2024 AMDR Member Data: Definitions & Collection Methodology

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Dataset Summary:

Our goal is to produce a fully-anonymized, open-access dataset that shows sales of all reprocessed devices to hospitals and surgical centers working with AMDRmember reprocessors. The dataset also includes an estimate or actual financial savings from the purchase of reprocessed devices compared to the purchase of the same device as manufactured by the original equipment manufacturer (OEM). We also seek to quantify the pounds of waste diverted by using reprocessed devices. The end product anonymizes the names of the reprocessors and blinds their association with their hospital client, while data on the type of hospital, regional location, and urban/rural status is included.

With a signed NDA and DUA, researchers may be able to access partial or full datasets, including name of participating reprocessor and name of hospital purchaser. However, use of data requires anonymization of these details.

Purpose:

The purpose of this document is to define the data request made of members, and the methodology employed by the Association of Medical Device Reprocessors (AMDR) to aggregate, compile and extrapolate the data set in order to best represent AMDR members and the valuable role reprocessing plays in reducing cost and waste in healthcare.

There are several types of data collected from AMDR's members:

- 1. Product Data information about the products reprocessed and sold
- 2. Account Data information about who the products were sold to
- 3. Sales Data information about the quantity of products sold and to who
- 4. Company Data information about AMDR member companies

The above data is collected from the members on an annual basis in Q1 for the previous year ending December 31. AMDR to request data of members by January 15 of each year for the prior year. Members are required to submit the data sets by February 15 of each calendar year. Once the data is received, it is reviewed (pursuant to our data intake procedure) by AMDR's President for data quality issues. Any issues identified are to be resolved by AMDR and members no later than February 24 as AMDR is to aggregate and anonymize the dataset by this date each year. AMDR to work with data committee to prepare for release by March 30, making a report to the AMDR Board and AMDR's deadline to release/publicize the data is April 30. This is all consistent with AMDR's data collection plan amended in September 2024 (see AMDR data/procedures file folder). This document details the data request as well as how the data will be validated to ensure completeness and accuracy.

Background:

Because AMDR's member data is sensitive and contains proprietary information, each member enters into a Data Use Agreement (DUA) with AMDR. AMDR's President, outside counsel and independent data analysts are all subject to DUAs with AMDR, which permit the collection and use of member data so it may be aggregated to develop collective contributions to various metrics. Outside counsel reviews the data request and responses are provided by members directly to AMDR's President. AMDR's President reviews data outputs, and seeks input from other AMDR. AMDR staff and consultants (including AMDR's independent data analyst), as necessary, the AMDR Board, on potential legal issues involved with the public release of such data.

All raw AMDR member data will be kept solely on a secure, shared sync file and only AMDR counsel, AMDR President, Communications Director, and AMDR data analysts will be given access. Counsel to AMDR will remove access to the data set to any of these staff upon their termination, retirement, incapacitation, etc. AMDR counsel wants to ensure that raw member data is NOT in the AMDR files and this system ensures that it is not. However, in the course of communicating with AMDR members, AMDR President will have emails with data attachments. At the end of each year's data collection, anonymization and aggregation, AMDR President will move all data files from email to the SharedSync file and remove from AMDR's mail servers. An annual calendar item reminder has been set to do this each spring.

Data Sources by Workstream:

The below lists the various data sources by workstream. The goal is to capture the inputs for each workstream and identify data that is used multiple times (and in multiple workstreams).

Product Data

Product data is provided for the various medical devices that a member reprocesses. The data provided comes from a member's ERP system. A description of each field is provided below. **Note:** Product data related to intercompany transactions is excluded. AMDR is only seeking data related to healthcare delivery clients.

No	Field	Description
1	Item #	A unique reference number maintained by the member reprocessing the medical device.
2	GTIN*	The Global Trade Item Number that provides a unique identification for a product. All products have a GTIN which can be cross referenced with the Access GUDID Database managed by the National Institutes of Health (NIH). The GTIN numbers allows AMDR to uniquely identify a device as the number is universal. Some members do not provide GTINs
3	Product Description	The product description is as accurate and complete as possible to allow analysis to group similar products together. They are listed by product family, for example, "Achieve," "Nellcor Pulse Oximeter," etc.

4	Product category	The product category allows for product data to be easily analyzed in aggregate and for data professional to verify consistency. Preset tags for Cardiology, Patient Care or Surgical.
5	OEM	The Original Equipment Manufacturer. Members use the most recent, most complete name of manufacturer and use division name for large companies (J&J); this data allows AMDR to demonstrate reach across the industry.
6	Original Item #	The unique reference number for a medical device as assigned by the OEM.
7	# of Turns	The number of times a medical device can be reprocessed before it must be discarded. Note: The number of turns will NOT be used for direct AMDR messaging, but strictly for academic purposes, such as in an LCA.
8	Device Weight	The weight of the medical device itself (excluding packaging). For consistency, we ask you calculate all weights into US pounds and provide the weight per unit. If something is sold in a multi-unit pack, we ask for the per device unit weight so that our total weights are all by device, not by pack.
9	UoQ	The unit of quantity for a device (i.e. how many devices are in a pack, case, etc.). Device Weight / UoQ = Weight Per Device
10	Reprocessing location	Where a device is reprocessed if a member has more than one facility.

* Primary Key (Unique Identifier)

Account Data

Account data is provided for all members' customer accounts that use reprocessed medical devices. The data provided comes from a member's ERP or CRM system. A description of each field is provided below.

No	Field	Description
1*	NPI (National Provider Identifier) or Equivalent	A unique 10-digit identification number issued to health care providers in the United States by the Centers for Medicare and Medicaid Services (CMS).
2*	Account Number	The unique identification number assigned to an account.
3	Account Name	The name of the healthcare facility receiving the reprocessed device. The

4	Туре	lowest level facility name should be used. This allows AMDR to identify like facilities between members as well as identity and avoid duplication. The facility type. "Acute care (Hospitals)" is used for hospitals and "Non Acute Care for OBL, doctor offices, ASCs, etc" for all other medical facilities, including labs, surgery centers, offices and clinics. Other is used if the customer is a distributor, this is a white label product/account, or the end point of sale is some sort of healthcare distributorship. If, however, the healthcare distribution point will go to acute care facilities, mark as acute care please.
5	Military	Denotes a military vs. non-military facility.
6	Address	The facility address including suite number if applicable. Addresses are used to identify like facilities between members as well as identify and avoid duplication.
7	City	The facility city.
8	State	The facility state if the facility is in the US.
9	ZIP	The facility zip if the facility is in the US.
10	Country	The country the facility is located in.

* Primary Key (Unique Identifier)

Sales Data

Product data by Account is provided by each member. A description of each field is provided below.

No	Field	Description
1*	NPI (National Provider Identifier) or Equivalent	A unique 10-digit identification number issued to health care providers in the United States by the Centers for Medicare and Medicaid Services (CMS). If you do not have this figure, AMDR will provide it in Q4, 2023 and we request you associate the NPIs with all accounts in your reporting back with the 2023 data submission. This immensely reduces the work load in de-duplicating the data set. If no NPI, members left empty to denote distributorships, hospital aggregation points, etc.
2	Account Number	The unique identification number assigned to an account.

3	Account Name	The name of the healthcare facility receiving the reprocessed device. The lowest level facility name should be used. This allows AMDR to identify like facilities between members as well as identity and avoid duplication.
4**	GTIN	The Global Trade Item Number that provides a unique identification for a product. All products should have a GTIN which can be cross referenced with the Access GUDID Database managed by the National Institutes of Health (NIH). The GTIN numbers allows AMDR to uniquely identify a device as the number is universal.
5	Product Description	The product description should be as accurate and complete as possible to allow analysis to group similar products together. Please list by product family, for example, "Achieve", "Nellcor Pulse Oximeter", etc.
6	Product type	Drop down provided. Please identify if device is "cardiovascular," "patient care" or "surgical."
7	Total Devices Collected (for Reprocessing)	This is the total number of devices collected from the facility; this data point allows AMDR to address issues such as savings per device. Members who collect in partnership with another reprocessor: only the member who collects the device at the customer should count the device. Thus if you receive devices from a different member, do not count the device.
8	Total Reprocessed Devices Sold	This is the total number of devices sold to the facility; this data point allows AMDR to address issues such as savings per device. Devices collected and sold to the same institution should be on the same line so we can compare collections to buy-back across the industry. Members who reprocess in partnership with another member: only the member who delivers the sold device to the customer should report the product sale. Thus if you collect devices but delivery them to another member for reprocessing, do not count the device.

9	Savings	Savings calculations are the difference between the reprocessed sales price and the Average Sales Price (ASP) OR actual costs paid by the facility; this allows AMDR to calculate estimated savings across facilities within the membership. The methodology used by each member is provided to AMDR. As per reference item 5 below, please provide all savings in US dollars using the prior use's average rate of conversion. Please do not report negative savings or explain why.
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* Provides linkage to Account Data

** Provide linkage to the Product Data

Company Data

Company data is provided by each member reprocesses. A description of each field is provided below.

No	Field	Description
2	Employees	We want to paint a picture of a large, green workforce. Please indicate the number of full time employees dedicated to Reprocessing. This is for industry statistical purposes and will be aggregated for public consumption to demonstrate our impact.
3	Part time employees	Number of part-time employees, technicians, contractors, and related working in support of the R business - W2 or 1099.
4	# of Manufacturing Facilities	The number of reprocessing facilities, if things have changed.
5	Reprocessing Facility Location	If things have changed, the address, city, state, and zip of the reprocessing facility. Multiple locations should be listed on separate lines.

Reference Data:

The below lists the reference data that was used in the analysis and reporting of the Member data.

- Access GUDID The Global Unique Device Identification Database (GUDID) contains key device identification information submitted to the FDA about medical devices. <u>https://accessgudid.nlm.nih.gov/</u>
- 2. GMDN The Global Medical Device Nomenclature (GMDN) is a system of internationally agreed generic descriptors used to identify all medical

device products.

https://www.gmdnagency.org/https://www.gmdnagency.org/

- DMIDS The German Medical Devices Information and Database System. <u>https://www.bfarm.de/EN/Medical-</u> <u>devices/Portals/DMIDS/_node.htmlhttps://www.bfarm.de/EN/Medical-</u> <u>devices/Portals/DMIDS/_node.html</u>
- Definitive Healthcare Hospital database that lists the name, address and bed count for all hospitals in the US. Note: In 2020-2021, this information was provided by Lars Thording of Innovative Health. <u>https://www.definitivehc.com/</u>
- FX Rates The annual average exchange rate is used to covert from USD to EUR at 12/31/24. https://www.federalreserve.gov/releases/g5a/current/
- US News & World Report Hospital Rankings Global authority in hospital rankings. <u>https://www.prnewswire.com/news-releases/us-news-releases-2020-21-best-hospitals-rankings-and-special-hospital-heroes-seriesduring-historic-year-for-health-care-301100746.html
 </u>
- Military Hospitals Listing of all military healthcare facilities. <u>https://www.medicineandthemilitary.com/community-and-lifestyle/military-medical-facilities-map</u>
- Defense Medical Information System (DMIS) Listing of past and current United States Department of Defense (DOD) medical facilities <u>https://health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Military-Hospitals-and-Clinics/Geographic-Reference-Information/DMIS-ID-Tableshttps://health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Military-Hospitals-and-Clinics/Geographic-Reference-Information/DMIS-ID-Tableshttps://health.mil/Military-Hospitals-and-Clinics/Geographic-Reference-Information/DMIS-ID-Tables
 </u>
- 9. Waste Disposal the cost for medical waste disposal. We are using the "All" column, regulated medical waste, to assume \$1286 per ton." There are 2,000 pounds in a ton. Or \$0.643 per pound. <u>https://practicegreenhealth.org/membership/awards/sustainability-</u> benchmark-reports

(Median cost per ton):					
Median cost per ton	All	Small	Large	Top 25	Waste Circle
Solid waste	\$134	\$146	\$122	\$132	\$170
Recycling	\$157	\$165	\$151	\$194	\$157
Regulated medical waste (onsite and offsite)	\$1,286	\$1,435	\$1,135	\$1,835	\$2,402
Hazardous waste	\$5731	\$7378	\$4736	\$6243	\$6512
Total waste	\$308	\$322	\$305	\$325	$\triangle - \hat{a}^{372}$
Note: Total waste is the sum of solid waste, recycling, regulated medical waste, and hazardous waste. Pharmaceutical and food waste are counted as subsection to sufficient waste streams. Cost for recycling includes only those facilities that had a net cost (not a profit) for their recycling program.					

Tools Used:

- 1. Python Notebooks : Local Python scripts utilized to transform the data and generate results.
- 2. Tableau Used to generate the visualizations.
- 3. Google Sheets To maintain data consistency while sharing data between Dan and Pranay
- 4. Dropbox (maintained by Mason Weeda at OFW) for keeping sensitive member data (raw data) that is not anonymized or aggregated.

5. Microsoft Office – Used for data collection from AMDR's members as well as reporting.

Data Preparation:

From the data sources listed above, we identified synergies to reduce data duplication between the various tables. For each area, the data was cleansed and validated as follows:

Product Data

Field	Data Preparation	
Item #	 Confirm this field is not NULL or blank 	
GTIN	 Confirm this field is not NULL or blank 	
	- Reconcile to Access GUDID database	
Product Description	- Confirm this field is not NULL or blank	
Product category	 Confirm the Product Category is one of the following three values (3): Cardiovascular, Patient Care, Surgical 	
OEM	- Confirm this field is not NULL or blank	
Original Item #	- Confirm this field is not NULL or blank	
# of Turns	- Confirm this field is populated with an integer value	
Device Weight	 Confirm this field is populated with a decimal value in US pounds 	
UoQ	- Confirm this field is populated with an integer value	
Reprocessing location	 Confirm reprocessing location reconciles with the information listed on the 'Company' tab 	

Account Data

Field	Data Preparation
NPI (National	 Confirm this field is not NULL or blank
Provider Identifier) or Equivalent	- Reconcile to CMS Database
Account Number	- Confirm this field is not NULL or blank
Account Name	- Confirm this field is not NULL or blank
Туре	 Confirm the Type is one of the following two values (2): Acute Care, Other
Military	 Confirm Military is one of the following two values (2): Military, Non-Military
Address	- Confirm this field is not NULL or blank

	- Confirm address string is a valid address
City	 Confirm this field is not NULL or blank Confirm address string is a valid address
State	 Confirm this field is not NULL or blank Confirm address string is a valid address
ZIP	 Confirm this field is not NULL or blank Confirm address string is a valid address
Country	 Confirm this field is not NULL or blank Confirm address string is a valid address

Sales Data

Sales Dala	
Field Name	Data Preparation
NPI (National	 Confirm field is not NULL or blank
Provider Identifier) or Equivalent	 Confirm this value exits on the 'Accounts' tab
Account Number	- Confirm this field is not NULL or blank
Account Name	- Confirm field is not NULL or blank
GTIN	- Confirm field is not NULL or blank
	- Confirm this value exits on the 'Products' tab
Product Description	- Confirm field is not NULL or blank
Product type	 Confirm drop down field is chosen to identify one of three categories for the device
Total Devices Collected (for Reprocessing)	 Confirm this field contains an integer value and please confirm collections and sales for the same device for the same client are on the same line.
Total Reprocessed Devices Sold	- Confirm this field contains an integer value
Savings	 Confirm this field contains a decimal value in US dollars

Company Data

Field Name	Data Preparation
Full time employees	 Confirm this field is populated with an integer value in US dollars
Part time employees	
# of Manufacturing Facilities	- Confirm this field is populated with an integer value

	-
Reprocessing Facility Location	 Confirm address string is a valid address Confirm reprocessing location reconciles with the information listed on the 'Product tab

Methodology:

All members is provided with a "validation" report for the data they submitted. The report will list any data quality issues or errors the member needs to address. The member will then be asked to submit corrected data in a timely manner and the process re-run.

In all workflows, Tool Containers will be used to break out sub-processes and highlight areas that could need updating or judgement when the workflow is run. Additionally, comments will be listed at each step of the workflow allowing an end user to understand what is happening at each step in the process.

Data Governance:

Data Quality

The Python notebooks workflows are designed to be run annually without having to modify the workflow unless a change is requested or made to dataset. The notebook uses multiple flat files and other sources as inputs. Each of the various data sources is validated as follows:

Member Data – these are captured in an Excel template. These inputs are then converted to Excel (database) files which are read-only. A validation is performed on each file received. A listing of all supplemental data sources used are provided in an Excel report.

Year over Year Changes

It is critical that Members reporting the numbers for their respective companies do so in a consistent manner year over year to ensure the accuracy of reporting. If discrepancies are observed by AMDR's data scientist, they will reach out to the member for clarification.

Appendix:



Summary Reporting Template – Example

	Prior Year	Current Year	% Difference
Number of Accounts (hospitals & surgical centers)			
Total Devices Collected (for Reprocessing)			
Total Reprocessed Devices Sold			
Savings US\$			
Savings €			
Waste Diverted LBS			
Waste Diverted KG			
Waste Savings US\$			
Waste Savings €			
Number of Countries with Accounts			
US Military Bases			
German University Hospitals			
Jobs			