ODATABASE & METHODS CYBERSEMINAR SERIES

FY24 Session #6:

Understanding and Accessing the Office of Connected Care's Patient-Generated Health Data (PGHD) Database

March 4, 2024



Terry Newton, MD, Director of Clinical Analytics, VA Office of Connected Care

Mark Zocchi, PhD, Health Science Specialist, Center for Healthcare Organization and Implementation Research (CHOIR), VA Bedford Healthcare System

Stephanie Shimada, PhD, Investigator, Center for Healthcare Organization and Implementation Research (CHOIR), VA Bedford Healthcare System



DATABASE & METHODS CYBERSEMINAR SERIES

Informational seminars to help VA researchers access and use VA databases.

Sessions cover...

- VA data sources & data access systems
- Application of VA data to research and quality improvement questions
- Limitations of secondary data use
- Resources to support VA data use

WELLING OF THE OF SESSIONS

First Monday of the month | 1:00pm-2:00pm ET

Date	Topic
4/1/24	Assessing Race and Ethnicity in VA Data
5/6/24	An Introduction to VA Pharmacy Data: Sources and Uses for Medication Information

Visit the VIReC

<u>Database & Methods</u>

<u>Cyberseminar</u> page for more information & registration links.

Visit <u>HSR&D's VIReC</u>

<u>Cyberseminar Archive</u>

page to watch previous sessions.

Where can I download a copy of the slides?



SAMPLE EMAIL

A Practical Approach to Working with VA-Purchased Community
Care Data

Thursday, October 13, 2022 2:00 PM | (UTC-04:00) Eastern Time (US & Canada) | 1 hr

Please download today's slides
Please click here for today's live captions

Join webinar

More ways to join:

Join from the webinar link

https://veteransaffairs.webex.com/veteransaffairs/j.php?

Poll #1:

What is your primary **role** in projects using VA data?

- Investigator, PI, Co-I
- Statistician, methodologist, biostatistician
- Data manager, analyst, or programmer
- Project coordinator
- Other please describe via the chat function



Poll #2:

How many years of experience working with VA data?

- None I'm brand new to this!
- One year or less
- More than 1, less than 3 years
- At least 3, less than 7 years
- At least 7, less than 10 years
- 10 years or more



ODATABASE & METHODS CYBERSEMINAR SERIES

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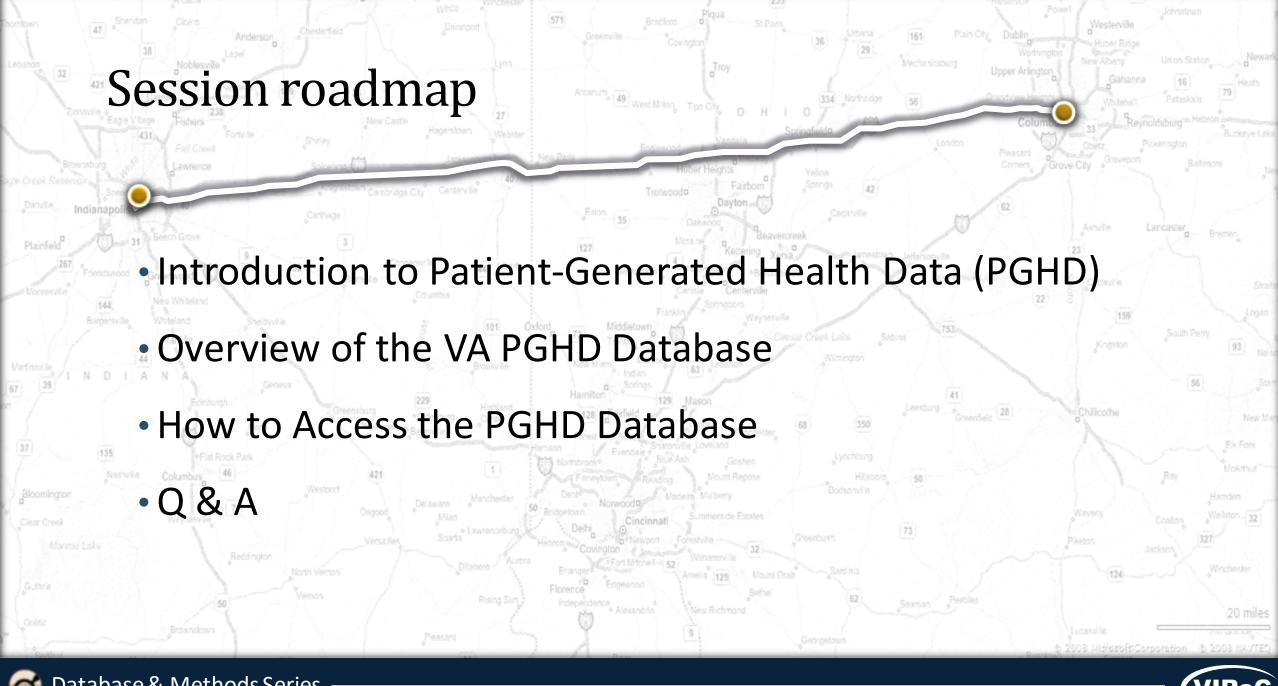
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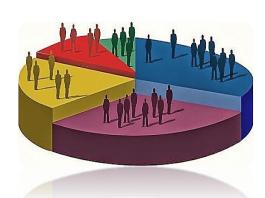






Poll #3:

How would you rate your overall knowledge of Patient-Generated Health Data (PGHD)?



- 1 (No knowledge)
- 2
- 3
- 4
- 5 (Expert-level knowledge)



Introduction to PGHD

Terry Newton, MD

Director of Clinical Analytics, VA Office of Connected Care





Patient-Generated Health Data (PGHD) are health-related data created, recorded, or gathered by or for patients (or family members or other caregivers) to promote health and wellness or to help address a health concern.

What is PGHD?

SOURCE: <u>VHA Directive 6506</u>

<u>Patient-Generated Health Data (PGHD)</u>

Office of Connected Care (OCC) Operations Manual





PGHD is distinct from data generated in clinical settings.

Patients are primarily responsible for capturing and/or recording these data, and patients explicitly decide to share these data through some form of authorization or consent process, or by voluntarily sending or transmitting their data.

PGHD may include:

- Remote device-generated consumer-collected clinical data
- Biometric data
- Symptoms and other types of patient-reported outcomes
- Clinical screeners
- Perceived quality of life data
- Patient goals, values and lifestyle choices

PGHD Definition

- Continued



There are Three Categories of PGHD

SOLICITED

- PGHD that is collected and shared by a patient in response to a specific request by a VA HCP as part of a care management program protocol is solicited PGHD.
- If a VA HCP explicitly requests that a patient collect and share PGHD in accordance with the program protocol, the VA HCP has a responsibility to review the data.

SUGGESTED

- PGHD that is collected and shared by a patient in response to a suggestion from a VA HCP is suggested PGHD but falls short of a formal consent or enrollment process.
- The Clinician should use professional judgment to determine when the data will be viewed and how it will be used in clinical decision-making, and then communicate this with the Veteran.

UNSOLICITED

- PGHD that is collected and shared by a patient without a request from a VA HCP or health care staff is unsolicited PGHD.
- PGHD is shared solely at the discretion of the Veteran or Caregiver. There is no expectation for the clinician to review such data until they become aware of it.

EXAMPLE

Solicited PGHD is collected and used as a part of patient enrollment in the VA RPM-HT Program

EXAMPLE

The provider suggests that the patient use a BP cuff to record their BP readings at home and share the data with their VA HCP during their next visit

EXAMPLE

A patient downloads a VA mobile application or logs into a VA web portal and chooses to connect their wearable biometric device or manually enter health data

Categories of PGHD

VINCI currently only has PGHD from suggested and unsolicited use-cases

PGHD that is not monitored in real time

•





Benefits of Collecting PGHD



Improve understanding of patients' health between visits.



Empower patients to engage as an active partner in their care.



Support shared decision making and delivery of care.



Identify meaningful health trends over time.



Connected Devices Ecosystem

- Numerous clinical and consumer health data sources.
 - Wearable devices (e.g., Fitbit)
 - Smartwatches (e.g., Apple Watch)
 - Sleep Tracking
 - Heart Rate
 - Health and Nutrition Apps
 - Blood Pressure Monitors

- Glucose Meters
- Pulse Oximeters
- Weight Scales
- Thermometers
- And More





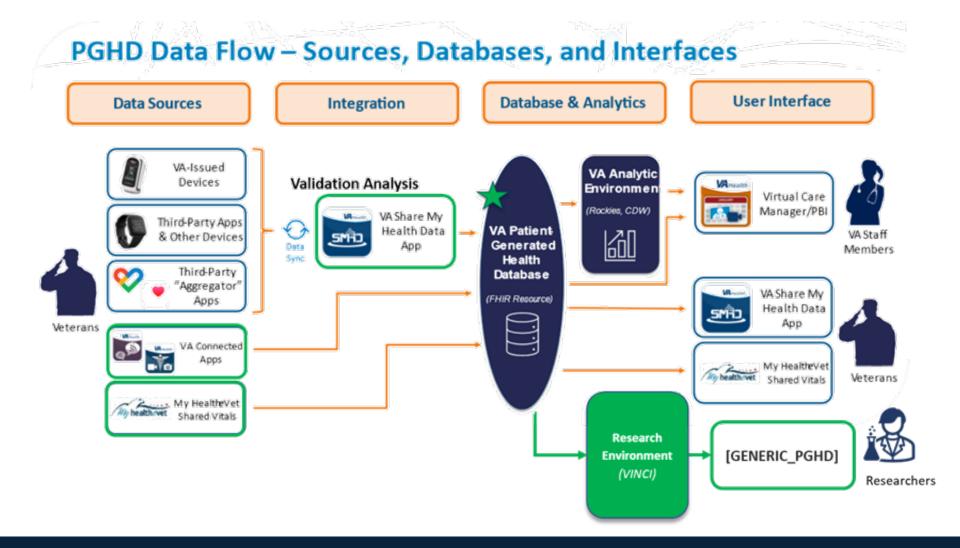








How does the data get to the PGHD database?





Term Agreements



Prior to using the app, the user must accept the End-User License Agreement (EULA) and the Data Collection Agreement.

Mobile END USER License Agreement

V1, 3/1/2018

BY agreeing TO ACCESS VA's mobile application ("Application") on your device and by subsequent use of the Licensed Software, you agree to comply with the terms of this general End User License Agreement ("EULA") and Notice of Privacy Practices ("Notice"). If you do not agree to the terms of this EULA and Notice, do not access or use the Licensed Software from your device. This EULA and Notice applies to any upgrades and supplements to the original Licensed

Cancel

Accept

The Data Collection Agreement informs the user that the VA may collect and store any patient generated health data that the user has agreed to share with the VA.

Patient Generated Health Data Collection Agreement

VA may store personal and self-entered information and data that a user has chosen to share with VA licensed software. VA web and mobile services use encryption to securely store and transmit all data including personal and self-entered information.

VA use and/or release of your information, including your health information, must comply with federal privacy laws and regulations. Access to your VHA information may only be given to an agency or an individual as permitted by law and policy as outlined in the VHA Notice of Privacy Practices.

Examples of data that can be shared with VA are self-entered or patient generated health data (PGHD) from mobile health applications, wearable devices or Bluetooth devices. Though VA health care team members can access this data, they may not regularly monitor it. It is the responsibility of VA Patients to track their self-entered or device generated health data, monitor their output, and communicate with their health care team if health concerns occur. If you want any specific data viewed by your health care team, please contact your health care team directly.

VA may partner with outside parties to provide users with health information or information services. Patient generated health data may be

Accept

Do Not Accept





New Approved Consent Language

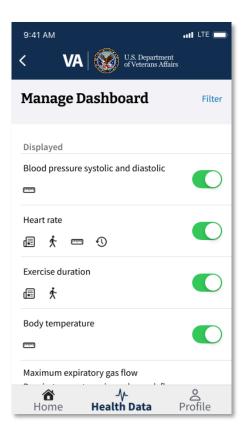
- "...VA staff may analyze Patient Generated Health Data (PGHD) shared by Veterans for many purposes such as;
 - Clinical Care- sharing your data helps your VA care team understand your daily activities (sleep, diet, and exercise etc.) in between your visits. This data helps you and your VA healthcare team make informed decisions about your care plan.
 - Veteran Health Data- sharing your data helps your VA care team monitor or even predict your risk factors for certain health conditions. Your data adds value to the larger data pool and can help VA care team understand these health trends and patterns. This data can be used to adapt care plans for you, and fellow Veterans, to stay as healthy as possible.
 - VA approved quality efforts sharing your data helps VA learn how to improve care using health technologies such as virtual care tools. This data can be used to add virtual care tools into care plans for you, and fellow Veterans.
 - VA approved research sharing your data helps VA researchers better understand how to prevent and manage certain health conditions. This data can be used by your VA care team to adapt care plans for you, and fellow Veterans."



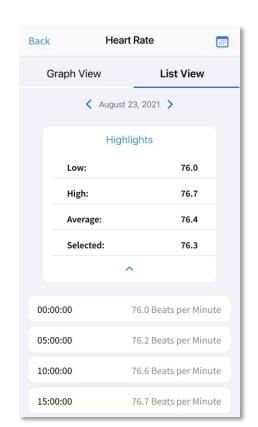
Share My Health Data (SMHD) App

Data Dashboard

Patients can view data trends in graphs and list format.

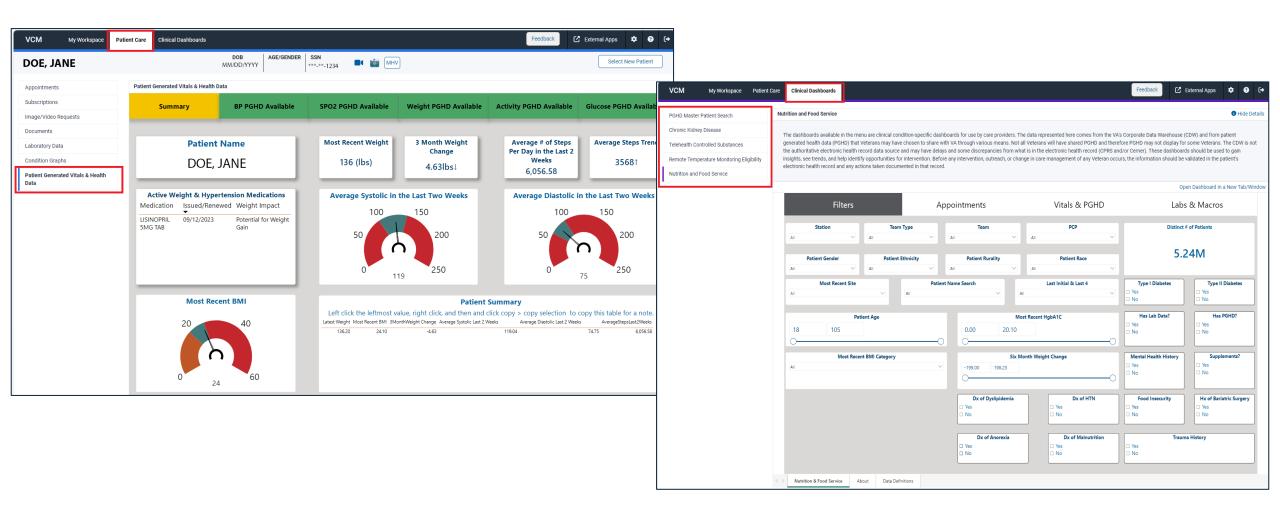








Accessing PGHD: Virtual Care Manager (VCM)







0

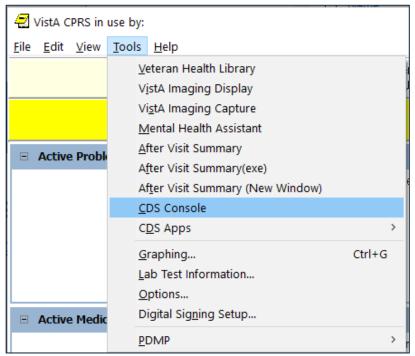
Search for an application

Accessing PGHD:

Clinical Decision Support (CDS) Console

SMART Apps

Keep this tab open to ensure apps can function properly



*Note, the CDS Console may be in a different location within your facility's CPRS Tools or may not yet be available.

LAST NAME, FIRST NAME ALL APPLICATIONS FAVORITES **COVID Patient Manager** CRISTAL MedPIC Diabetes Dashboard Disposition recommendations based on patient health Home Blood Glucose data shared by patients Medication adherence Summary report to review risk and protective factors for suicide, and relevant recent treatment history 0 LAUNCH MORE INFO MORE INFO LAUNCH MORE INFO ratification Tool for Opioid Risk Mitigatio STORM Patient Generated Vitals & Voogle **Health Data Dashboard** Estimate and manage opioid related risk via Fast user-friendly patient search on clinical notes and Stratification Tool for Opioid Risk Mitigation structured data, consolidated from all VAMCs running Patient Generated Health Data (PGHD) shared by

Contact your Clinical Application Coordinators (CACs) for assistance with <u>installation</u>.

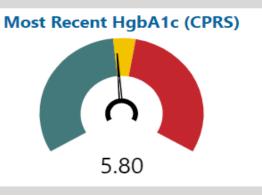




Patient Name

Last Name, First Name

Active (CPRS) Weight & Hypertension Medications							
Medication	Issued/Renewed ▼	RxStatus	Weight Imp				
TAMSULOSIN HCL 0.4MG CAP	02/14/2024	SUSPENDED	Potential fo Neutral or \				
CARVEDILOL 6.25MG TAB	12/26/2023	ACTIVE	Potential fo Neutral or \				
LISINOPRIL 5MG TAB	12/26/2023	ACTIVE	Potential fo Gain				



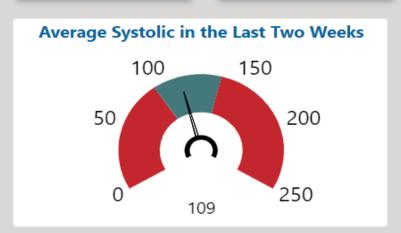
Most Recent Weight

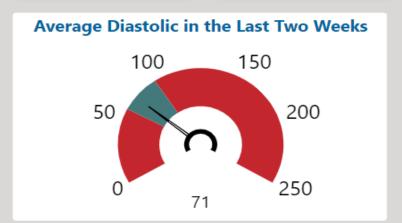
421 (lbs)

3 Month Weight Change

2.90lbs↑

Average # of Steps Per Day in the Last 2 Weeks 143.67 Average Steps Trend
5↑





Patient Summary

Left click the leftmost value, right click, and then and click copy > copy selection to copy this table for a note.

Latest Weight Most Recent BMI Most Recent HgbA1c 3MonthWeight Change Average Systolic Last 2 Weeks Average Diastolic Last 2 Weeks Average StepsLast2Weeks

421.10 60.90 5.80 2.90 109.08 71.17 143.67

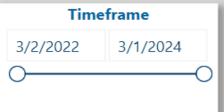
Oracle Health Data Not Yet Available

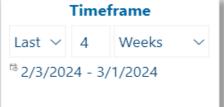






✓ fitbit ✓ garmin



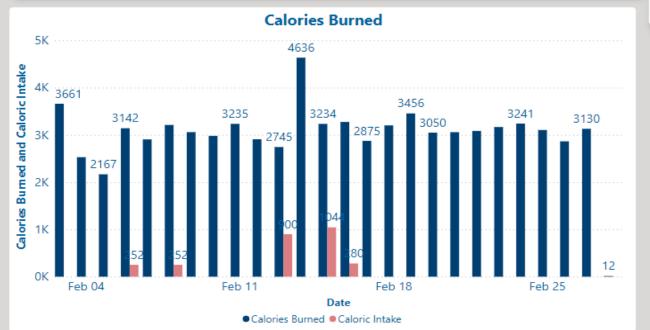


% Of Days with at Least 500 Calories Logged

40.00% of days have at least 500 calories logged

Patient Name Last Name, First Name





Click Here To Go To the Nutrition & Food Service Dashboard

Most Recent Weight w/ Date 244 (lbs) 2/27/2024



Measurement	Avg Amount Per Day	Goal Per Day	Left
Calorie intake 24h Est	546	2000	1454.40
Carbohydrate intake 24h Est	53g	275g	221.65g
Fat intake 24h Est	24g	78g	53.60g
Fiber intake 24h Est	2g	28g	25.75g
Fluid intake 24h	8fl oz	64fl oz	56.00fl oz
Protein intake 24h Est	9g	50g	41.14g
Sodium intake 24h Est	756mg	2300mg	1543.75mg

Oracle Health Data Not Yet Available

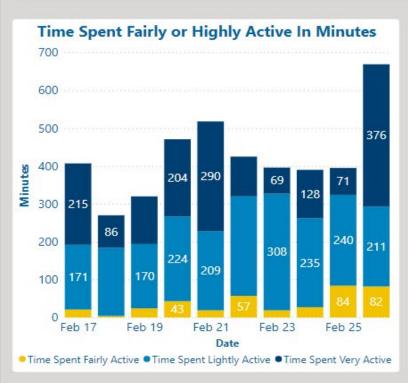


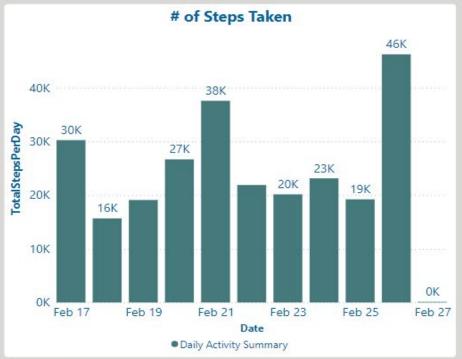


Patient Name Last Name, First Name



Average Daily Time Average Daily Distance Spent Active (Minutes) Traveled (Miles) 426 10.81









Oracle Health Data Not Yet Available





Overview of the VA Patient-Generated Health Data (PGHD) Database

Mark Zocchi, PhD

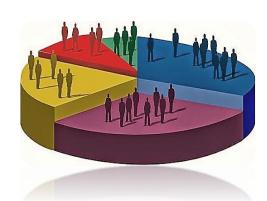
Health Science Specialist Center for Healthcare Organization and Implementation Research (CHOIR) VA Bedford Healthcare System, Bedford MA





Poll #4:

Have you ever used Patient-Generated Health Data (PGHD) for a project?



- Yes
- No
- No, but I'm planning to in the future



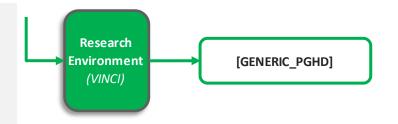
Where does data in the PGHD database come from?

Data sources:

Sources	Devices	Categories
Share My Health Data App	Apple Health, Fitbit, Garmin, Bluetooth digital devices	Daily activity summary, sleep, vital signs, workout, nutrition, anthropometric measurement
My HealtheVet (shared vitals)	None (Patient self-entered)	Vital signs
Annie for Veterans	None (Patient self-entered)	Vital signs



Overview: **PGHD Measurement View**

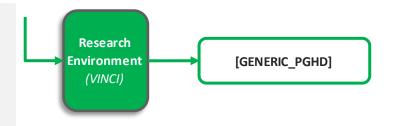


Veteran connects
Apple
Health to
SMHD

ICN	Observation PID	Observation Component SID	Source	Device	Category	Measurement	Code	Value	Units	Measurement Date
XXXXXXXX01	1	11	SMHD	apple_health	Vital Signs	Systolic blood pressure	8480-6	161.33	mm[Hg]	17dec2023 12:18:42
XXXXXXXX01	1	12	SMHD	apple_health	Vital Signs	Diastolic blood pressure	8462-4	93.33	mm[Hg]	17dec2023 12:18:42
XXXXXXXXX01	2		SMHD	apple_health	Vital Signs	Heart Rate	8867-4	86	{beats}	17dec2023 12:18:42
XXXXXXXX02	3	31	SMHD	bluetooth omron bp7350	Vital Signs	Systolic blood pressure	8480-6	170.43	mm[Hg]	01feb2023 11:10:09
XXXXXXXX02	3	32	SMHD	bluetooth omron bp7350	Vital Signs	Diastolic blood pressure	8462-4	90.11	mm[Hg]	01feb2023 11:10:09
XXXXXXXX02	4		SMHD	bluetooth omron bp7350	Vital Signs	Heart Rate	8867-4	90	{beats}	01feb2023 11:10:09



PGHD Measurement View



ICN Observation Observation Source **Device** Category Code Value Units **Measurement Date** Measurement PID Component SID 17dec2023 12:18:42 XXXXXXXXX01 11 SMHD apple health Vital Signs Systolicblood 8480-6 161.33 mm[Hg] pressure XXXXXXXXX01 12 SMHD apple health Vital Signs 8462-4 93.33 mm[Hg] 17dec2023 12:18:42 Diastolic blood pressure XXXXXXXXX01 SMHD apple health Vital Signs 8867-4 86 {beats} 17dec2023 12:18:42 Heart Rate bluetooth 01feb2023 11:10:09 XXXXXXXXX02 31 **SMHD** Vital Signs Systolic blood 8480-6 170.43 mm[Hg] omron bp7350 pressure XXXXXXXXX02 32 bluetooth 01feb2023 11:10:09 **SMHD** Vital Signs Diastolic blood 8462-4 90.11 mm[Hg] omron bp7350 pressure XXXXXXXXX02 **SMHD** bluetooth Vital Signs **Heart Rate** 8867-4 90 {beats} 01feb2023 11:10:09 omron bp7350

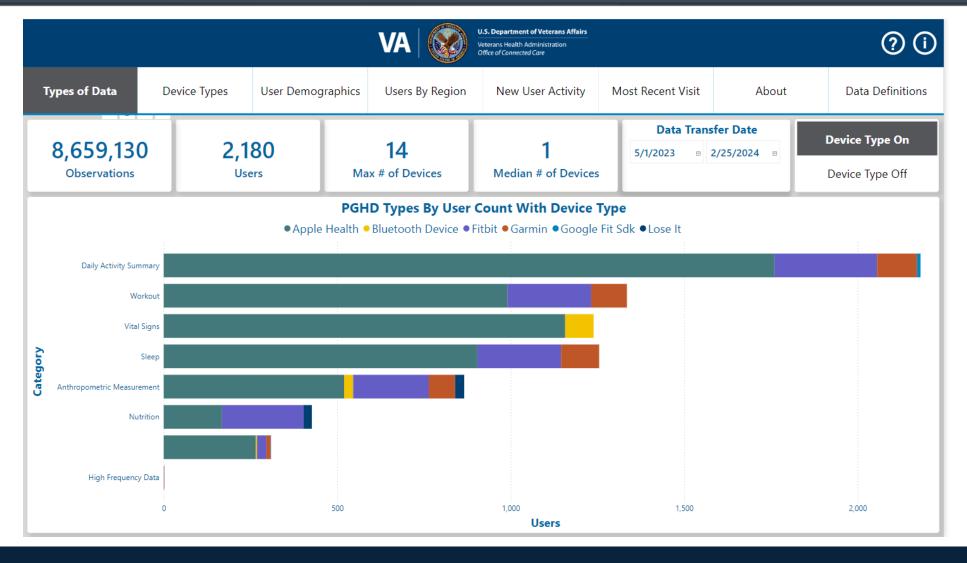
Veteran pairs
Bluetooth

device to

SMHD

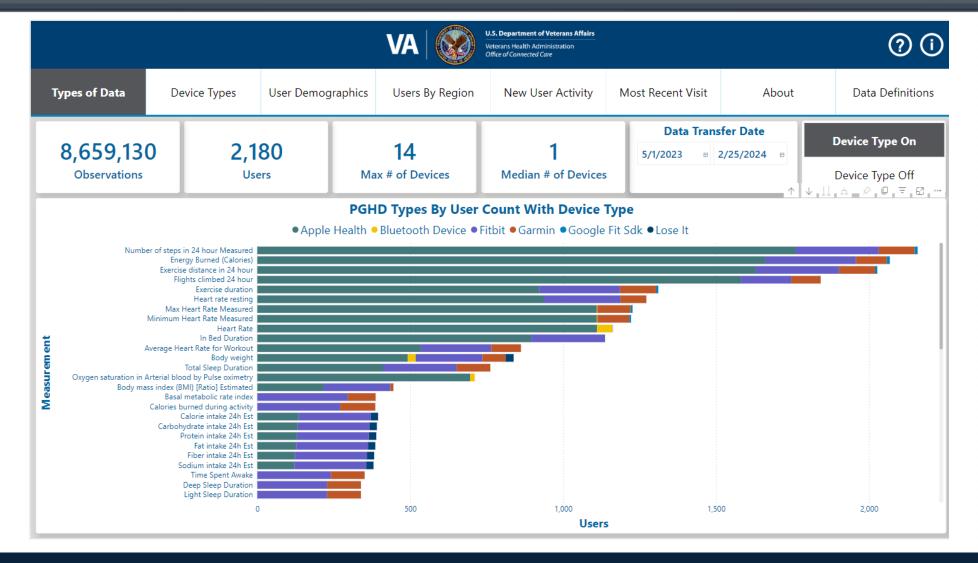


Share My Health Data: Categories





Share My Health Data: **Measurements**





My Healthe Vet & Annie

Source	Category	Device(s)	Total Observations	Total Users
MyHealth e Vet	Vital Signs	N/A	372,728	3,123
Annie	Vital Signs	N/A	95,087	1,415
Annie	Vital-signs	N/A	285,630	2,223
Annie	Laboratory	N/A	88,741	748
Annie	NA	N/A	196,111	6,142

^{*} Total observations with measurement dates between 5/1/2023 and 2/25/2024.





Nuances of PGHD

- PGHD can be messy!
- The FHIR specification standardizes data across many different sources of PGHD, but it does not "clean" or validate the accuracy of the data.

What to look out for:

Duplicate values

Zero and null values

Values out of range

Limited meta-data

Pay attention to date/time stamps



How to Access the PGHD Database

Stephanie Shimada, PhD

Investigator, eHealth Partnered Evaluation Initiative Center for Healthcare Organization and Implementation Research (CHOIR) VA Bedford Healthcare System, Bedford MA





Documents Required by Type of Access

IRB-approved Research Study



Must Upload:

- PODAA for Research Use Form
- IRB Protocol
- IRB Committee Approval Letter

Preparatory to Research



Must Upload:

 PODAA for Preparatory to Research Use Form Quality Improvement / Program Evaluation (Operations)



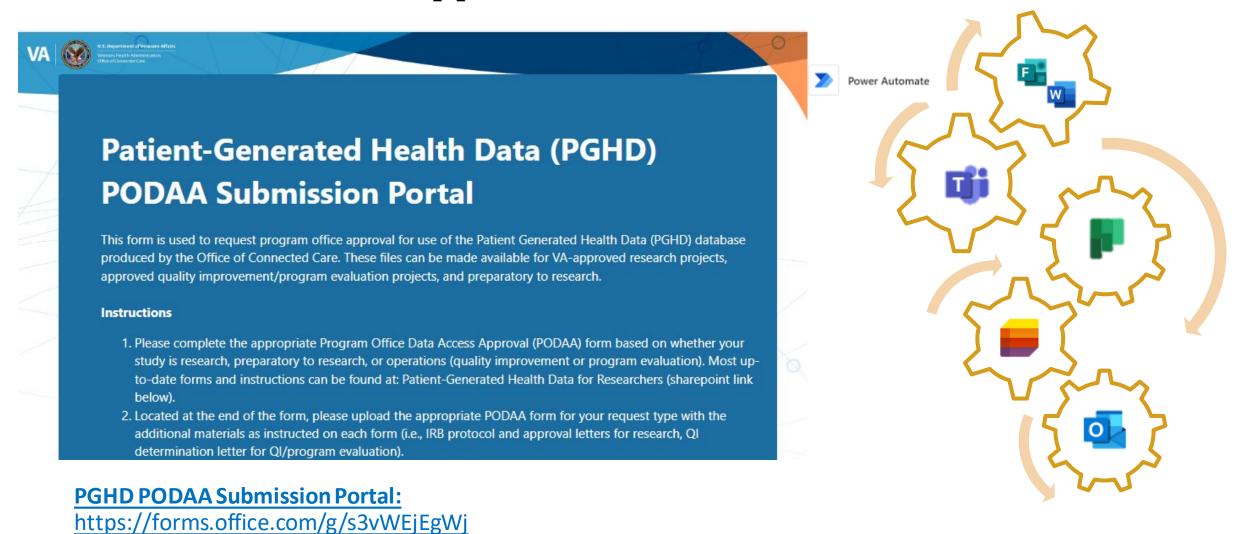
Must Upload:

- PODAA for Operations Use Form
- QI Determination Letter

PODAA forms at: Patient-Generated Health Data (va.gov)



Online Data Access Approval Process







PODAA Form Request/Submission Workflow

Researcher completes PODAA Form

 Researcher receives a detailed email confirming request submission and outlining the anticipated next steps.

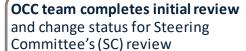
Initial Inquiry and Submission of PODAA Form



Upon submission the OCC PGHD access approval team receives:

- A message on Teams
- A task created in their Planner
- An item created in the SharePoint repository

Documenting Request and Initiating Review Process



- An automated message is sent via Teams alerting the Steering Committee
- The Steering Committee can post comments/ ask questions

Internal Initial Review and Steering Committee Engagement



Steering Committee makes decision:

- Approved:
- An email is sent providing next steps
- Not Yet Determined/Denied (eligible for resubmission):
- SC will request additional information or changes
- Request a conference call

Request Reviews, Votes, and Next Steps



Upon approval of request, the

Researcher will do one of the following:

- Upload the approval to DART and work with VINCI to access PGHD data (Research and Preparatory to Research)
- Obtain a CDW Workgroup (BaseCamp) for QI Project and request shared data access (Operations/QI Project requests)

Researchers are asked to review the Conditions for Use and adhere to the agreed-upon processes for reporting:

- Conference abstracts
- Manuscripts, reports, and other publications:
- New uses of data

Conditions for Use and Processes for Data



Data Access





Required Notifications to OCC

WHEN

- New analyses that differ substantially from originally approved PODAA
- Upon <u>submission</u> of a conference abstract
- Upon <u>acceptance</u> of a conference abstract
- Prior to initial submission of a manuscript (At least 14 days prior)
- At time of <u>acceptance</u> for publication of a manuscript

WHY

- To enable OCC to be aware of emerging research resulting from PGHD data
- To support more rapid translation of research/QI findings into action

HOW

 Upload documents via the same <u>PODAA portal</u> where you sought initial access to the PGHD database, referencing OCC Record ID (PGHD ###) at bottom of approved PODAA



Resource List

For All Requests:

- VHA Data Portal Page
- OCC PGHD for Researchers Sharepoint
- OCC Patient-Generated Health Data Sharepoint

For Operations Access Only:

- ➤ Make sure you have required CDW permissions: <u>Access & Permissions Lookup Tools</u> (va.gov)
- ➤ Request permissions if you do not: NDS ePAS UserRequestGuide.pdf (va.gov)
- ➤ Request a consult for new CDW Workgroup (for QI/Operations access): <u>BaseCamp (va.gov)</u>







THANK YOU! Questions?

PGHD Database Office Hours

2nd and 4th Wednesdays at 3:30pm ET

Starts March 13, 2024

Click here to join the meeting

Please check <u>OCC PGHD for Researchers</u> <u>Sharepoint</u> for any calendar updates.



CONTACT INFORMATION

Office of Connected Care:

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eHealth Partnered Evaluation Initiative:

Mark Zocchi, PhD Mark.Zocchi@va.gov

Stephanie Shimada, PhD

Stephanie.Shimada@va.gov







DATABASE & METHODS CYBERSEMINAR SERIES

Next session:
April 1, 2024 at 1 pm Eastern

Assessing Race and Ethnicity in VA Data

Learn more and register to attend

Data Spelunking: Strategies for Exploring VA Data Thursday, March 14, 2024 (2:00pm-3:00pm ET)

VA Informatics and Computing Infrastructure (VINCI)

Learn more and register to attend





Database & Methods BONUS SLIDES





Agenda for PGHD-related Research in the VA

Prioritize PGHD Use Cases and Data Types

Identify PGHD most relevant for patient care improvement.

Standardize Practice Protocols for PGHD

Develop user-centered PGHD protocols ensuring safety and effectiveness.

Enhance Interoperability and Integration

Address barriers to PGHD integration with the EHR.

Advanced Data Analysis Tools

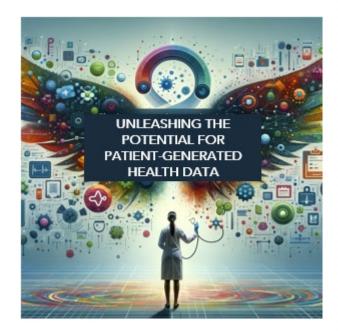
- Implement tools and algorithms for efficient analysis and risk prediction.

Evaluate Impact on Patient Outcomes

Assess PGHD's effect on health status and healthcare utilization.

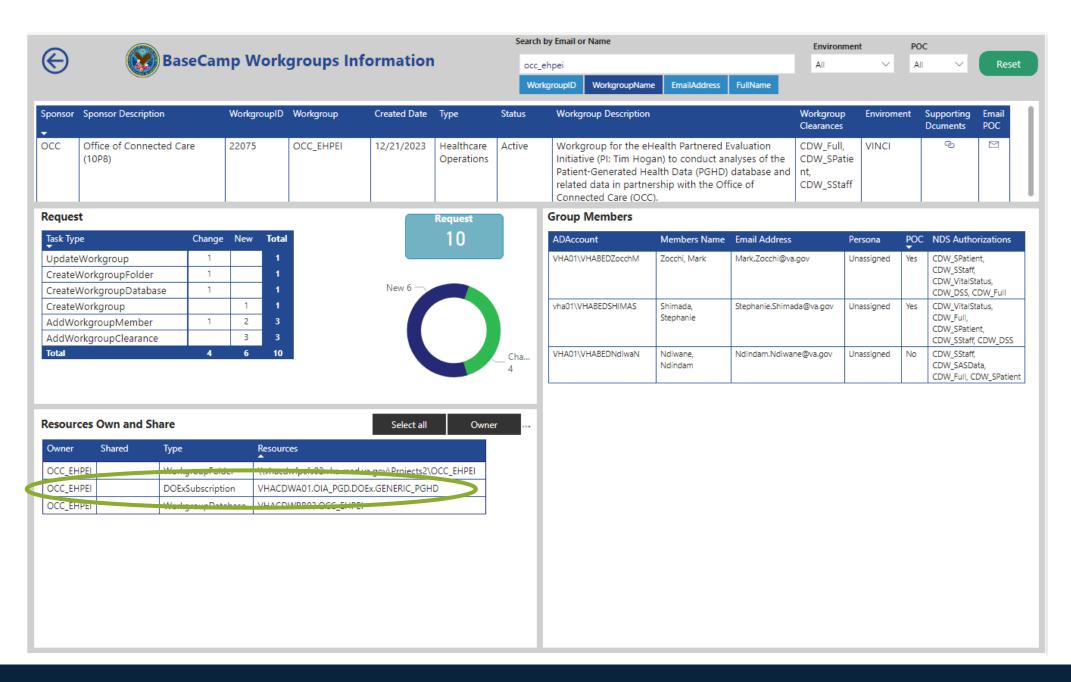
Implementation and Scalability

Research strategies for widespread PGHD adoption in healthcare.



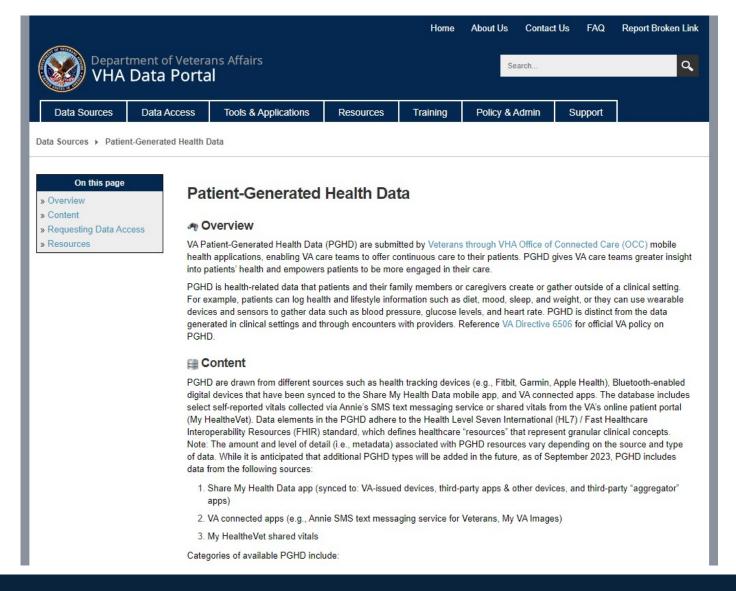
Nazi KM, Newton T, Armstrong CM. Unleashing the Potential for Patient-Generated Health Data (PGHD). *J Gen Intern Med*. Published online January 22, 2024. doi:10.1007/s11606-023-08461-4





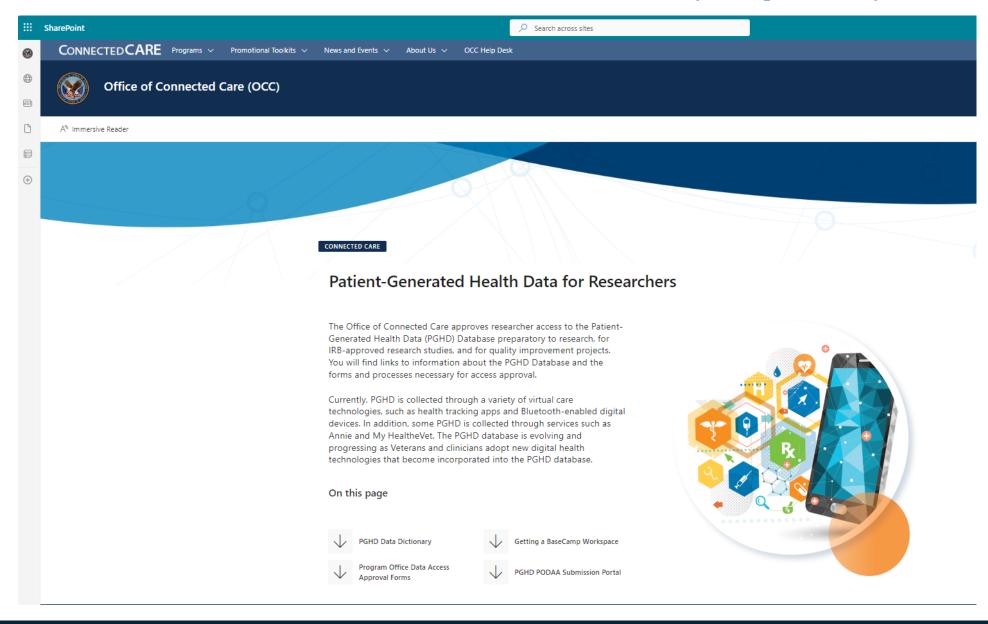


VHA Data Portal Page: Patient-Generated Health Data (va.gov)





<u>Patient-Generated Health Data for Researchers (sharepoint.com)</u>





Program Office Data Access Approval for Research Use

Patient Generated Health Data

This Program Office Data Access Approval (PODAA) form is used to request program office approval for research use of the Patient Generated Health Data (PGHD) database produced by the Office of Connected Care (OCC). This form should be used for IRB-approved research projects.

INSTRUCTIONS

- Complete the required information in Section 1.
- 2. Sign the form in Section 2. (Handwritten or digital signatures are accepted.)
- Upload this form along with your project's IRB Committee approval letter and IRB protocol via the submission form at the PGHD PODAA Submission Portal.
- 4. OCC will review your submission and either:
 - Email you a signed version of this form for you to upload to VINCI Data Access Request Tracker (DART),
 - b. Request additional information or changes from you, or
 - c. Request a conference call with you to discuss issues.
- Once you receive the approved form from OCC, upload it to DART in the Required Documents section to submit it with your request.
- After you receive the DART approval letter for your project, the assigned VINCI IT data manager will
 provide you with a link to a secure correspondence site for your project. Use this site to describe your
 study cohort inclusion criteria and your project's specific data needs.





Program Office Data Access Approval for Preparatory to Research Use

Patient Generated Health Data

This form is used to request program office approval when planning for research use of the Patient Generated Health Data (PGHD) database produced by the Office of Connected Care (OCC). This form should be used when requesting limited access preparatory to research. A new request using the Program Office Data Access Approval (PODAA) for Research Use form must be submitted to use the data for research once a study is funded and has obtained IRB and local R&D approvals.

INSTRUCTIONS

- Complete the required information in Section 1.
- 2. Sign the form in Section 2. (Handwritten or digital signatures are accepted.)
- Upload this document via the <u>PGHD PODAA Submission Portal</u>.
- 4. OCC will review your submission and either:
 - Email you a signed version of this form for you to upload to VINCI Data Access Request Tracker (DART),
 - b. Request additional information or changes from you, or
 - c. Request a conference call with you to discuss issues.
- 5. Once you receive the approved form from OCC, upload it to DART in the Required Documents section to submit it with your request as part of the DART Preparatory to Research Request Process.
- After you receive the DART approval letter for your project, the assigned VINCI IT data manager will
 provide you with a link to a secure correspondence site for your project. Use this site to describe your
 preparatory to research needs.





Program Office Data Access Approval for Operations Use

Patient Generated Health Data

This Program Office Data Access Approval (PODAA) form is used to request program office approval for quality improvement, program evaluation, or other time-limited operations projects that require the Veterans Health Administration (VHA) Patient Generated Health Data (PGHD) produced by the Office of Connected Care (OCC).

Instructions

- 1. Complete required information in Section 1.
- 2. Sign the form in Section 2. (Handwritten or digital signatures are accepted.)
- 3. Upload this document along with the QI Determination Letter and Sponsor Memo (if applicable) via the submission form at the PGHD PODAA Submission Portal.
- 4. OCC will review your submission and
 - May request additional information, changes, or a conference call with you to discuss data access if needed.
 - b) Approve time-limited access to the PGHD via BaseCamp if your request is approved.
- 5. Ensure NDS operations access is in place. Note: Submitting a NDS Access Form for Health Operations in VA's Electronic Permission Access System (ePAS) will be required if you are requesting access to the Corporate Data Warehouse (CDW) for the first time, or if you need to modify existing data access permissions to either of these data sources.
- Request a new workgroup consultation via <u>BaseCamp</u>.
- 7. Once your CDW Workgroup has been created, OCC will share PGHD with your Workgroup.





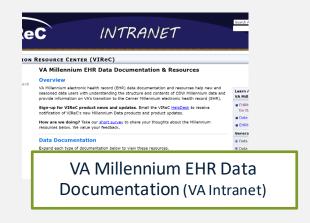
Resources for VA Data Users

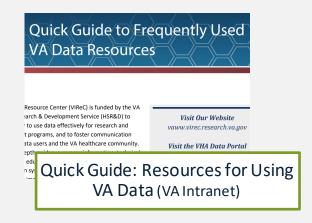
Select image to visit page



















Questions about using VA Data?

HSRData Listserv

- Community knowledge sharing
- ~1,400 VA data users
- Researchers, operations, data stewards, managers
- Subscribe by visiting
 vaww.virec.research.va.gov/Support/HSRData-L.htm (VA Intranet)

VIReC HelpDesk

- Individualized support
- O Request Form:

varedcap.rcp.vaec.va.gov/redcap/surveys/?s=KXMEN77LXK (VA Intranet)

