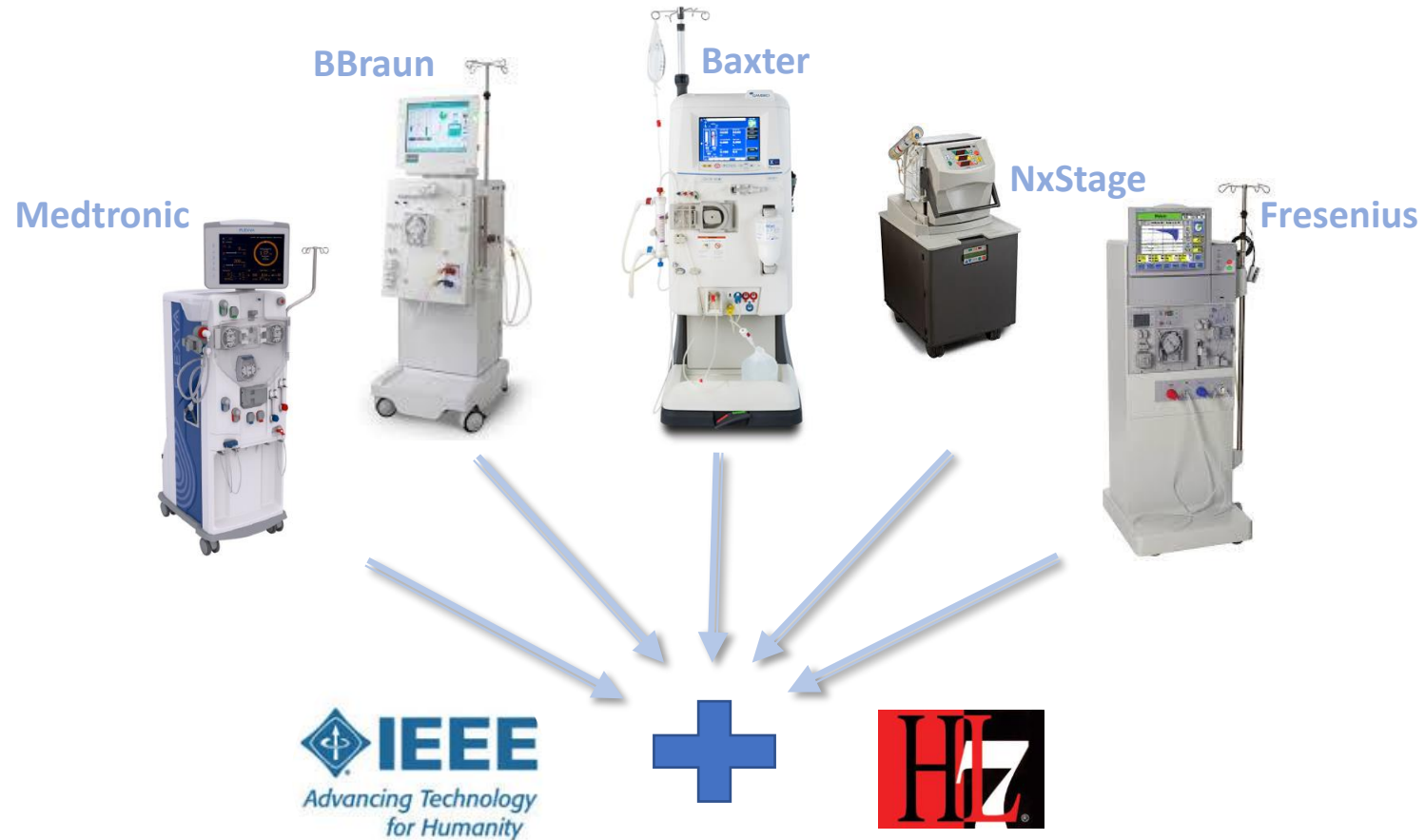


Dialysis Device Interoperability



Introduction

Dialysis Device Consortium

- Partnered Market Leaders in Hemodialysis Products & Services
- Initiated and Managed by DaVita Kidney Care
- Contributing Service Partners:
 - DaVita Kidney Care
 - Fresenius Medical Care
 - Dialysis Clinic, Inc.
- Contributing Vendor Partners:
 - Fresenius Medical Care
 - NxStage
 - Baxter
 - BBraun
 - Medtronic

Service Providers

DaVita[®]
Kidney Care

FRESENIUS
MEDICAL CARE

DCi Dialysis Clinic, Inc.
A Non-Profit Corporation

Manufacturers / Vendors



Fresenius



NxStage



Baxter



BBraun



Medtronic

Consortium Objective

Develop IEEE Nomenclature Standards for Dialysis Devices
and HL7 V2.6 Implementation Guideline for
Hemodialysis Device Interoperability

*Initial focus specific to hemodialysis device data export

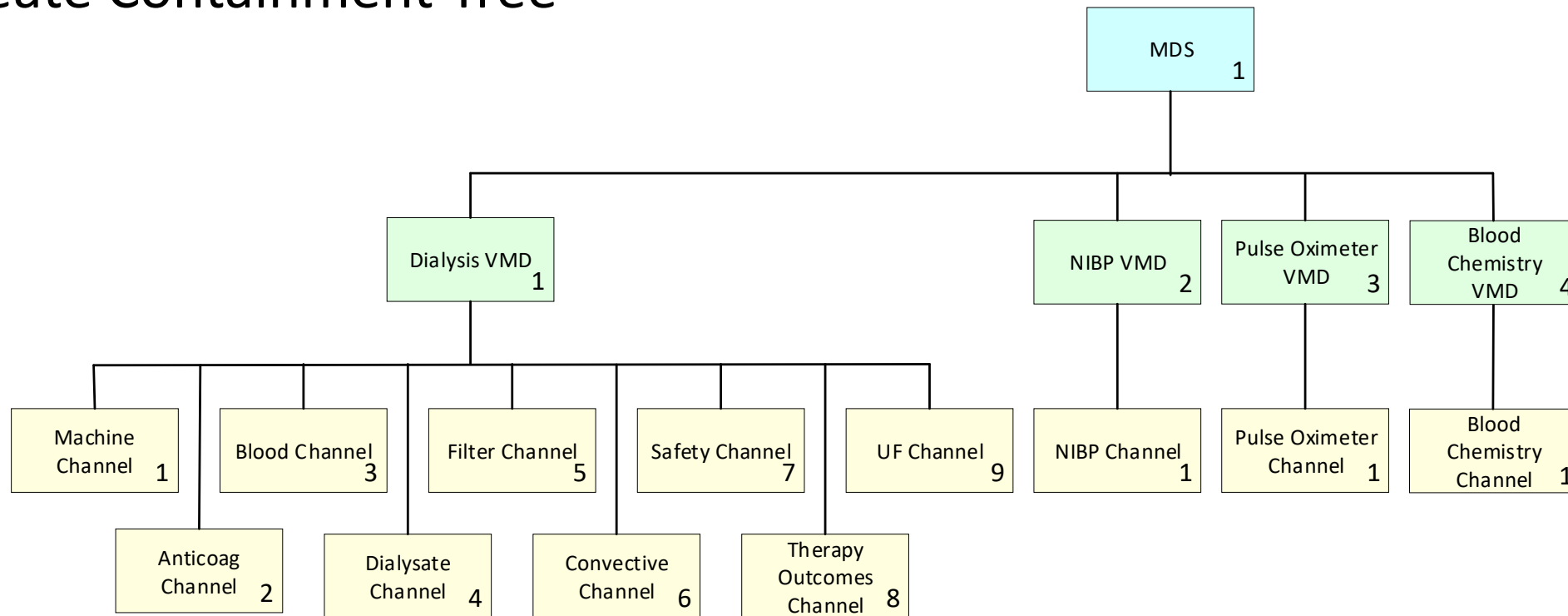
Development guidance provided by Paul Schluter

IEEE Nomenclature Requirements

- Develop Medical Device System Specifications for IEEE Addendum
- Define Device Data Objects
- Assign Common Names
- Define Data Object Format and UOM
- Determine (M)andatory, (O)ptional, and (C)onditional Status for HL7 OBX Results Reporting
- Create Universal List of Values, where applicable
- Define Valid Ranges / Limits
- Identify Valid Values for Sample Use / Reference

IEEE Deliverables

- Categorize Virtual Medical Devices (VMD)
- Identify VMD Channel(s)
- Create Containment Tree



IEEE Deliverables

- Assign REFIDs to each Data Object

Example of Blood Pump VMD Channel

REFID	Alert Type	Dialysis Device VMD	Dialysis Common Name	Definition	Observation Sub ID	Data Type	Format	UCUM UOM	CARD	USE
MDCX_DEV_HDIALY_BLOOD_PUMP_CHAN					1.1.3					
MDCX_HDIALY_BLD_PUMP_BLOOD_FLOW_RATE		Blood Pump	Actual Blood Flow Rate	Adjusted blood flow rate based on the blood flow rate setting and pressure drop caused by blood line, needle and vascular access	1.1.3.1	numeric	XXX	mL/min	0.1	O
MDCX_HDIALY_BLD_PRESS_ART	phys tech high low thr	Blood Pump	Arterial Pressure	Pressure of arterial access line pre blood pump	1.1.3.2	Numeric	±XXX	mm[Hg]	1.1	M
MDCX_HDIALY_BLD_PUMP_BLOOD_FLOW_RATE_AVG		Blood Pump	Average Blood Flow Rate	Average of the actual blood flow rate over the course of treatment.	1.1.3.3	Numeric	XXX	mL/min	0.1	O
MDCX_HDIALY_BLD_PUMP_BLOOD_FLOW_RATE_AVG_SETTING		Blood Pump	Blood Flow Rate Setting	The rate at which the user programmed the blood flow	1.1.3.4	Numeric	XXX	mL/min	1.1	M
MDCX_HDIALY_BLD_PUMP_MODE		Blood Pump	Blood Pump Mode	Therapy method in which blood is retrieved and returned to the patient.	1.1.3.5	_TBL_05	Alphanumeric	N/A	1.1	M
MDCX_EVT_HDIALY_BLD_PUMP_STOP	tech	Blood Pump	Blood Pump Stop	Notification that the blood pump has stopped	1.1.3.6	Bool	T / F	N/A	0.1	M
MDCX_HDIALY_BLD_PUMP_TUBING_SIZE		Blood Pump	Blood Tubing Size	Inner diameter of pump segment of tubing used in extracorporeal circulation	1.1.3.7	String	alphanumeric	N/A	0.1	O
MDCX_HDIALY_BLD_PUMP_PAT_BODY_TEMP_BY_BLOOD		Blood Pump	Body Temperature	Patient body temperature, directly measured or calculated based on temperature of blood	1.1.3.8	Numeric	XX.X	Cel	0.1	O
MDCX_HDIALY_BLD_PUMP_CHANGE_IN_ENERGY		Blood Pump	Change In Energy	Measurement of the energy (temperate) flux to and from the patient	1.1.3.9	Numeric	±XXX.X	kJ/h	0.1	O
MDCX_HDIALY_BLD_PUMP_PRESS_ART_POST_PUMP	tech high low thr	Blood Pump	Post Pump Arterial Pressure	Pressure of arterial access line post blood pump	1.1.3.10	Numeric	±XXX	mm[Hg]	0.1	O
MDCX_HDIALY_BLD_PUMP_PRIMING_VOL		Blood Pump	Priming Volume	Volume of fluid used to prime the extracorporeal circuit	1.1.3.11	Numeric	XXX	mL	0.1	O
MDCX_HDIALY_BLD_PUMP_SINGLE_NEEDLE_PRESS	tech high low thr	Blood Pump	Single Needle Switching Pressure	In single needle mode, the pressure used to switch phases at high pressure	1.1.3.12	Numeric	± XXX	mm[Hg]	0.1	O
MDCX_HDIALY_BLD_PUMP_STROKE_VOL		Blood Pump	Stroke Volume	The volume of blood passing through the dialyzer during each single needle cycle.	1.1.3.13	Numeric	XXX	mL	0.1	C5
MDCX_HDIALY_BLD_PUMP_BLOOD_PROCESSED_TOTAL		Blood Pump	Total Blood Processed	Accumulated volume of blood circulated by extracorporeal circulation.	1.1.3.14	Numeric	XXXX.XX	L	0.1	O
MDCX_HDIALY_BLD_PUMP_PRESS_VEN	phys tech high low thr	Blood Pump	Venous Pressure	Pressure of the venous access line	1.1.3.15	Numeric	±XXX	mm[Hg]	1.1	M
MDCX_HDIALY_BLD_PUMP_BLOOD_TEMP_VEN		Blood Pump	Venous Temperature	Temperature of the blood measured in the venous access line	1.1.3.16	Numeric	XX.X	Cel	0.1	O

HL7 Deliverables

- Follow HL7 V2.6 Standards & IHE PCD DEC Technical Framework
 - Integrating the Healthcare Enterprise Patient Care Devices Device Enterprise Communications
- Create Dialysis Device Implementation Guide
- Incorporates PCD-01 Report Data & PCD-04 Report Alert
- Define Message Segment Usage
 - MSA
 - MSH
 - PID
 - OBR
 - OBX
- Generate Sample Messages for Hemodialysis Device

HL7 Deliverables

Sample PCD-01 Message (Partial)

```
MSH|^~\&|Dialysis Machine |||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|||0^MDC_DEV_DIALYSIS^MDC||20191003092005+0000
OBX|1|ST|0^MDC_ATTR_ID_MODEL^MDC|1.1.1.1|NxStage System One|||||F
OBX|2|ST|7682^MDC_ID_MODEL_MANUFACTURER^MDC|1.1.1.2|NxStage|||||F
OBX|3|ST|7681^MDC_ID_MODEL_NUMBER^MDC|1.1.1.3|System One|||||F
OBX|4|ST|7684^MDC_ID_PROD_SPEC_SERIAL^MDC|1.1.1.4|1000478|||||F
OBX|5|ST|7667^MDC_ID_PROD_SPEC_SW^MDC|1.1.1.5|1.2.3.4|||||F
OBX|6|DTM|0^MDCX_HDIALY_MACH_TIME^MDC|1.1.1.1|20191003092005+0000|||||F
OBX|7|ST|0^MDCX_HDIALY_MACH_MODE_OF_OPERATION^MDC|1.1.1.3|Treatment|||||F
OBX|8|ST|0^MDCX_HDIALY_MACH_BLD_PUMP_ON^MDC|1.1.1.6|T|||||F
OBX|9|ST|0^MDCX_HDIALY_MACH_TX_FLUID_BYPASS^MDC|1.1.1.7|F|||||F
OBX|10|ST|0^MDCX_HDIALY_MACH_TX_MODALITY^MDC|1.1.1.8|HDF|||||F
OBX|11|NM|0^MDCX_HDIALY_MACH_THERAPY_TIME^MDC|1.1.1.9|180|min^minutes^UCUM|||||F
OBX|12|NM|0^MDCX_HDIALY_MACH_THERAPY_TIME_REMAIN^MDC|1.1.1.10|0|min^minutes^UCUM|||||F
OBX|13|NM|0^MDCX_HDIALY_MACH_COAG_PUMP_NUMBER^MDC|1.1.1.7|1|||||F
OBX|14|NM|0^MDCX_HDIALY_BLD_PRESS_ART^MDC|1.1.3.2|-75|mm[Hg]^Millimeters of Mercury^UCUM|< -200|||||F
```

Identifier

Value

Alarm
Limit

Unit of
Measure

HL7 Deliverables

Sample PCD-04 Message

```
MSH|^~\&|Dialysis Machine|||20191003092025+0000||
ORU^R40^ORU_R40|20191003092024|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|||0^MDC_DEV_DIALYSIS^MDC||20191003092024+0000
OBX|1|CWE|196670^MDC_EVT_LO^MDC|1.0.0.0.1|0^MDCX_HDIALY_ALARM_PRESS_VEN^MDC|PH~SP|||F
OBX|2|NM|0^MDCX_HDIALY_BLD_PUMP_PRESS_VEN^MDC|1.1.3.15.2|15|mm[Hg]^Millimeters of Mercury^UCUM |20-400|||F
OBX|3|ST|68481^MDC_ATTR_EVENT_PHASE^MDC|1.0.0.0.3|start|||F
OBX|4|ST|68482^MDC_ATTR_ALARM_STATE^MDC|1.0.0.0.4|active|||F
OBX|5|ST|68483^MDC_ATTR_ALARM_INACTIVIATION_STATE^MDC|1.0.0.0.5|enabled|||F
```

Industry Review & Feedback

Documents to be Distributed for Review

- Overview Slide Deck
- Hemodialysis Device Detailed Spreadsheet
- IEEE Hemodialysis Description
- IEEE Containment Tree HTML File
- Draft HL7 V2.6 Implementation Guide

Responses to Consortium requested by March 12, 2020

- Please submit to Project Manager at
John.Mulholland@davita.com

What's Remaining

- Review and apply, as necessary, industry feedback
- NIST RTMMS and NIST Test Tools available Q2 2020
- IEEE Amendment and HL7 Organization Submissions planned Q2 2020

- Incorporate Prescription Import Messaging
- Update Standards with Peritoneal Dialysis Device Details
- Determine / develop FHIR Guidelines

Questions

