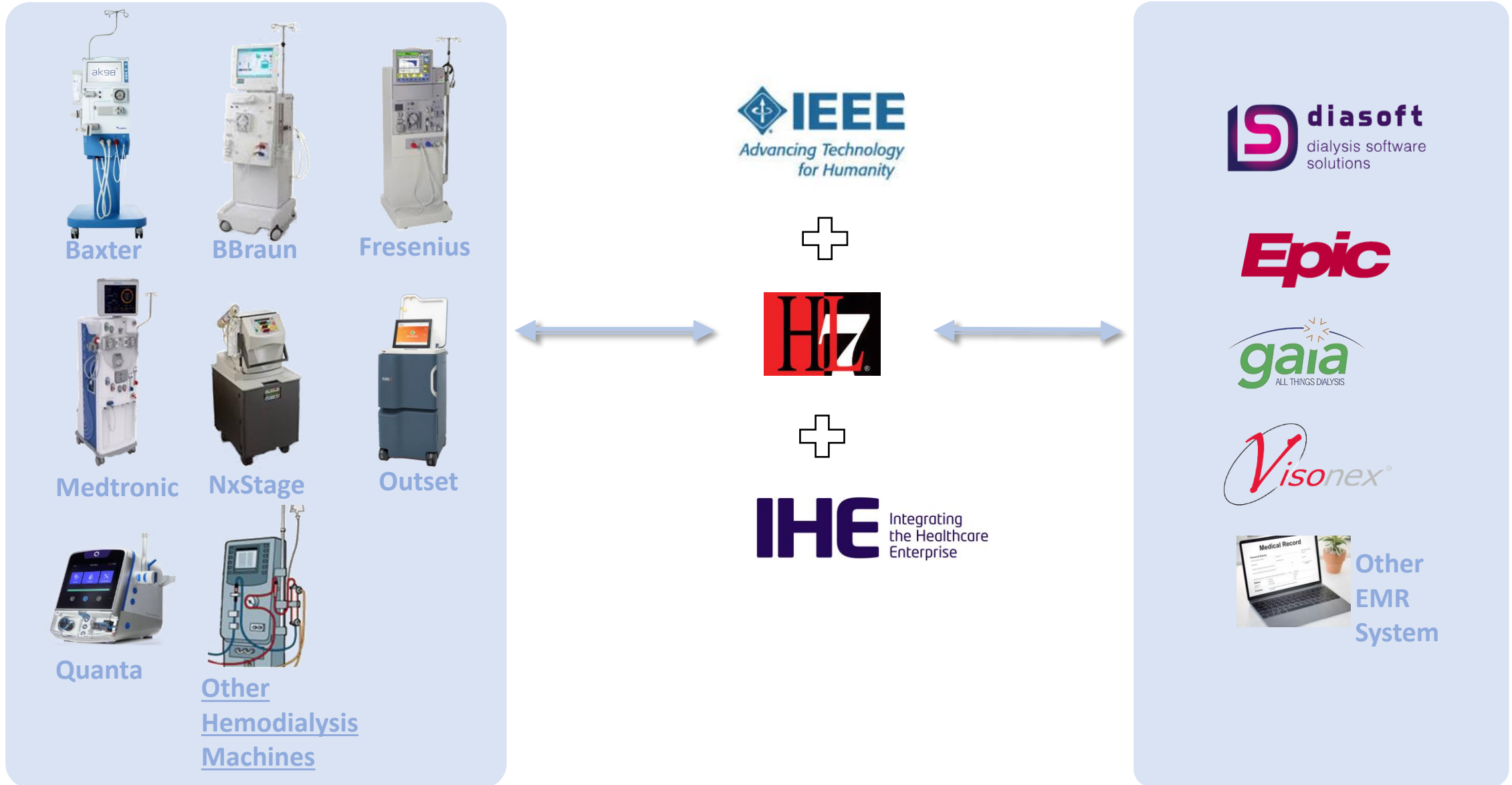


Dialysis Interoperability



Introduction

Dialysis Interoperability Consortium

- Partnered Market Leaders in Hemodialysis Products & Services
- Initiated and Managed by DaVita Kidney Care

Service Partners:

- DaVita Kidney Care
- Fresenius Medical Care
- Dialysis Clinic, Inc.
- Renal Healthcare Association

Vendor Partners:

- Fresenius Medical Care
- NxStage
- Baxter
- B-Braun
- Medtronic
- Quanta
- Outset Medical

EMR Partners:

- Epic
- Diasoft
- Gaia
- Visonex

Consortium Objective

Develop Standards that Promote Dialysis Device
Interoperability

Initial focus specific to acute and chronic hemodialysis devices

Development guidance provided by Paul Schluter

History

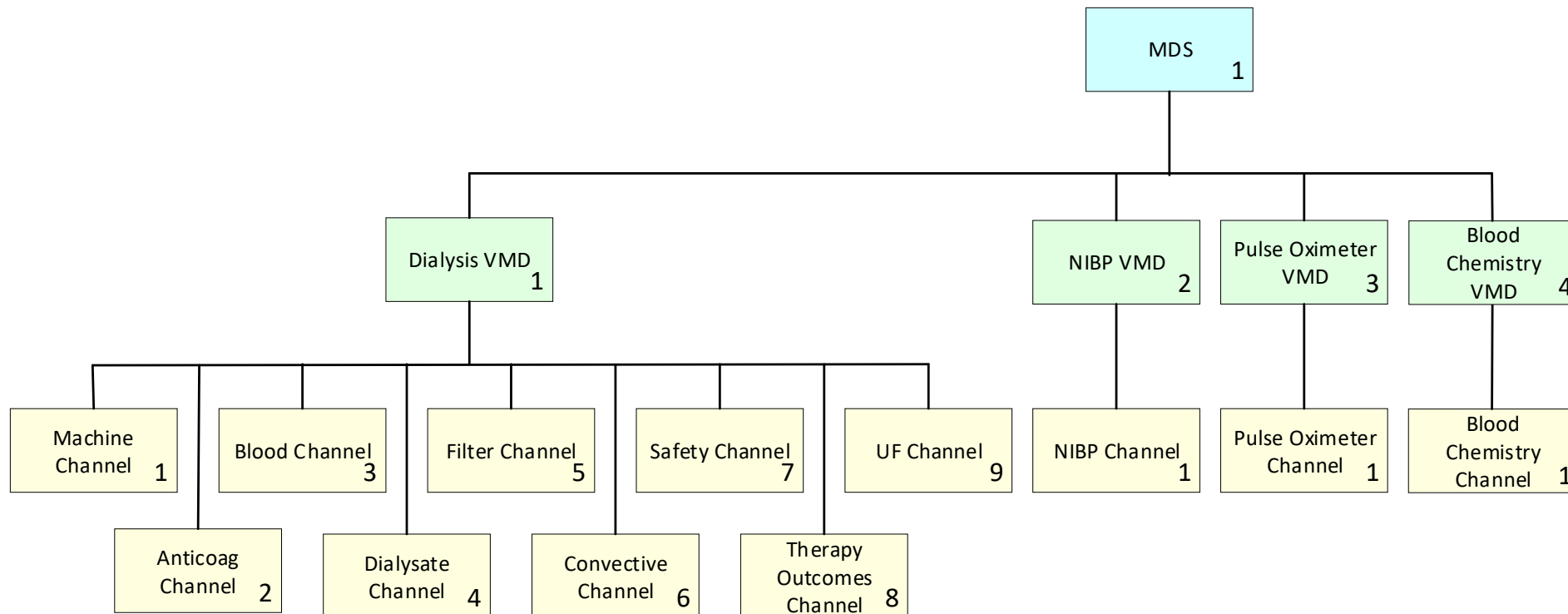
- Release 3 – Released January 2021
 - Defined terminology
 - Defined Treatment Status Message (PCD-01)
 - Defined Alarm Status Message (PCD-04)
- Release 4 – Expected Release April 2023
 - Defines Patient Identification using IHE Patient Demographic Query (PDQ)
 - Defines Prescription Transfer from EMR to dialysis machine using HL7 Query By Parameter with a Segment Pattern Response (QBP/RSP)

IEEE Nomenclature

- Define data objects that are needed for communicating device, treatment, and prescription information.
- Each data object is assigned a unique name and number
- Define data object format and unit of measure
- Determine (M)andatory, (O)ptional, and (C)onditional status
- Create universal list of values, where applicable
- Define valid ranges / limits

Containment Tree

- Categorize Virtual Medical Devices (VMD)
- Identify VMD Channel(s)
- Each channel contains the data object values which are called Metrics.



Data Objects

Example of Blood Pump Objects

REFID	Alert Type	Dialysis Device VMD	Dialysis Common Name	Definition	Phase	Message	Temporal	Data Type	Format	UOM	CARD	USE	Rx Use
.. MDC_DEV_HDIALY_BLOD_PUMP_CHAN (70947)											1..1	M	M
... MDC_HDIALY_BLD_PUMP_BLOOD_FLOW_RATE_SETTING (16935956)		Blood Pump	Blood Flow Rate Setting	The rate at which the user programmed the blood flow	Intradialytic	Parameter	Episodic	Numeric	XXX	mL/min	1..1	M	M
... MDC_HDIALY_BLD_PUMP_BLOOD_FLOW_RATE (158740)		Blood Pump	Actual Blood Flow Rate	Adjusted blood flow rate based on the blood flow rate setting and pressure drop caused by blood line, <u>needle</u> and vascular access	Intradialytic	Status	Periodic	numeric	XXX	mL/min	0..1	O	X
... MDC_HDIALY_BLD_PUMP_BLOOD_FLOW_RATE_MEAN (158743)		Blood Pump	Average Blood Flow Rate	Average of the actual blood flow rate over the course of treatment.	Intradialytic	Status	Periodic	Numeric	XXX	mL/min	0..1	O	X
... MDC_HDIALY_BLD_PRESS_ART (158744)	phys tech high low thr	Blood Pump	Arterial Pressure	Pressure of arterial access line pre blood pump	Intradialytic	Status	Periodic	Numeric	±XXX	mmHg	1..1	M	X
... MDC_HDIALY_BLD_PUMP_MODE (158604)		Blood Pump	Blood Pump Mode	Therapy method in which blood is retrieved and returned to the patient.	Intradialytic	Parameter	Episodic	TBL 05	Alphanumeric	N/A	1..1	M	M
... MDC_EVT_HDIALY_BLD_PUMP_STOP (198242)	tech	Blood Pump	Blood Pump Stop	Notification that the blood pump has stopped	Intradialytic	Alert	Episodic	Bool	T / F	N/A	0..1	M	X

Device and Treatment Status

- Device and treatment observations are periodically transmitted to the EMR using an IHE PCD-01 messages.
- The messages are conveyed to a site specific TCP port.
 - Note: This does not mean that the machine directly connects to EMR server. There may be cases where an intermediate server converts machine data to the HL7 messages.
- The message contains the Data Object Values that are appropriate for the machine state and type of therapy.

Device and Treatment Status – Sample Message

Sample PCD-01 Message (Partial)

MSH|^~\&|ACME_Dialysis_Machine^080019FFFE3ED02D^EUI-
64|||20191003092006+0000||ORU^R01^ORU_R01|20191003092005|P|2.6|||AL|NE|||IHE_PCD_001^IHEPCD^1.3.6.1.4.12559.11.1.1.129^ISO
PID|||Scrubber 2000/SC678932^^^"^U||^U
OBR|1||080019FFFE3ED02D20110602045842^ACME_Dialysis_Machine^080019FFFE3ED02D^EUI-
64|70929^MDC_DEV_HDIALY_MACHINE_MDS^MDC|||20191003092005+0000
OBX|1|ST|70929^MDC_DEV_HDIALY_MACHINE_MDS^MDC|1.0.0|||||F
OBX|2|ST|67880^MDC_ATTR_ID_MODEL^MDC|1.0.0.1|NxStage System One|||||F
OBX|3|ST|531970^MDC_ID_MODEL_MANUFACTURER^MDC|1.0.0.2|NxStage|||||F
OBX|4|ST|531969^MDC_ID_MODEL_NUMBER^MDC|1.0.0.3|System One|||||F
OBX|5|ST|531972^MDC_ID_PROD_SPEC_SERIAL^MDC|1.0.0.4|1000478|||||F
OBX|6|ST|531975^MDC_ID_PROD_SPEC_SW^MDC|1.0.0.5|1.2.3.4|||||F
OBX|7|ST|70934^MDC_DEV_HDIALY_VMD^MDC|1.1|||||F
OBX|8|ST|70939^MDC_DEV_HDIALY_MACH_CONFIG_CHAN^MDC|1.1.1|||||F
OBX|9|DTM|158592^MDC_HDIALY_MACH_TIME^MDC|1.1.1.1|20191003092005+0000|||||F
OBX|10|ST|158594^MDC_HDIALY_MACH_MODE_OF_OPERATION^MDC|1.1.1.3|TX|||||F
:
OBX|16|ST|70947^MDC_DEV_HDIALY_POD_PUMP_CHAN^MDC|1.1.3.2|250|ml/min^milliliters per minute^UCUM|||||F
OBX|17|NM|16935956^MDC_HDIALY_PUMP_BLOOD_FLOW_RATE_SETTING^MDC|1.1.3.2|250|ml/min^milliliters per minute^UCUM|||||F
OBX|18|NM|158744^MDC_HDIALY_BLD_PRESS_ART^MDC|1.1.3.4|-75|mm[Hg]^Millimeters of Mercury^UCUM|< -200|||||F

Identifier

Value

Alarm
Limit

Unit of
Measure

Alarm Status

- Alarm status is reported to an Alert Manager using IHE PCD-04 messages.
- The messages are conveyed to a site-specific TCP port. This typically uses a different port than the Treatment Status Messages.

Alarm Status – Sample Message

Sample PCD-04 Message

```
MSH|^~\&|ACME_Dialysis_Machine^080019FFFE3ED02D^EUI-  
64|||20191003092025+0000||ORU^R40^ORU_R40|20191003092024|P|2.6|||AL|NE|||IHE_PCD_001^IHEPCD^1.3.6.1.4.1.19376.1.6.1.4.1^ISO  
PID|||Scrubber 2000/SC678932^^^"^U|^^^^^^U  
OBR|1||080019FFFE3ED02D20110602045842^ACME_Dialysis_Machine^080019FFFE3ED02D^EUI-  
64|196616^MDC_EVT_ALARM^MDC|||20191003092024+0000  
OBX|1|ST|70929^MDC_DEV_HDIALY_MACHINE_MDS^MDC|1.0.0|||||F  
OBX|2|ST|70934^MDC_DEV_HDIALY_VMD^MDC|1.1|||||F  
OBX|3|CWE|196670^MDC_EVT_LO^MDC|1.0.0.0.1|158776^MDC_HDIALY_BLD_PUMP_PRESS_VEN^MDC|||PH~SP|||F  
OBX|4|NM|158776^MDC_HDIALY_BLD_PUMP_PRESS_VEN^MDC|1.1.3.15.2|15|mm[Hg]^Millimeters of Mercury^UCUM|20-400||||F  
OBX|5|ST|68481^MDC_ATTR_EVENT_PHASE^MDC|1.0.0.0.3|start|||||F  
OBX|6|ST|68482^MDC_ATTR_ALARM_STATE^MDC|1.0.0.0.4|active|||||F  
OBX|7|ST|68483^MDC_ATTR_ALARM_INACTIVATION_STATE^MDC|1.0.0.0.5|enabled|||||F
```

Patient Identification

- The dialysis machine may query the EMR for a unique patient identifier using the IHE Patient Demographic Query (PDQ).
- The dialysis machine sends as much identifying information as it has available.
 - First name
 - Last name
 - Date of birth
 - Gender
- The EMR sends back an enterprise qualified list of patients that match the information as requested by the dialysis machine.
- The user selects one of the patients from the list.

Patient Identification – Sample Messages

Sample PDQ Request Message

```
MSH|^~\&|ACME Dialysis Machine^00059AFFFE3C7A00^EUI-  
64|||202204120831230000||QBP^Q22^QBP_Q21|20220412083123138|P|2.6|||AL|NE||||  
QPD|IHE PDQ Query|20220412083123153|@PID.5.1^Smith~@PID.5.2^John  
RCP|||R|
```

Sample PDQ Reply Message

```
MSH|^~\&|||ACME Dialysis Machine^00059AFFFE3C7A00^EUI-  
64||202204120831230000||RSP^K22^RSP_K21|20220412083123170|P|2.6|||NE|NE||||  
MSA|AA|20220412083123138  
QAK|20220412083123153|OK|IHE PDQ Query|2|2|0  
QPD|IHE PDQ Query|20220412083123153|@PID.5.1^Smith~@PID.5.2^John  
PID|||555444222111^MR||Smith^John^U||19640306  
PID|||555444999999^MR||Smith^John^U||20000921
```

Prescription Transfer

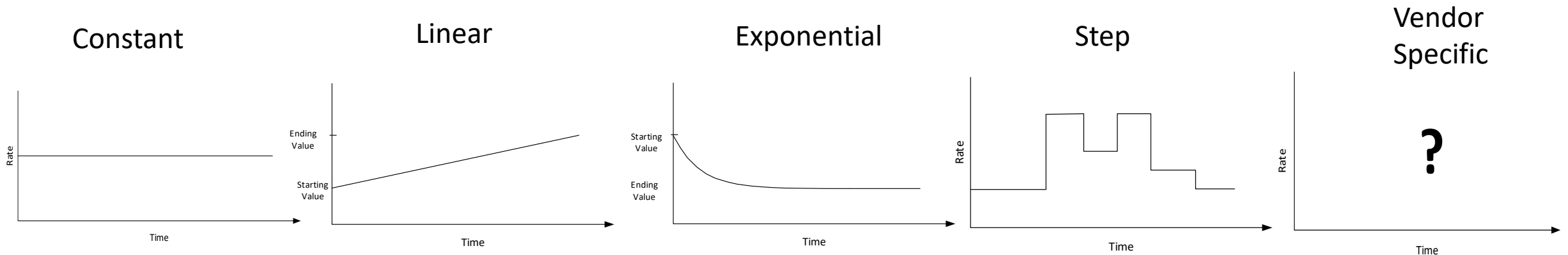
- The dialysis machine uses a unique patient identifier to request the current prescription from the EMR.
- The EMR responds with the current prescription.
 - The EMR is responsible for selecting the current prescription from a possible list of prescriptions.
 - This includes values for all known data objects that are needed to perform the selected therapy.
 - If the machine needs a value that was not provided by the EMR, the machine should prompt the user for a value.

Prescription Transfer (continued)

- The user confirms the prescription before starting the treatment.
- The dialysis machine does NOT allow the EMR to change the prescription once treatment has started.
- The dialysis machine returns the device settings which would include changes made by the operator during treatment.

Prescription Profiles

- The standard supports five different profiles: constant, linear, exponential, step, and vendor specific.
- Profiles can be applied to Blood Flow, Dialysate Flow, Replacement Fluid Flow, Ultrafiltration, Sodium Delivery, and Anticoagulant Delivery.



Prescription Transfer – Sample Messages

Sample Prescription Request Message

```
MSH|^~\&|ACME_Dialysis_Machine^00059AFFFE3C7A00^EUI-  
64|||20220330125317+0000||QBP^D01^QBP_D01|PQ20211216144700|P|2.6|||AL|NE||||  
QPD|0^MDC_HDIALY_RX_QUERY^MDC|Q001|@PID.3^555444222111^^^^MR  
RCP|I||R|
```

Prescription Transfer – Sample Messages

Sample Prescription Reply Message

MSH|^~\&|ACME_Dialysis_Machine^00059AFFFE3C7A00^EUI-
64|||20220330125317+0000||RSP^K22^RSP_K21|20220330125317627|P|2.6|||AL|NE||||
MSA|AA|PQ20211216144700
QAK|Q001|OK|0^MDC_HDIALY_RX_QUERY^MDC|1|1|0
QPD|0^MDC_HDIALY_RX_QUERY^MDC|Q001|@PID.3^555444222111^MR
OBC|NW|A226677^PC||||N|||444-44-4444^HIPPOCRATES^HAROLD^MD
OBX|1|ST|70929^MDC_DEV_HDIALY_MACHINE_MDS^MDC|1|||||F
OBX|2|ST|70934^MDC_DEV_HDIALY_VMD^MDC|1.1|||||F
OBX|3|ST|70939^MDC_DEV_HDIALY_MACH_CONFIG_CHAN^MDC|1.1.1|||||F
OBX|4|ST|158598^MDC_HDIALY_MACH_TX_MODALITY^MDC|1.1.1.1|HD|||||F
OBX|5|ST|70967^MDC_DEV_HDIALY_THERAPY_OUTCOMES_CHAN^MDC|1.1.2|||||F
OBX|6|ST|158618^MDC_HDIALY_THERAPY_COMPLETE_METHOD^MDC|1.1.2.1|UF|||||F
OBX|7|ST|70947^MDC_DEV_HDIALY_BLOOD_PUMP_CHAN^MDC|1.1.3|||||F
OBX|8|NM|16935956^MDC_HDIALY_BLD_PUMP_BLOOD_FLOW_RATE_SETTING^MDC|1.1.3.1|250|ml/min^milliliter per minute^UCUM||||F
OBX|9|ST|158604^MDC_HDIALY_BLD_PUMP_MODE^MDC|1.1.3.2|2N|||||F
OBX|10|ST|70951^MDC_DEV_HDIALY_FLUID_CHAN^MDC|1.1.4|||||F
OBX|11|ST|158606^MDC_HDIALY_DIALYSATE_FLOW_MODE^MDC|1.1.4.1|CONST|||||F
OBX|12|NM|16936008^MDC_HDIALY_DIALYSATE_FLOW_RATE_SETTING^MDC|1.1.4.2|120|ml/min^milliliter per minute^UCUM||||F
OBX|13|NM|0^MDC_HDIALY_DIALYSATE_VOL_SETTING^MDC|1.1.4.3|25|L^liter^UCUM||||F
OBX|14|ST|158608^MDC_HDIALY_DIALYSATE_NAME^MDC|1.1.4.4|RFP-204|||||F
OBX|15|ST|70971^MDC_DEV_HDIALY_UF_CHAN^MDC|1.1.5|||||F
OBX|16|ST|158619^MDC_HDIALY_UF_MODE^MDC|1.1.5.1|CONST-WT|||||F
OBX|17|NM|16936252^MDC_HDIALY_UF_RATE_SETTING^MDC|1.1.5.2|400|ml/h^milliliter per hour^UCUM||||F
OBX|18|NM|159028^MDC_HDIALY_UF_TARGET_VOL_TO_REMOVE^MDC|1.1.5.3|1000|ml^milliliters^UCUM||||F

Key Questions

- Does the proposed workflow align with how prescriptions are currently managed in your environment(s)?
- Do you have issue with not allowing prescription changes during treatment initiated by the EMR?
- Do the defined protocols meet your needs?
- Does your institution use HL7 V2 or FHIR?
- What would you have the consortium work on next?
 - Determine / develop FHIR Guidelines
 - Update Standards to support Peritoneal Dialysis

Industry Review & Feedback

Documents to be Distributed for Review

- Webinar Presentation
- Dialysis Machine HL7 Implementation Guide, Rev 3.1
- Hemodialysis Objects Spreadsheet , Rev 3.1
- Hemodialysis Description
- IEEE Containment Tree HTML File

Responses to Consortium requested by February 17, 2023

- Submit comments to info@dialysisinterop.org.

Consortium Website

www.dialysisinterop.org

Dialysis Interoperability Consortium

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The goal of the Dialysis Interoperability Consortium is to develop a standard mechanism for communicating dialysis treatment information to and from an EMR system. The Consortium builds upon existing HL7, IHE, IEEE, and UCUM standards to deliver dialysis treatment information to the EMR and to receive prescription information from the EMR.



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Last Updated on May 11, 2022

What's Remaining

- Review and apply industry feedback as necessary
- Update NIST RTMMS and NIST Test Tools.
 - Available Q4 2022
- IEEE P11073-10101b Amendment approval.
 - Expected completion Q3 2023.

Questions



Thank You

Thank you for participating and we look forward to your comments. If you have any questions, please reach out at info@dialysisinterop.org.