWH non-AIDS/aware):** In jurisdictions with name- and/or code-based HIV reporting, this input will also come from local or State HARS data. In jurisdictions without HIV reporting, or where HIV data are not yet usable because of recent implementation of HIV reporting, you have two other data options:
  - **Midpoint of CDC estimate:** The Centers for Disease Control and Prevention (CDC) and HRSA/HAB periodically work together to provide an estimate of the number of people who have been diagnosed with HIV in each EMA and State without fully implemented HIV reporting. The midpoint of that estimate is a convenient source for this input. The benefit of this data source is that it is available for all States and EMAs. The limitation is that the estimates are not updated every year.
  - **Alternative estimates:** Jurisdictions with the capacity to create methodologically sound models for calculating the number of HIV+/aware individuals may choose to use their own estimates.

## 2. Care Patterns

Care Patterns are measures of how many HIV+/aware persons are receiving HIV primary medical care from any provider (not just Ryan White care providers). Like Population Size, this requires two separate inputs

- a. **Percent (or number) of PLWA in care** – individuals with AIDS who meet the operational definition of met need for primary medical care
- b. **Percent (or number) of PLWH non-AIDS/aware in care** – individuals with HIV disease who know their status and meet the operational definition of met need for primary medical care

Total count methods will provide data in numbers, while methods based on sampling will typically provide data in a percentage format.

Whenever possible, you should separate care pattern data or estimates for those with advanced HIV disease (AIDS) from estimates for PLWH non-AIDS/aware. This is because care patterns differ substantially by severity of illness. Data can be separated by whether the individual has ever been diagnosed with AIDS or by lowest CD4 count.

Data providing the percent or number of HIV+/aware (AIDS and non-AIDS) meeting primary medical care definition generally come from three major data sources:

- **HIV/AIDS related surveillance data** (CD4 and viral load reporting)

- **Linked utilization databases** (from CARE Act client-based data systems and claims databases such as Medicaid and the AIDS Drug Assistance Program or ADAP)
- **Special studies** (e.g., Adult Spectrum of Disease or ASD, or studies done within a specific jurisdiction)

**a. HIV/AIDS-Related Surveillance Data**

In jurisdictions with mandatory viral load and CD4 reporting, you can use surveillance data for the care inputs. The advantage in using this data source is that reporting applies to all sources of care. This is a simple method for ensuring the inclusion of information that is sometimes difficult to obtain from other sources, such as number of people receiving privately provided care (e.g., care obtained from private physicians or health maintenance organizations, typically funded by private health insurance).

The value of surveillance reporting data depends on both what is mandated in a given jurisdiction and how those mandates are implemented. For example, laboratory reporting provides better estimates for fulfilling the definition of HIV primary medical care than does provider-based reporting. Laboratory reporting is more comprehensive. This is true because typically a limited number of laboratories are used by all HIV-testing and monitoring providers and the laboratories overall tend to be timelier and more complete in their reporting practices than individual health care providers.

Jurisdictions where HIV surveillance requires that all CD4 and viral load tests be reported will find their data more useful than jurisdictions that use an initial CD4 and/or viral load report only to confirm an HIV diagnosis, but require no further reporting. Some States require reporting of CD4 counts at 500 or below, while others require reporting at 200 or below.

Because surveillance is generally based on where an individual was diagnosed (as opposed to where they live or actually receive their care), jurisdictions that are concerned with migration issues may choose to make adjustments to the surveillance data based on estimates of in- and out-migration. Currently, the rules and implementation vary widely by State. Thus, each jurisdiction must evaluate the usefulness of surveillance data in the context of local and State factors.

**b. Linked Utilization Data**

You can also obtain measures of patterns of HIV primary medical care by linking billing or service information included in various client-level databases, using adequate measures to protect confidentiality (a non-identifying unique identifier or soundex code,<sup>1</sup> for example). In many jurisdictions, combining data from CARE Act (ideally Titles I-IV providers), Medicaid, and the Department of Veterans Affairs will cover the largest sources of HIV primary medical care in the jurisdiction.

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<sup>1</sup> A soundex code is a coded last name index based on the way a surname sounds rather than the way it is spelled. It is a census coding system developed so you can find a surname even if it may have been recorded under various spellings. A soundex code consists of a letter and three numbers.

Keep in mind that data from large public insurers and providers will not capture information on medical care funded privately, so an adjustment will be required. While CARE Act grantees may track medical care services that are paid for privately (e.g., private insurance or “self pay”), you will still need to make adjustments for numbers or percentages of people who receive their HIV care only through private sources. The percentage of individuals with private insurance can be estimated from hospital discharge data (using HIV diagnosis codes, for example) such as that being collected for the Healthcare Cost and Utilization Project (HCUP)<sup>2</sup>, data sources that capture insurance information in outpatient care, or polling of private medical providers in your jurisdiction who provide HIV-related primary care.

### c. Special Studies Data

When it is not feasible to obtain total counts of people receiving HIV primary medical care, special studies can sometimes be used. The availability of existing special studies depends on the jurisdiction. For example, in some jurisdictions, data may be available from existing studies<sup>3</sup> such as the CDC Adult/Adolescent Spectrum of Disease (ASD) studies that monitor clinical outcomes and mortality in persons with HIV/AIDS and look at the use and effectiveness of recommended preventive treatments. The Supplemental HIV/AIDS Survey (SHAS), which obtains descriptive information on persons reported to State/local health departments with HIV infection and/or AIDS, can be useful, but usually the sampling does not provide representative data.

Your jurisdiction may be able to use patient chart reviews or develop your own studies, making sure they are representative of all HIV+/aware individuals and not just those in care or within the particular CARE Act (or other) service system.

Estimates for private care utilization among HIV+/aware persons may also come from special studies. In jurisdictions where the number of providers is limited, it may be possible to survey the primary care providers. Another option is to perform chart reviews, either a total count or through sampling depending on the number involved.

The table at the end of this section (Table 2) outlines potential data sources and their usefulness within the unmet need framework. However, you should consult with those in your jurisdiction who are most familiar with these data sources and others like them, since there tend to be wide variations in what data are collected, how data are collected, new sources of data, and discontinuities in data.

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<sup>2</sup> *Healthcare Cost and Utilization Project (HCUP), 1988-2000: A Federal-State-Industry Partnership in Health Data*. August 2002. Rockville, MD: Agency for Healthcare Research and Quality. Download from <http://www.ahrq.gov/data/hcup/hcup-pkt.htm>.

<sup>3</sup> You can view an inventory of Federally sponsored HIV and HIV-relevant databases at: <http://aspe.hhs.gov/health/reports/hivdatabases/>. A chart of major databases is also included in the *Integrated Guidelines for Developing Epidemiologic Profiles*, which will be available on the HRSA/HAB website (<http://www.hrsa.gov>) during 2003.

The text in this section provides a more detailed description of some of the issues presented in abbreviated format in Table 1. In addition, sources marked with an asterisk (\*) have an expanded description in the CDC/HRSA *Integrated Guidelines for Developing Epidemiologic Profiles*. Please contact your HRSA/HAB Project Officer for more information.

### C. Setting Up the Framework

The table below (Table 1) shows you how the data described above are put into the table and used to calculate unmet need. Later sections of the Guide provide examples and specific guidance in using the framework.

**Table 1: Setting Up the Framework**

| Input   | Value | Data Source |
|---|-------|-------------|
| <b>Population Sizes</b>   |       |             |
| A. Number of persons living with AIDS (PLWA), recent time period  |       |             |
| B. Number of persons living with HIV (PLWH non-AIDS/aware), recent time period  |       |             |
| <b>Care Patterns</b>  |       |             |
| C. Number/percent of PLWA who received the specified primary medical care services in 12-month period                   |       |             |
| D. Number/percent of PLWH (aware, non-AIDS) who received the specified primary medical care services in 12-month period |       |             |
| <b>Calculated Results</b>   |       |             |
| E. Number of PLWA who did not receive primary medical services  |       |             |
| F. Number of PLWH (non-AIDS, aware) who did not receive primary medical services.                                       |       |             |
| G. Total HIV+/aware not receiving specified primary medical care services (quantified estimate of unmet need)           |       |             |

**Table 2 – Potential Data Sources and Utility within Framework**

Sources with an asterisk (\*) have expanded descriptions in CDC/HRSA *Integrated Guidelines for Epidemiologic Profiles*

| Data Source   | Content   | Timing          | # Sites       | Utility for Unmet Need Framework   |
|---|---|-----------------|---------------|--|
| <b>AIDS Surveillance*</b>   | All persons who have met the 1993 CDC AIDS surveillance case definition         | AIDS Diagnosis  | All           | <b>Population Input: PLWA.</b> Very good as is. Jurisdiction may choose to adjust for migration if data are available.   |
| <b>HIV Surveillance*</b>  | All persons who test HIV - positive and are reported to the surveillance system | HIV Diagnosis   | All except GA | <b>Population Input: PLWH non-AIDS/aware.</b> Very good if surveillance system long-established. Some testing (e.g., anonymous) not reported, and some surveillance too recently implemented to reflect all HIV+/aware.  |
| <b>HARS - CD4 reporting</b>   | Mostly CD4 < 200  | HIV and/or AIDS | >27           | <b>Care Input:</b> Useful for <b>PLWA</b> where reporting is required for all CD4 counts <200, and for <b>PLWA and PLWH non-AIDS/aware</b> where reporting is required for all tests or all counts < 500. Underestimate if omits CD4 counts above certain level. Completeness of reporting also an issue, especially if non-lab based. |
| <b>HARS - Viral load reporting</b>  | Where reported, may be all, last, or confirmatory for HIV only                  | HIV/AIDS        | Unknown       | <b>Care Input: PLWA and PLWH/non-AIDS/aware,</b> where reporting is required for all viral load counts or where last count is tracked. Where HIV confirmatory only, information already should be captured in population inputs from surveillance, but will not be useful as a Care Input.   |
| <b>NEDSS</b><br>(designed to replace HARS)<br>National Electronic Disease Surveillance System | HARS, SHAS, ASD, more; will allow tracking of multiple CD4 & viral load counts  | HIV/AIDS        | n/a           | <b>Care Input: PLWA and PLWH non-AIDS/aware.</b> Once implemented, will be an excellent data source in locations tracking multiple CD4 and viral load counts.  |

**Table 2 – Potential Data Sources and Utility within Framework**

Sources with an asterisk (\*) have expanded descriptions in CDC/HRSA *Integrated Guidelines for Epidemiologic Profiles*

| Data Source   | Content   | Timing           | # Sites | Utility for Unmet Need Framework  |
|---|---|------------------|---------|---|
| <b>SHAS*</b><br>Supplement to HIV/AIDS Surveillance       | 12-month lookback from HARS entry   | HIV and/or AIDS  | 21      | <b>Care Input:</b> Depending on site, representative data for either <b>PLWA</b> or both <b>PLWA and PLWH non-AIDS/aware</b> , (or) non-representative data with a potential for linking or statistical manipulation. Completeness and interview assessment time frame can be issues. |
| <b>APS*</b><br>AIDS Progression Study                     | 12-month medical records lookback from AIDS diagnosis                                   | HIV              | 6       | <b>Care Input:</b> Representative data for <b>PLWH non-AIDS/aware</b> , assuming completeness of medical records.   |
| <b>ASD*</b><br>Adult/adolescent Spectrum of Disease Study | Longitudinal medical record reviews of a cohort of HIV+/aware                           | HIV/AIDS         | 11      | <b>Care Input:</b> Depending on site, representative data or non-representative data (with potential for linking or statistical manipulation) for both <b>PLWA and PLWH/non-AIDS</b> . Completeness of medical records can be an issue.   |
| <b>PSD*</b><br>Pediatric Spectrum of Disease Study        | Longitudinal medical record reviews of a cohort of HIV+ and HIV -exposed children       | HIV/AIDS         | 8       | <b>Care Input:</b> Depending on site, representative data or non-representative data (with potential for linking or statistical manipulation) for both <b>PLWA and PLWH non-AIDS/aware</b> . Completeness of medical records can be an issue.   |
| <b>HERS*</b><br>HIV Epidemiology Research Study           | Longitudinal interviews/med exams and abstractions of a cohort of HIV+ women aged 16-55 | HIV/AIDS         | 4       | <b>Care Input:</b> Non-representative data (with potential for linking or statistical manipulation) for both <b>PLWA and PLWH/non-AIDS</b> .  |
| <b>SHDC*</b><br>Survey of HIV Disease & Care              | Medical chart abstraction from representative sample of HARS reports                    | HIV and /or AIDS | 12      | <b>Care Input:</b> Representative data for either <b>PLWA</b> or both <b>PLWA and PLWH non-AIDS/aware</b> . Completeness of medical records can be an issue.  |

**Table 2 – Potential Data Sources and Utility within Framework**

Sources with an asterisk (\*) have expanded descriptions in CDC/HRSA *Integrated Guidelines for Epidemiologic Profiles*

| Data Source  | Content  | Timing                 | # Sites    | Utility for Unmet Need Framework  |
|--|--|------------------------|------------|---|
| <p><b>HCUP</b><br/>Healthcare Cost &amp; Utilization Project</p> | <p>State-specific hospital-discharge databases and a national sample of discharges from community hospitals</p>  | <p>HIV/AIDS</p>        | <p>29</p>  | <p><b>Care Input:</b> Insurance data from hospitalizations. Depending on site, representative data or non-representative data (with potential for linking or statistical manipulation) for both <b>PLWA and PLWH non-AIDS/aware</b>. Completeness of medical records can be an issue.</p> |
| <p><b>Medicaid</b></p>   | <p>Data systems vary by state and within some states, there is variation by managed care vs. fee-for-service</p> | <p>HIV and/or AIDS</p> | <p>All</p> | <p><b>Care Input:</b> Non-representative data (with potential for linking or statistical manipulation) for both <b>PLWA and PLWH non-AIDS/aware</b>.</p>  |
| <p><b>Medicare</b></p>   | <p>Data systems vary by state and within some states, there is variation by managed care vs. fee-for-service</p> | <p>HIV and/or AIDS</p> | <p>All</p> | <p><b>Care Input:</b> Non-representative data (with potential for linking or statistical manipulation) for both <b>PLWA and PLWH non-AIDS/aware</b>.</p>  |
| <p><b>ADAP</b><br/>AIDS Drug Assistance Program</p>              | <p>Data systems vary by state</p>  | <p>HIV/AIDS</p>        | <p>All</p> | <p><b>Care Input:</b> Non-representative data (with potential for linking or statistical manipulation) for both <b>PLWA and PLWH non-AIDS/aware</b>.</p>  |
| <p><b>VA</b><br/>Veterans Affairs</p>                            | <p>Database (Immunology Case Registry) automatically abstracts demographic and clinical data</p>                 | <p>HIV/AIDS</p>        | <p>All</p> | <p><b>Care Input:</b> Non-representative data (with potential for linking or statistical manipulation) for both <b>PLWA and PLWH non-AIDS/aware</b>.</p>  |

### **III. The Unmet Need Estimation Process: Six Steps**

The following six steps will help your Title I or Title II jurisdiction develop a quantitative estimate of the unmet need for HIV primary medical care among HIV+/aware individuals in your service area. The process assumes you will use the Unmet Need Framework described in this Guide as a way to organize and interpret State and local data. However, a similar process could be used to implement other models for estimating unmet need.

#### **Step 1: Review your objectives for estimating unmet need.**

Before you begin to estimate unmet need, be sure you agree on the purpose and specific objectives of your effort. A principal objective should be the creation of a quantitative estimate of unmet need for HIV primary medical care in your jurisdiction. Other objectives might include the following:

- To generate data that will inform planning and decision making to respond to unmet need
- To obtain data that let us track our progress in reducing unmet need over time
- To be able to link these data to other indicators of unmet need to obtain a more complete understanding of unmet need
- To meet CARE Act legislative requirements and HRSA/HAB expectations related to estimating unmet need

Be sure to review CARE Act guidelines and data requirements within applicable sections of the Title I and II applications as you develop your objectives. This will help you understand HRSA/HAB expectations regarding estimating unmet need. It will also help you identify possible uses of the data in planning and decision making.

#### **Step 2: Review and select among options for estimating unmet need.**

To decide how you will go about estimating unmet need, read HRSA technical assistance materials, such as the rest of this *Guide* and the following:

- The Ryan White CARE Act *Needs Assessment Guide* (the 2003 version can be downloaded from the HRSA website at [www.hrsa.gov](http://www.hrsa.gov)).
- The CDC/HRSA *Integrated Guidelines for Developing Epidemiological Profiles* (available on the HRSA website in 2003).

If you decide to use the Unmet Need Framework described in this Guide, you will need to investigate potential data sources for the Population Size and Care Patterns inputs. Data on Care Patterns are likely to be especially important and perhaps challenging to identify. Invite collaborators, such as data managers from State HIV/AIDS surveillance and Medicaid departments, to help you assess currently and potentially available data sources. Assess technical, personnel, and financial resources, outline options, and choose the best option—keeping in mind that the best short- and long-term strategies for estimating unmet need may differ. Since you are

likely to need to estimate unmet need regularly, it makes sense to identify a framework and a set of data sources that you can continue to use in future years. This enables you to improve your estimates with experience and to be able to compare levels of unmet need over time.

When you meet with potential collaborators in the unmet need estimation process, discuss not only data availability but also capacity – including both technical skills and time and other resources – to do data handling or special studies. For example, suppose you decide to use linked databases including your CARE Act client-level database, Medicaid data, and Veterans Affairs data. You will need a team with the skills and resources to link and “unduplicate” the data using a soundex code or other unique identifier, to ensure that individuals are not double-counted. If you decide to conduct a special study such as records review of a sample of PLWH, you will need to arrange for the necessary resources.

During this period, you need to decide whether your focus will be a single-number estimate of unmet need, or whether you want to go beyond this basic analysis and look at other services, population subgroups, or specific geographic areas. This requires consideration of data availability, technical expertise, and resources.

Your intent during this step is to understand different approaches and data sources available in your jurisdiction for estimating unmet need, and to choose those most appropriate for your situation. You will also want to decide on a planned level and scope of analysis using these data.

### **Step 3: Develop your work plan.**

Once you have agreed on objectives and decided what approaches and data sources to use, you are ready to develop a work plan to guide the entire process. The work plan typically includes the following tasks:

- Select and refine the team who will participate in your process. The team should generally be both internal and external, including data specialists and planners from within the CARE Act system as well as individuals with access to other major data sources and/or researchers who can assist with analyses and special studies.
- Agree on your technical strategy.
- Agree on the responsibilities the grantee and all team members in helping to implement that strategy.
- Estimate the effort required of each team member for all planned tasks and be sure all team members are prepared to provide that level of effort.
- Develop a timeline with benchmarks to guide your work. Give yourselves enough time to complete the work, but not so much that the process drags on and loses momentum.
- Seek technical assistance as needed through local expertise and your HRSA/HAB Project Officer.

#### **Step 4: Implement the work plan.**

Now bring your team together to implement your work plan. As you work, regularly reassess and refine your technical strategy as logistic challenges and opportunities become clearer. Be sure team members meet regularly to review progress and challenges. Periodically report back to the planning body(ies) in your jurisdiction. As you insert data into the Unmet Need Framework, review, document, and refine your data inputs. Again, seek technical assistance through local expertise and your HRSA/HAB Project Officer as needed.

#### **Step 5: Prepare a report on estimating unmet need for HIV primary medical care.**

Once your estimates are complete, prepare a report that presents those estimates, how you obtained them, and any constraints or limitations. Include background information on the options discussed and the reasons for choosing the particular strategy and data sources used. Explain methods. If you did special studies, be explicit about data sources, definitions, and methodology, including sample size and recruitment activities as applicable, data collected, analyses, and results. If you were able to go beyond the minimum analysis and look at other services, population subgroups, or specific geographic areas, present both overall unmet need (i.e., single estimate) and the additional results. Discuss the implications of the estimate for your jurisdiction's efforts to meet unmet need. Present lessons for future unmet need estimates as well as needs assessments.

#### **Step 6: Disseminate the information.**

Distribute your report broadly. Begin with team members and your own planning body(ies). Also disseminate the report to HIV care providers including non-Ryan White providers, the HIV prevention community planning group, community members, and elected officials. Make the report available electronically. Present results and implications in venues that allow community members and providers to ask questions and better understand the results. Present findings in your CARE Act applications, Incorporate results into your decision making about service priorities and resource allocations, your needs assessment, and your comprehensive plan – and continue working to reduce unmet need.

## **IV. Setting Up and Using the Unmet Need Framework in Different Jurisdictions: Some Examples of Data Sources**

This section provides examples to help you see how other jurisdictions have set up and used the Unmet Need Framework, using data sources available in their jurisdictions.

Table 3 provides some examples of how four jurisdictions set up an Unmet Need Framework, based on the data sources available for the Population Size and Care Patterns inputs. This table is based on actual field-testing of the framework in States and EMAs, although the numbers provided in the table are for illustration only.

## A. Population Size Data Input Examples

All four jurisdictions in the chart are using surveillance data from their HARS to calculate the number of PLWA. Jurisdictions 3 and 4 are HIV-reporting States and are also using their HARS data to calculate PLWH non-AIDS/aware. Jurisdictions 1 and 2 do not yet have HIV reporting. To calculate PLWH non-AIDS/aware, Jurisdiction 1 is using CDC's midpoint estimate for its geographic location, while Jurisdiction 2 is using modeled estimates created within its own HIV/AIDS surveillance and epidemiology department.

**Table 3: Setting Up and Using the Framework in Different Jurisdictions**

|   | Jurisdiction 1                                      | Jurisdiction 2                         | Jurisdiction 3                                  | Jurisdiction 4                   |
|---|---|--|---|----------------------------------|
| <b>Population Sizes</b>   |   |  |   |                                  |
| A. Number of persons living with AIDS (PLWA), recent time period  | HARS  | HARS                                   | HARS  | HARS                             |
| B. Number of persons living with HIV (PLWH non-AIDS/aware), recent time period                                  | CDC midpoint estimate                               | Estimates based on local modeling      | HARS (HIV-reporting State)                      | HARS (HIV-reporting State)       |
| <b>Care Patterns</b>  |   |  |   |                                  |
| C. Percent of PLWA who received the specified primary medical care services in a 12-month period                | Chart review of all PLWA (or representative sample) | Linked claims databases + private care | Demonstration of viral load, CD4, or ART in ASD | CD4/viral load reporting in HARS |
| D. Percent of PLWH non-AIDS/aware who received the specified primary medical care services in a 12-month period | AIDS progression study                              | Linked claims databases + private care | Demonstration of viral load, CD4, or ART in ASD | CD4/viral load reporting in HARS |

## B. Care Patterns Data Input Examples

Each jurisdiction is using different data sources for Care Patterns inputs, as explained below.

**Jurisdiction 1:** This jurisdiction already conducts extensive chart reviews of all PLWA, including viral load, CD4, and ART information. Since the same information does not exist for individuals who are PLWH non-AIDS/aware, the jurisdiction uses data from its AIDS progression study, which is an interview conducted with people upon AIDS diagnosis. This information is not a care input for people living with AIDS, because the interview includes questions on whether or not the individual received different types of primary care services in the 12 months prior to her/his AIDS diagnosis (i.e., while s/he was still HIV+/non-AIDS).

**Jurisdiction 2:** In this example, the jurisdiction is using its client-level database of CARE Act services, since this particular jurisdiction pays for viral load testing, CD4 counts, and the provision of ART through its ADAP program. Through agreement among State agencies, the jurisdiction is able to link Ryan White CARE Act and Medicaid data using a unique identifier to protect the confidentiality of client-level data. Through a formal agreement with the Department of Veterans Affairs, and by using the same unique identifier, the jurisdiction is also able to link Veterans Affairs HIV primary medical care data. The estimate for how many HIV+/aware individuals are receiving their HIV primary medical care through private sources alone will come from an existing study of local hospital discharge data.

**Jurisdiction 3:** In this example, the jurisdiction uses its CDC-funded Adult Spectrum of Disease (ASD) study to calculate numbers of people who meet the basic definition for HIV primary medical care and are in care at an ASD facility. It is also using a match between ASD and HARS data to estimate how many individuals are at an ASD or non-ASD care site.

**Jurisdiction 4:** Since this jurisdiction has mandatory reporting of viral load and CD4 counts, it uses surveillance data for both population and care inputs. The strength of this data source is that it will include these particular primary care measures for all HIV primary medical care sources. In some jurisdictions, it may include the actual lab counts. It may or may not include up-to-date information on anti-retroviral therapy, but if a jurisdiction is reasonably confident that anyone being prescribed ART would also be receiving viral load testing and/or CD4 counts within the time frame of interest, then this may not be a problem.

## V. Calculating Unmet Need Estimates

Once you have identified and where necessary linked or combined data sources, you are ready to begin calculating unmet need estimates for your jurisdiction. Tables 4 and 5 demonstrate how unmet need estimates can be calculated, depending on the population and care inputs used. The tables provide examples from two different sample jurisdictions. Both these examples demonstrate a single-number unmet need estimate.

These examples assume some familiarity with databases, methods of linking multiple databases, and HIV/AIDS surveillance data sets. Review them with data specialists from your health department or planning body. If you have no one available who is familiar with these databases or methods, contact your HRSA/HAB Project Officer for technical assistance.

These examples show how you can generate an overall estimate of the number of HIV+/aware individuals in your jurisdiction who are not in care. This meets the minimum requirement of a quantitative estimate. However, in order to make the information as useful as possible for planning and decision making, you will want additional information about the characteristics of individuals who are not in care. Where you have the necessary data, you should do further analysis of sociodemographic variables, including gender, age, and race/ethnicity for both Population Size and Care Patterns data in order to compare levels of met and unmet need

among different subpopulations. You may also want to look at data by geographic area, since outreach to identify such individuals will need to be geographically focused.

**Table 4: Unmet Need Calculations: Jurisdiction 1, Example Data Sources**

| <b>Input</b>   | <b>Value</b> | <b>Data Source &amp; Calculations</b>   |
|--|--------------|---|
| <b>Population Sizes</b>  |              |   |
| A. Number of persons living with AIDS (PLWA), recent time period (as of 12/01)   | 7,812        | Local AIDS Reporting System. Counts for the 20 County EMA in year 2001.   |
| B. Number of persons living with HIV (PLWH, non-AIDS) and aware, recent time period (as of 12/01)  | 7,550        | CDC Estimates, midpoint, for 20 County EMA in year 2001.  |
| <b>Care Patterns Among PLWA</b>  |              |   |
| C1. Percent of PLWA who use private care only in a 12-month period   | 15.4%        | State inpatient/discharge data among HIV+/aware from National HCUP project (1998)*.   |
| C2. Estimated number of PLWA with met need through private care in a 12-month period   | 1,203        | A x C1<br>7812 x .154   |
| C3. Number of PLWA with met need through public care sources in a 12-month period  | 5,032        | Linked client data (based on date of birth, race and gender) from Medicaid, Veterans Administration, and CARE Act databases for year 2001 |
| C4. Number of PLWA with met need for HIV primary medical care in a 12-month period.  | 6,235        | C2 + C3<br>1203 + 5032  |
| <b>Care Patterns Among PLWH (aware, non-AIDS)</b>  |              |   |
| D1. Percent of PLWH (aware, non-AIDS) who use private care only in a 12-month period.  | 15.4%        | State inpatient/discharge data among HIV+/aware from National HCUP project (1998)*.   |
| D2. Estimated number of PLWH (aware, non-AIDS) with met need through private care in a 12-month period                                   | 1,163        | B x D1<br>7550 x .154   |
| D3. Number of PLWH (aware, non-AIDS) who received the specified HIV primary medical care services from public sources in 12-month period | 3,019        | Linked client data (based on date of birth, race and gender) from Medicaid, VA, and CARE Act databases for year 2001.                     |

| <b>Input</b>  | <b>Value</b> | <b>Data Source &amp; Calculations</b> |
|---|--------------|---------------------------------------|
| D4. Number of PLWH (aware, non-AIDS) with met need for HIV primary medical care in a 12-month period.             | 4182         | D2 + D3<br>1163 + 3019                |
| <b>Calculated Results</b>   | <b>Value</b> | <b>Calculation</b>                    |
| E. Number of PLWA who did not receive specified HIV primary medical care services                                 | 1,577        | = A – C4<br>= 7812 – 6235             |
| F. Number of PLWH (aware, non-AIDS) who did not receive specified HIV primary medical care services               | 3,368        | = B – D4<br>= 7550 – 4182             |
| G. Total HIV+/aware not receiving specified HIV primary medical care services (quantified estimate of unmet need) | 4,945        | = E+ F                                |

\* You will want to be careful not to assume that private care coverage and/or use of any medical care through private coverage confirms that someone is actually receiving HIV primary medical care. You may need to make adjustments to your private care estimate depending on the data you use and what the data really mean. Additionally, while we used an example here that showed private care use to be the same for both PLWA and PLWH (aware, non-AIDS), you can easily use different percentages if you have data that differentiates based on AIDS status.

**Table 5: Unmet Need Calculations: Jurisdiction 2, Example Data Sources**

| <b>Input</b>  | <b>Value</b> | <b>Data Source</b>  |
|---|--------------|---|
| <b>Population Sizes</b>   |              |   |
| A. Number of persons living with AIDS (PLWA), recent time period (do you want to define recent time period here?) | 6,682        | Jurisdiction-specific surveillance data.  |
| B. Number of persons living with HIV (PLWH, non-AIDS) and aware, recent time period (same here)                   | 7,000        | Midpoint of estimates provided by CDC.  |
| <b>Care Patterns</b>  |              |   |
| C. Percent of PLWA with met need for HIV primary medical care in 12-month period                                  | 72%          | CD4 +/-or viral load +/-or ART from HARS-linked chart reviews.  |
| D. Percent of PLWH (aware, non-AIDS) with met need for HIV primary medical care in 12-month period                | 47%          | CD4 +/-or viral load +/-or ART, retrospective from AIDS progression study, adjusted for sampling bias due to ART effects. |
| <b>Calculated Results</b>   |              |   |
|   | <b>Value</b> | <b>Calculation</b>  |
| E. Number of PLWA with unmet need for HIV primary medical care  | 1,871        | = A x (1 - C) or<br>6,682 x (.28) = 1,871   |
| F. Number of PLWH (non-AIDS, aware) with unmet need for HIV primary medical care                                  | 3,710        | = B x (1 - D) or<br>7,000 x (.53) = 3,710   |
| G. Total HIV+ / aware with unmet need for HIV primary medical care (quantified estimate)                          | <b>5,581</b> | = E + F   |

## VI. Cost of Implementing the Unmet Need Framework

The cost of implementing this framework is mainly a function of the data sources and approach you use in obtaining input data for Population Sizes and Care Patterns. In general, the following ranges apply:

- **Analysis of Existing Data Set:** Field testing suggests that this process requires about two weeks of time for a programmer familiar with the data set, or about \$2,500 - \$3,000. This cost is likely to drop substantially in subsequent years, assuming the same methods are used. The required time will be less since details of data extraction and analysis will not need to be worked out again.
- **Analysis of Utilization Databases:** Analysis of Medicaid and other utilization databases is likely to require 1-2 months of programmer time. Costs can vary widely (e.g., from \$8,000 to \$25,000 or more) depending on the number of databases and whether existing staff can perform this work or outside consultants are required. Costs should be less in subsequent years.
- **Collecting New Data:** Fielding a survey or conducting chart reviews is likely to cost \$25,000 to \$75,000 or more, depending on whether survey instruments already exist, the size of the sample, and whether staff or consultants perform the work. Cost may not drop much in subsequent years.
- **Client-level Databases:** These databases are likely to be used for many purposes (e.g., billing). Establishing such databases may cost hundreds of thousands of dollars or more. The added cost for use in estimating unmet need is likely to be low, similar to that for analysis of an existing data set.

## VII. Enhancing the Basic Definition of Unmet Need

One way to enhance the basic definition of unmet need is by using 6-month in addition to 12-month increments to test whether HIV+/-aware individuals received primary medical care. This is consistent with knowledge that PLWH/A receiving appropriate care will be accessing care more than one time a year.

Another way to strengthen the definition is to require at least two separate occurrences of the primary care measures in a particular time period (such as 12 months) for an individual to be counted as “in care.” One benefit of using multiple occurrences is that you are then less likely to misinterpret a single event as “in care.” For example, this refinement will avoid counting an individual as “in care” because s/he received a CD4 count used to diagnose AIDS but never previously accessed care and did not continue in care after diagnosis.

The basic definition can also be expanded to include other primary care measures and support services, as indicated in the examples below.

- **Definition 1: Unmet Need for HIV Primary Medical Care:** No demonstration of a viral load count (or) a CD4 count (or) ART for 6-month and 12-month periods for years 2000 and 2001.
- **Definition 2: Unmet Need for Core Health Care Services:** No demonstration of utilization in 6-month and 12-month periods for years 2000 and 2001 of any of the

following services: primary care, mental health, oral health, substance abuse, and all meds on ADAP formulary. Hospitalization/emergency room and ambulance services are excluded, since these can be indicative of no care or inappropriate outpatient care access (e.g., someone's hospitalization at AIDS diagnosis should not be counted as "in care").

- **Definition 3: Unconnected to Any Care:** No demonstration of any utilization of any billable service, excluding hospitalization/emergency room and ambulance.

## **VIII. Analyzing Unmet Needs of Subpopulations: Adding to the Picture of Who Needs HIV Care**

### **A. Importance of Subpopulation Analysis**

For planning and decision making, it is not enough to determine the total number of people who are HIV+/aware and are not receiving HIV primary medical care. Jurisdictions must also be able to describe who and where these people are. This detail helps the planning body consider what the State or EMA should do to improve primary care access overall and for specific populations and locations.

Further, Ryan White CARE Act Title I grantees are required to provide an "Assessment of Populations with Special Needs" (Table 6 in the FY 2003 Title I grant applications) for six populations: youth (13-24 years old), injecting drug users (IDUs), other substance users, men of color who have sex with men, white/Caucasian men who have sex with men, and women of child-bearing age (13 years old and older). Additional categories, which may or may not be mutually exclusive, are to be determined by each EMA. Examples of these subpopulations may include homeless, immigrants (e.g., undocumented, documented, newly arrived), residents of a specific geographic area who are particularly affected by the epidemic, or any other identified subpopulation that an EMA feels needs more discussion.

The Instructions for Title I Grant Application Table 6 are to: "Describe the extent to which members of this population are not in a system of HIV/AIDS primary care and the barriers to care for those individuals." The data needed to quantify the number of HIV+/aware persons who are out of care also generally allow the jurisdictions to look at who those people are in terms of gender, race/ethnicity, and age, and potentially other important demographic and behavioral characteristics. Some population and care pattern data can also be analyzed for smaller geographic areas, such as Public Health Service Areas or Counties, allowing for even better targeting of resources and activities. Unfortunately, risk behavior (or route of HIV acquisition) is often not coded in medical care data.

## **B. Factors Affecting Analysis of Subpopulations**

The ability to analyze subpopulations depends on two factors: the availability of data to define the subpopulations and adequate sample size. These two requirements for subpopulation analysis are described below.

### **1. Subpopulation analysis requires the availability of person-level descriptive variables for both Population Size and Care Patterns.**

Subpopulation requires both that you have access to person-level descriptive data for both Population Size and Care Patterns, and that these variables be similarly defined. If you have access to client-level data bases, it is likely that they will provide data on race/ethnicity, gender, and age. Often, you are able to describe the total HIV+/aware population and those individuals who are in care. As with the basic estimation of unmet need, you will subtract the “in care” population from the total HIV+/aware population and assume that the characteristics of the remaining individuals reflect those who are not in care.

It is important that these variables are similarly defined by all data sources. For example, a jurisdiction may want to use the framework to look at differences in numbers or proportions of individuals out of care by race/ethnicity. If so, the jurisdiction will first need to answer such questions as:

- Are race/ethnicity markers present, and defined similarly, in both the numerator (Care Patterns) and the denominator (Population Size)?
- If “white/Caucasian” includes Latinos in the population estimates, but Latinos are broken out separately within Care Pattern data, can Latinos also be broken out separately in the population estimates?
- If race/ethnicity is defined in one place by self report and in the other by the eligibility worker, are the definitions sufficiently similar?

It is important to identify problems or inconsistencies between data sets before attempting to interpret any results. This allows for corrections—and the opportunity to make changes in the future collection of data.

### **2. The number of individuals in the subpopulation sample must be large enough to offer precision.**

In doing subpopulation analyses, be sure the numbers are large enough to provide information you can trust. With small numbers (e.g., only 25 female IDUs in the data used for care estimates), the uncertainty of calculations based on the data is substantial. Such estimates should be characterized as very approximate, or not made. On the other hand, you can feel comfortable with analyses of 1,120 women with HIV or 692 African American men. You may find that categories remain large enough for analysis when your groupings involve only two of the following three variables: broad age categories, race/ethnicity, and/or gender. Numbers may become smaller when you look at groups

described by all three variables – such as Latina women under 25 or African American men over 45.

## **IX. Complementary Data within the Needs Assessment Process**

A comprehensive needs assessment comprises multiple components, rather than the results of a single data source. The different components together create a picture of need. The framework presented in this Guide is one of many components needed to estimate and assess unmet need for HIV care and to determine service gaps other than primary care, overall and for specific populations and particular geographic areas within your jurisdiction.

The Ryan White CARE Act *Needs Assessment Guide* describes needs assessment as a “process of collecting information about the needs of persons living with HIV (both those receiving care and those not in care), identifying current resources (CARE Act and other) available to meet those needs, and determining what gaps in care exist.”

Thus, your estimates of numbers (and, where possible, characteristics) of HIV+/aware individuals who are “out of care” are most useful if they are linked to your investigations into reasons for unmet need for care. These investigations may focus on structural and individual barriers that keep people from care. Your findings may describe services or systems that need to change in order to reduce the gap between what people need and what your care system provides them.

The research methods may be quantitative, using the framework for measuring unmet need for HIV primary medical care and surveys of PLWH, or qualitative, employing client or patient interviews and focus groups. Ideally, your estimates for numbers of HIV+/aware individuals who are “in care” should be linked to your quality management program and your evaluation of quality of care, patient satisfaction, and improvements in health outcomes within the community.

Below is one example of a subpopulation analysis that links unmet need data to clinical outcomes data. Earlier in this document, you saw the presentation of unmet need estimates in terms of numbers. The following map is an example using preliminary San Francisco data and demonstrates geo-mapping techniques. It demonstrates an example of unmet need broken out by neighborhood of residence. This map was used to relate to an important clinical outcome. Unmet need was shown to be highest in the same neighborhoods where five-year survival rates after AIDS diagnosis were lowest.

For more information on the needs assessment process, refer to your *Needs Assessment Guide* and use other technical assistance resources available from HRSA/HAB.

## Geo-Mapping Example Using Preliminary San Francisco Unmet Need and Outcome Data

