



**The Miriam Hospital Immunology Center, Providence, RI**

# **Immunology Center Database (ICDB)**

**Annual Data Report**

**1/1/2019 -12/31/2019**

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**Fizza S. Gillani, PhD  
Jillian Murphree, MS  
Joseph M. Garland, MD**

**Note to Clinic Physicians and Staff:**

With the implementation of a new EMR (EPIC), the scope of the Immunology Center Database (ICDB) has increased significantly. On CFAR platform, ICDB falls under the larger umbrella of CFAR Clinical Research Database (CCRD) systems to capture its increased scope. Presented in this report are data that passed through the Immunology Center Electronic Medical Records (EPIC) and the ICDB direct data entry process. These same data are used in reports to government agencies.

## Section 1

### Introduction and History

#### 1-1) ICDB - Usage

The Immunology Center Database (ICDB) is one of the best healthcare databases available for research at The Miriam Hospital, Providence, RI; however, it does have many limitations for its use. ICDB data release policies have been outlined in Section 3 of this report.

#### 1-2) ICDB - History

The ICDB was originally created in November 2003 with CFAR funding for the purposes of patient tracking, Ryan White program reporting, and CFAR research activities. Calendar year 2011 was the last year that data elements were manually entered into the ICDB database. With the acquisition of electronic medical records (EMRs) from the vendor eClinical Works (ECW) in December 2011, manual entry of data elements was no longer required for the majority of data items. For the period December 2011 through March 2015, ICDB was mostly populated from direct downloads of the ECW backend data system, known as ECW-EBO.

The Miriam Immunology Center (MIC) started utilizing EPIC, the current EMR system of Lifespan, in March 2015. During EPIC implementation, CFAR/Lifespan staff worked in collaboration with the Lifespan IS department to adjust and redesign the ICDB system to start getting data from EPIC system specifically for Ryan White reporting, CFAR research, and reporting to other funding agencies. At Lifespan, Epic data is stored in a set of Caboodle Data Warehouses (CDWs) that can be accessed using SAP Business Objects (BO) via Business Intelligence (BI) Launch Pad. Currently, we access these CDWs using SAP Business Analytic techniques and Web Intelligence software to populate the ICDB system with clinical data related to HIV care. MIC also created a customized HIV Case Management Flowsheet within EPIC to collect other program-specific data items not already present in EPIC. Presently, only 5% of the data elements related to current enrollment, and some baseline HIV specific *information*, are manually entered into ICDB. The rest of the data elements are drawn down directly through EPIC's CDWs.

#### 1-3) ICDB - Layout

ICDB is a relational (longitudinal) database on a secure SQL server that is hosted and maintained by the Lifespan IS department. It contains demographic data, the history of medical and social service visits to the clinic, labs results including CD4 and HIV viral loads tests, HIV specific history of medical ailments or diagnoses, HIV treatment histories, and vaccinations.

The ICDB annual report is created each April following the annual Ryan White Services Report (RSR: includes patient level data) submission to the HIV/AIDS Bureau (HAB) of the Health Resources and Services Administration (HRSA). This annual report provides a summary of essential data items that are most frequently requested. It also provides general demographic profiles that can be used in grant applications or presentations in which summarizing the clinic population may be necessary. When applicable, field definitions with data items are provided. This report has been approved by the Lifespan HIPAA office and follows all HIPAA regulations.

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## Section 2

### Data Items

#### 2-1) Enrollment

**Active Patients:** Starting in 2012, an active patient is defined as a patient who had at least one visit (medical or other core medical service, including an Intake visit) recorded in the EMR; OR a patient who is newly registered to the clinic, OR a patient who died (without any visit) during the calendar year. All reactivated patients are included in the active patient list for the year. New diagnoses are defined as any patient who was diagnosed within the last 12 months of their registration to clinic date.

**Reactivated Patients:** A reactivated patient for the 2019 calendar year is defined as a patient who was not active during the 2018 calendar year but returned to the clinic in 2019. This data item is entered into ICDB via clinic staff's Activation/Reactivation process forms.

Enrollment Status	Patients
Total Active Patients	1829
New to clinic	132
New diagnoses	59
Transfers In	73
Deceased during the year	19
Moved Away/Transferred Care	25
Reactivated during the year	24
Active patients with at least 1 Medical visit during the year	1803

#### 2-2) Demographics

##### a) Gender

All current gender data are self-reported. For 2019, the gender distribution is as follows:

Gender	Patients	% of Total
Male	1307	71.5
Female	505	27.6
Transgender	17	0.9

\* Percentage of total active patients (n=1829).

##### b) Age (groups)

Below, the total active patients are grouped together in different age groups. The Immunology Center does not treat patients less than 18 years of age. Age is calculated as of December 31, 2019.

Age Group	Patients	% of Total
18 - 24 Years	36	2.0
25 - 44 Years	553	30.2
45 - 64 Years	1078	58.9
Over 65 Years	162	8.9

\* Percentage of total active patients (n=1829).

The average age of active patients as of December 31, 2019 was 49.5 years with a minimum of 19 and maximum age of 84 years.

##### c) Race/Ethnicity

Race and ethnicity are classified in two different fields in the ICDB; as a result, any classifications or combinations of race and ethnicity together can be obtained. This data item is

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entered directly into the ICDB via new patient intake forms. For the purposes of this report, we include only the primary race reported by the patient on the intake form.

Race	Patients	% of Total
White	1163	63.6
Black	580	31.7
Asian	36	2.0
Native Hawaiian or Pacific Islander	1	0.05
American Indian or Alaska Native	13	0.7
More than 1 Race/Unknown/Not Reported	36	2.0

\* Percentage of total active patients (n=1829).

Ethnicity	Patients	% of Total
Hispanic/Latino	477	26.1
Non-Hispanic/Latino	1352	73.9

\* Percentage of total active patients (n=1829).

## d) Place of Birth

Place of Birth (POB) is self-reported and country of birth is derived from the Place of birth information. US-born category includes only persons born in all 50 states, US-Puerto Ricans are reported as a separate category and all others are grouped together into Foreign-Born category.

Country of Birth	Patients	% of Total
US-Born	1056	57.7*
US-Puerto Rico Born	138	7.5*
Foreign-Born	492	26.9*
POB Missing	143	7.8*

\* Percentage of total active patients (n=1829).

## 2-3) Socio-economic Indicators

### a) Insurance

The following table shows the insurance data for 2019. Medicaid/CHIP/Other public includes VA, Tri-Care and other Military insurance. Private Insurance includes private insurance provided by an employer or individual. The table represents the insurance information provided by patients at their last medical or other core services visit in 2019.

Insurance Type	Patients	% of Total
Private (Individual + Employer)**	964	52.7*
Medicare	282	15.4*
Medicaid, CHIP/Other Public	311	17.0*
Medicare and Medicaid both	136	7.4*
No Insurance/Uninsured	136	7.4*

\* Percentage of total active patients (n=1829).

\*\*Private Insurance includes insurance purchased by the individual/family or insurance provided by the employer.

### b) Housing status

Housing status is the housing status as of the last visit in 2019 entered via HIV-FS OR updated by the clinic staff in the ICDB.

Housing Status	Patients	% of Total
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Stable/Permanent Housing	1538	86.4*
Temporary housing	174	9.8*
Unstable Housing arrangements	68	3.8*

\* Percentage of total active patients who had at least 1 Medical Visit and housing status documented (n=1780).

## 2-4) Clinical Indicators

### a) HIV/AIDS Status

HIV/AIDS Status is defined by the CDC as a CD4 count < 200 or CD4% < 14 and including any diagnosis with AIDS in the clinic based on the presence of opportunistic infections. Data reported in the following table are the HIV/AIDS status of patients as of December 31, 2019.

HIV/AIDS Status	Patients	% of Total
HIV+, not AIDS	1013	55.4*
CDC-defined AIDS	816	44.6*

\* Percentage of total active patients (n=1829).

### b) Risk Factors

All risk factors are self-reported and are generally collected at the time of new patient intake by clinic staff. This data item is manually entered into ICDB and is the Primary HIV Risk Factor reported by the patient.

Primary Risk Factors	Patients	% of Total
MSM	811	44.3*
Heterosexual contact	700	38.3*
IDU	198	10.8*
MSM/ IDU	39	2.1*
Perinatal transmission	18	1.0*
Blood Transfusion	15	0.8*
Hemophilia/ coagulation disorder	3	0.2*
Others/ Unknown/ Unreported	45	2.5*

\* Percentage of total active patients (n=1829).

## 2-5) Clinical Care

### a) Lab Tests

The following table displays the most important lab tests performed in the reporting year.

Column 2 represents the total number of tests completed on active patients; Column 3 represents the number of unique patients who had at least one test completed; and Column 4 represents the percentage (%) of total active patients who had at least one Outpatient Ambulatory Medical Care (OAMC) visit in the reporting year, except for the Pap smear test, where the last column is % of females who had a Pap smear test performed in the past 3 years (per latest guidelines), out of the female patients who had at least one medical visit during the 2019 year. This table represents the total number of patients tested during the year and is not adjusted for any additional criteria.

Lab Test	# of Tests Done	# of Unique Patients	% of Active Patients
CD4 Test	1930	1330	74.7*
PVL Test	3608	1743	97.9*
<b>Other Annual Tests</b>			

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Screened for Cervical Cancer (PAP) in last 3 years (per new standards)	363	77.1**
Screened for Syphilis in year	795	44.7*

\*Percentage is out of the total number of patients who had at least one OAMC visit during 2019 (n=1780).

\*\*Percentage is out of the total females who had at least 1 medical visit in 2019 and were eligible for PAP Smear Test (n=471 excluding 34 Not Medically Indicated category).

## b) Treatment

Patients' usage of HIV treatment is determined by current use of medications (as of December 31, 2019). Ever since we started using the new EMR (EPIC), this data item is only available through a query for medications ordered and are completely dependent on medications ordered within the EMR. The following table includes the medications ordered (within Epic) from 1/1/2018-12/31/2019 as well as a manual chart review (from physician's notes) for about 52 patients.

Medication Status	Patients	%
Yes - on HIV treatment	1807	98.8*
No - not on HIV treatment/Unknown/Unreported	22	1.2*

## c) Clinical Outcomes

Clinical outcomes are based on the last available lab value for the 2019 reporting year. Most of the viral load and CD4 test results are downloaded from EPIC but results from outside labs are generally manually entered into ICDB from the scanned documents in EPIC.

Viral Load Suppression (PVL < 200)	Patients	%
Yes (PVL < 200)	1635	93.8*
No (PVL >= 200)	108	6.2*
No PVL result available for the year	37	2.1**

\* Percentage of total patients who have at least one OAMC visit and had viral load test done in 2019 (n=1743).

\*\*Percentage of total patients who have at least one OAMC visit during 2019 (n=1780).

*Note: CD4 test results are the last available lab value for the patient, irrespective of if it was done in 2019 or earlier.*

CD4 Test Results	Patients	%
CD4 counts 500 or greater	1203	67.8*
CD4 count between 200 and 499	463	26.1*
CD4 counts less than 200	108	6.1*

\* Percentage of total Active patients who have at least 1 medical visit during 2019 with a documented CD4 test (n=1774).

## d) Services Provided

Service encounters provided by TMH IC clinic staff for 2019 are reported in the table below. Ambulatory/Outpatient visits include all patient visits (e.g., initial visit, follow-up exams, or office visit with a completed visit status) with any prescribing provider including physicians, Physician Assistants (PAs), or Nurse Practitioners (NPs). Other encounters include services such as mental health services, medical case management services and substance use services (as defined by the Ryan White Program). Of note, specific screenings (health education/risk

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reduction, mental health, and substance use screens) are tracked via the implementation of an EMR tool that creates extractable data fields for these data points.

<b>Services Provided</b>	<b>Total # of Visits</b>	<b>Unique Patients</b>
Ambulatory/Outpatient Encounters	5223	1780
Mental Health Services	2893	750
Medical Case Management (including Treatment Adherence Services)	3342	762
Substance Abuse Outpatient Care	279	122
Health Education/Risk Reduction	1705	803
Medical Transportation	52	42
Outreach Services	3844	1085
Psychosocial Support Services	418	243

**END of the Data Section**

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## **Section 3**

### **ICDB System: Data Release Policies**

Data presented in the ICDB Annual Data Report are for clinical and government reporting purposes only. This data report may be used to summarize the Immunology Center population (for presentations and grant applications), but cannot be published without obtaining appropriate IRB approval. If you intend to use these data or need more detailed data for any research purpose, please follow the procedure noted below:

- 1) All requests for data from ICDB must be done through the completion of a “CFAR Clinical Data Request Form (DRF)”, which is located on the CFAR website (<https://www.brown.edu/academics/medical/about-us/research/centers-institutes-and-programs/aids/cfar-clinical-research-database-ccrd>). If the requestor is not a member of Infectious Diseases Division, then the applicant must select someone within the Division to act as the sponsor. Data will only be released to faculty members; we are not authorized to provide data to staff (i.e., research assistants, project directors).
- 2) If the data report requested is purely for research purposes, IRB approval information must be filled in and a copy of the IRB approval letter must be uploaded with the data request. Your IRB approval letter can be found within your IRBNet study documents. If the request is for clinical use at the Immunology Center or for government reporting, IRB approval is not needed.

The DRF will be forwarded to the Data Release Authorization Committee (A group of senior physicians from the Immunology Center at The Miriam Hospital). The committee will review the Data Request (approval from at least two committee members is required). If approval is granted, the data will then be sent to the requestor.

- 3) Data (after steps above are successfully completed) which includes individual identifiers will not be sent via e-mail. Requestor must contact Dr. Fizza Gillani ([fgillani@lifespan.org](mailto:fgillani@lifespan.org)) at the Immunology Center to obtain the data.
- 4) Names of patients for research purposes will be issued only if appropriate IRB approval is obtained and/or preparatory to research has been arranged with the Lifespan IRB office. See IRBNet Forms and Templates for accounting of disclosure information and instructions.
- 5) Each PI (requestor) is responsible for the confidentiality, privacy and proper use of data that is released to him/her (specifically when the data includes patient identification variables).
- 6) Everyone performing human subject research must have educational training in the protection of study volunteers. It is the Principal Investigator’s (PI’s) responsibilities to make sure any colleague who has access to the data or who uses the data have appropriate training. It is also the researcher’s responsibility to properly discard or file the data after project is completed. Please call the Research Protection Office (RPO) for guidelines.