Overview & Rationale

The impetus for this (ISO/TC 215, HL7, IHE) technical report, Accelerating Safe, Effective and Secure Remote Connected Care and Mobile Health Through Standards-Based Interoperability Solutions Addressing Gaps Revealed by Pandemics, was born out of the global COVID-19 pandemic challenge and the need to accelerate the implementation and use of interoperable remote connected care and mobile health (RCC-MH) based approaches, while at the same time ensure open standards-based interoperability as well as assess whether the rapid response being proposed is sufficiently safe and secure and effective - that is, it will actually perform as intended when it is needed! The results are not necessarily limited to the COVID-19 response but are relevant to the evolving area of remote connected care and mobile health during ‘normal’ times as well as future pandemics. The paper answers questions such as:

- What informatics standards should be considered when developing remote monitoring / mHealth solutions?
- What are the current gaps in the standards eco-system that should be plugged to enable RCC-MH?
- What safety, effectiveness & security (SES) standards should be leveraged to balance solution options with risk-based public good assessments?
- How can application of these standards be scaled in crisis situations where resources and time are highly constrained?
- ...

This technical report proposal (ISO/TC 215 WG2 PWI 5615, May 2020) was developed with strong facilitation by Konstantinos Makrodimitris, Ph.D. (US FDA/DHHS liaison to TC215 WG2), as well as a small team of subject matter experts:

Gora Datta (CAL2CAL)
Ken Fuchs (Draeger Medical Systems, Inc.)
Todd Cooper (Breakthrough Solutions Foundry)

The following "quad chart" captures the key elements of the proposal (this is "living" quad-chart and subject to revision as the project evolves):
And the following presentation by Dr. Makrodimitris provides additional background and intended content for the technical report:

Note that this technical report is also closely related to the more general Gemini SES MDI technical report project.

Roadmap & Team Collaboration

Technical Report Roadmap

1. Develop a joint HL7-IHE Gemini Technical Report
   - Balloted technical report that is approved and jointly published in both organizations
   - Home working groups: IHE DEVices (DPI) and HL7 DEVices (DoF)
   - Supporting working groups: IHE DEV (PCH & PCD); HL7 Mobile Health & ISO/TC215 WG#2
2. **ISO/TC 215 Coordination**
   - Add a preliminary work item (PWI) to the WG2; update TC215 CAG2 appropriately
   - Invite international expert participation in the Gemini technical report development
   - Once the technical report is completed in the HL7-IHE Gemini Project, it will be submitted for "fast track" processing via the IHE International Liaison A track to ISO/TC 215.
   - Since the technical report may include recommendations for further work in WG2 and JWG7, ensure that it is a topic to be included in the WG2 & JWG7 meetings
   - **TARGET:** ISO Preliminary Work Item established by July 2020; participation invitations starting 2020 May; technical report ballot Q2 2023

**Development Status**

1. **IHE Devices**
   - Work item approved at the monthly DEV meeting 2020.05.27

2. **HL7 Devices**
   - PSS Proposal to be submitted by Friday, 2020.05.22
   - NOTE: Plan is a single PSS for all three Gemini SDPi+FHIR technical report proposals, followed by a single PSS Form

3. **ISO/TC 215**
   - WG2 PWI approved in virtual meeting 2020.05.18; TC confirmation of resolution - APPROVED July 1, 2020

4. **Gemini Project Coordination**
   - Proposal reviewed at the 2020.05.19 Steering Committee meeting
   - TBD process & IP details on how and where to jointly publish a Gemini technical report

**Paper Team Participants**

The following individuals have requested to be included in the RCC/MH Editing Team:

<table>
<thead>
<tr>
<th>Konstantinos Makrodimitris</th>
<th>Gora Datta</th>
<th>Kenneth Fuchs</th>
<th>Todd Cooper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axel Wirth</td>
<td>Gregory Zeller</td>
<td>Paul Schluter</td>
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<tr>
<td>Raymond Krasinski</td>
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</tr>
</tbody>
</table>

Also these individuals/experts have participated in specific sessions:

- Orlando Lopez NIH
- Andrea Coravos CEO, digital health sector
- Larry Callahan FDA ISO
- Brian Fitzgerald FDA standards
- Asiyah Lin, NIH
- John G Rhoads, Philips
- Martin Rosner, Philips
- Cheryl Lohman, MedApptic
- John Garguilo, NIST
- See meeting notes for other participants

NOTE: Team participants who are also registered HL7 Confluence users be able to comment and add content.

**SES MDI Team Discussion Notes**

**NOTE:** Order newest & future-est to oldest.

Kenneth Fuchs  Gora Datta  Martin Rosner

Cheryl Lohman, Corey Weeden, Axel Wirth

Notes:

- Update the Confluence site with the new title, list of members, recent powerpoints (HIMSS, AAMI, ISO/TC 215 WG2), etc.
- Complete first draft
- Rollout plan - August 2022 - distribute 'draft' pdf to:
  - HL7 - Mobile Health, Devices
  - IHE - Devices
  - IEEE - MHA-SLS
  - ISO/TC 215 - WG2 (Committee Review)
- Present results in January 2023 TC215 WG2 meeting, and move to formal ballot
NOTES:
The team reviewed the current status of the report.
Decided to add a section on advanced technology such as: AI/ML, VR, AR, etc.

NOTES:
Meeting with IEEE P1752, please see attached powerpoint deck.
- Decided to create a short introductory deck for our project
- We now know the date and time of our presentation to HIMSS
- Discussed the IEEE Mobile Health Applications (MHA) Industry Connection project

Kenneth Fuchs  Paul Schluter  Axel Wirth  Raymond Krasinski  Konstantinos Makrodimitris  Isabel Tejero

NOTES:
- Reviewed current status of Report and assignments
- Discussed Use Cases and Gaps related to hospitals

Kenneth Fuchs  Paul Schluter  Axel Wirth  Raymond Krasinski  Konstantinos Makrodimitris  Isabel Tejero

NOTES:
- Reviewed current status of Report and assignments
- Discussed Use Cases and Gaps related to remote clinical trials

Kenneth Fuchs  Paul Schluter  Axel Wirth  Raymond Krasinski

NOTES:
- Short meeting due to small crowd

Kenneth Fuchs  Paul Schluter  Axel Wirth  Gora Datta  Raymond Krasinski  Konstantinos Makrodimitris  Isabel Tejero

NOTES:
- Reviewed current status of Report and assignments

Kenneth Fuchs  Paul Schluter  Axel Wirth  Gora Datta  Raymond Krasinski  Konstantinos Makrodimitris  Isabel Tejero

Dr. Jonathan Reich; Dr. Anita Krishnan; Dr. Bryanna Schwartz - all from Children's National Hospital

NOTES:
- Reviewed current status of Report and assignments

Kenneth Fuchs  Paul Schluter  Axel Wirth  Gora Datta  Raymond Krasinski  Konstantinos Makrodimitris  Isabel Tejero

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Kenneth Fuchs  Paul Schluter  Axel Wirth  Gora Datta  Raymond Krasinski  Konstantinos Makrodimitris  Isabel Tejero

NOTES:
- Reviewed current status of Report and assignments
- Discussed:

Kenneth Fuchs  Paul Schluter  Axel Wirth  Gora Datta  Raymond Krasinski  Konstantinos Makrodimitris  Isabel Tejero
• Reporting of cybersecurity issues (Axel Wirth)
• Big picture discussion (Gora Datta)

Kenneth Fuchs Paul Schluter Axel Wirth Gora Datta Raymond Krasinski Konstantinos Makrodimitris Isabel Tejero John Rhoads Asiyah Lin

NOTES:
• Reviewed current status of Report and assignments
• Made some adjustments
• Lined up 2 topic for next week:
  • Reporting of cybersecurity issues (Axel Wirth)
  • Big picture discussion (Gora Datta)

Meeting cancelled due to IEEE 11073/HL7 DEV virtual face to face

Kenneth Fuchs Paul Schluter Axel Wirth Gora Datta Raymond Krasinski Konstantinos Makrodimitris Asiyah Lin

NOTES:
• Ken reviewed the current agenda for next week’s IEEE 11073 / HL7 DEV meetings
  • The RCC/MH meeting for next week is cancelled
  • Asiyah Lin led a presentation and discussion concerning the FDA RAPID program for the evaluation of Peripheral Interventional Devices
  • Potential intersection with 11073-10201, 10206, 10207 and the USCDI
  • May be of interest to the HL7 Anesthesia group or some other WGs in HL7 or IHE

Kenneth Fuchs Paul Schluter Axel Wirth Gora Datta Martin Rosner

Asiyah Lin;

NOTES:
• Reviewed scope of the project with Asiyah Lin from NIH
• Continued review of Technical Report
• Ken had started to convert diagrams to grey-scale - was told to stop
• Ken moved the Nomenclature content that Paul Schluter had provided into an Annex
• Gora is working on preparing his content in conjunction with some other work he is doing
  • Presentation to CMS ISC
  • Discussions with IEEE related to App Identification

Kenneth Fuchs Paul Schluter Isabel Tejero Konstantinos Makrodimitris Axel Wirth Gora Datta Raymond Krasinski Erin Roche

NOTES:
• Continued review of Technical Report
• Ken had started to fill in the Foreword, Introduction and Scope sections
• Ken started to align the formatting and organization with other ISO TRs
• Ray had provided content for the 11073 PHD and DICOM content

Kenneth Fuchs Paul Schluter Konstantinos Makrodimitris Axel Wirth Gora Datta Raymond Krasinski Isabel Tejero

NOTES:
• Continued review of Technical Report
• Ken had started to fill in certain sections
• Kosta had contributed content for the Regulatory section

Kenneth Fuchs Paul Schluter Konstantinos Makrodimitris Axel Wirth Raymond Krasinski Isabel Tejero

NOTES:
• Continued review of Technical Report
• Added assignments of specific individuals to specific sections

Kenneth Fuchs Paul Schluter Konstantinos Makrodimitris Axel Wirth Gora Datta Raymond Krasinski Isabel Tejero
NOTES:

- Technical Report has been posted on a Google Drive for general collaboration
- Link is:
- Discussion centered on Table of Contents and TR organization
- Added some additional topics and bullets to specific sections of the TR

Kenneth Fuchs Paul Schluter Konstantinos Makrodimitris Gora Datta Axel Wirth Martin Rosner

NOTES:

- Kenneth Fuchs created a new document combining the current Table of Contents with the Abstract discussed last week.
- He will share the document via Google. This may be a little challenge for Konstantinos Makrodimitris since the FDA does not allow access to shared drives, however he can use a personal personal computer.
- The new document organization and some of the content was discussed.
- Gora Datta provided an overview of various MH related HL7 and HL7 FHIR standardization efforts such as cMHAF, MHAE and UMHDI.
- The UMHDI proposal has also been posted with the US ONC USCDI.
- Paul Schluter and Axel Wirth were encouraged to start thinking about their sections of the report.
  - Focus should be an overview of the current standards situation and any pandemic RCC/MH related gaps and how to address.
- Happy Thanksgiving!

Kenneth Fuchs Raymond Krasinski Isabel Tejero Paul Schluter Axel Wirth Konstantinos Makrodimitris

NOTES:

- Reviewed Abstract.
- Added additional content to the Abstract.

Kenneth Fuchs Konstantinos Makrodimitris Gora Datta Paul Schluter Raymond Krasinski

NOTES:

- Pro-active with security - don’t wait for the next pandemic. Employed telehealth w/o the necessary security safeguards.
- Infrastructure needs to have security built-in.
- Stockpile - SW based machines need to be ready to go, without patching.
- Zoom - initially anyone with the ID could connect. Now patients need to log in.
- Currently all the interoperability related standards are optional from the FDA perspective.
  - Some interoperability and cybersecurity standards should be mandated
  - What vs. How vs. Process standards
  - Semantics vs. Syntax vs.
- Need a ‘UDI’ for apps and applications (SaMD)
  - Need to track down to the component, SW/FW version, etc.
- FDA Digital Health CoE does not cover cybersecurity.
- Gora presented his proposal to USCDI concerning UDI for mobile health apps
  - Should this also include software applications in general?
  - Concern about over-reaching our scope and ability (world domination)

Todd Cooper Raymond Krasinski John J. Garguilo Konstantinos Makrodimitris Paul Schluter Axel Wirth

NOTES:

- Normally you would have a preliminary document which would be attached to the Form 4 an alternative is to “fast track” it via HL7 or IHE.
- Goal is to have a report before the end of the year without formal international review and involvement from this group.
- Then move to ISO for international input during 2021; engaging Asia, Europe, etc. in order to build support.
- @Todd demonstrated a potential use of the Gantt Chart macro for Confluence to help manage the project planning.
- Milestones were discussed and documented in the chart.
- The Report may lead to additional projects in HL7, IHE, TC 215, JWG7, etc.
Notes:

- Based on feedback from the WG2 meeting we should line up collaborators from at least 5 countries:
  - US:
  - Canada: Derek Ritz
  - Australia: Alan Taylor
  - Japan: Koichiro Matsumoto
  - United Kingdom: Malcolm Clarke
  - Korea: ??Ho??
  - Netherlands: Martin Rosner, Frank Ploeg
  - Sweden: ??
  - Germany: Christophe Fischer
  - Greece: Catherine Chronaki

- Need to contact Todd concerning the process.
- **Gora Datta Konstantinos Makrodimitris** Look into summary for the TC215 plenary - November
- Need to address the comment about ISO 14971
- Need to start preparation of the Form 4 - next WG2 meeting on January 19th
  - End of November for Form 4 completion (need 6 weeks lead-time)
  - The Form 4 then goes out for approval and countries nominate their experts
  - Require experts from at least 5 countries.

- HIMSS 2021 - need to prepare Abstract for presentation - deadline is November 2, 2020
- DiME - do we continue to engage? (Kosta will monitor)
- Need to review the Table of Contents and make sure it aligns with our WG2 presentation
- Participants are encouraged to start filling in sections of the report.
- Next meeting 10/20 is cancelled; following meeting (10/27) will start 4:00 PM Eastern

- Potential related projects with funding possibilities:
  - [https://www.nih.gov/research-training/medical-research-initiatives/radx](https://www.nih.gov/research-training/medical-research-initiatives/radx)
  - [https://mhealth-hub.org](https://mhealth-hub.org)
  - [www.pcori.org](http://www.pcori.org)

Attendees: Kenneth Fuchs Gora Datta Konstantinos Makrodimitris Paul Schluter John Rhoads Martin Rosner Raymond Krasinski

Axel Wirth, Larry Callahan, Special Guests - see below

Notes:

- Special session on Digital Health.
- Special Guests included:
  - Renee Rockwood - Mitre for ONC
  - Orlando Lopez - NIH
  - Catherine Kronaki - HL7
  - Vinay Pai - FDA - Digital Health Center of Excellence
  - Lawrence Callahan - FDA - Identification of Medicinal Products
  - Charles Ho - FDA

- During the discussion we were informed of a number of important references which were included in the chat.
  - The appropriate chat snippets follow:
  - from Gora Datta to Everyone: 3:15 PM
    - [https://mhealth-hub.org/](https://mhealth-hub.org/)
  - from Renee Rockwood to Everyone: 3:21 PM
  - from Renee Rockwood to Everyone: 3:22 PM
  - from Konstantinos Makrodimitris to Everyone: 3:24 PM
    - [https://www.nih.gov/research-training/medical-research-initiatives/radx](https://www.nih.gov/research-training/medical-research-initiatives/radx)
  - from Konstantinos Makrodimitris to Everyone: 3:33 PM
  - from Konstantinos Makrodimitris to Everyone: 3:34 PM
  - from Vinay Pai to Everyone: 3:36 PM
  - from Konstantinos Makrodimitris to Everyone: 3:45 PM
  - from Konstantinos Makrodimitris to Everyone: 3:46 PM
  - from Konstantinos Makrodimitris to Everyone: 3:50 PM
  - from Gora Datta to Everyone: 4:01 PM
  - from Konstantinos Makrodimitris to Everyone: 4:24 PM
Attendees: Kenneth Fuchs Gora Datta Konstantinos Makrodimitris Paul Schluter Isabel Tejero

Notes:

- Special session on Digital Medicine
- **Part 1**: Pierre D’Haese
  - Involved in large data collection efforts regarding digital health data
  - Participants use Aura, Fitbit, Garmin and other devices as data sources
  - 8,000 + participants
  - Goal is to develop early warning algorithms. Current projects include:
    - Pain prediction
    - Addiction relapse
    - Covid early detection
  - Issue include Ethics and Privacy
    - Patient owns the data
    - Subject compliance is a challenge. For example remembering to charge the device
    - In some cases looking at handling beat by beat data to derive Heart Rate Variability
- **Part 2**: Jennifer Goldsack - DiME; Andrea Coravos - Elektra
  - Focus on the Playbook from the DiME society
  - Large effort dealing with the use of devices for health use
  - Talk about interoperability and standards
  - Go to [https://playbook.dimesociety.org/](https://playbook.dimesociety.org/) for more information.
  - Effort is organized in "Tours" of 4 to 6 months duration

Attendees: Kenneth Fuchs Konstantinos Makrodimitris Gora Datta Paul Schluter Raymond Krasinski Isabel Tejero

Notes:

- Discussed logistics concerning upcoming virtual F2F
- Special Session on Nomenclature, led by Paul Schluter
  - See slide set
  - IEEE 11073 Medical Device Communication (MDC) Nomenclature
  - Numerics, waveforms, settings, alerts and events, commands
  - Intended for real-time, near real-time and persistent storage applications
  - Latest 2019 version combines previous versions into one combined standard
  - NIST RTMMS is an open database which provides access to the nomenclature. In addition specifies UoMs as appropriate.

This was a special meeting to discuss RCC & MG with physician providers.

We had 3 physicians that participated via WebEx:

- Dr. Michael Baluyut Family medicine physician – suburban location (via video call)
• Dr. Jessica Basa Family medicine physician – rural location (via video call)
• Dr. Ratul Chatterjee Internal medicine physician – suburban location (via video call)

Subsequently 3 FDA staff physicians responded in writing to our questionnaire.

• Dr. Mahadevappa Hunasikatti FDA – FCCP
• Dr. Jonatan Reich FDA – Pediatrics
• Dr. Greg Pappas FDA – CBER

Their responses are attached.

RCC-MH Questionnaire v1 (1).docx
RCC-MH Questionn... v1jedits.docx
RCC-MH Question...1 (002).MH.docx

Notes:
This was a special meeting to discuss Cybersecurity.

We had 4 presenters:

1. Axel Wirth (MedCrypt)
2. Brian Fitzgerald (FDA)
3. Christoph Fischer (Roche)
4. Sue Wang (NcCoE)

Their presentations are below. In addition we were able to record the first hour. The recording can also be found below.
Kenneth Fuchs, Gora Datta, Paul Schluter, Isabel Tejero, Konstantinos Makrodimitris, John J. Garguilo, John Rhoads

Michael Kirwan, Gregory Pappas,

Regrets: Todd Cooper

Notes:

- **Todd Cooper** - update the webex times and send new invites
- Updated calendar
- Review Provider Questionnaire
  - Added some additional questions
  - Need to move into a word document
  - Discussion about SHIELD program for lab result consistency
    - Some Covid results are manually reported
    - Lab data is still coded at the site based on the implementor's preference
    - Similar challenge for device data - need a mechanism to check conformance
    - IHE PCD has provided very stringent requirements around device data coding (NIST RTMMS)
      - Have tools to validate measurements and messages from devices
  - "Accelerate" - what do we mean and what do we do?
    - How to tailor cybersecurity to different settings? Minimum requirements per use case.
    - Need to take into account the pandemic needs and higher "appetite" for risk
    - Need to keep in mind that as time goes on this level of flexibility will not be acceptable
    - The bar for Safety, Effectiveness and Security will keep getting higher
  - Acceleration by using the patient as part of the solution
    - Non F2F encounters will be the norm
  - Similar issues for terminology, regulation, etc.
  - How does "Pandemic Mode" differ from "new Normal Mode" in the future?
    - Example transition from tele-health centers to anywhere the patients or docs are

Accelerate

- Review Provider Questionnaire

Participants

Todd Cooper, Paul Schluter, John J. Garguilo, Kenneth Fuchs, Gora Datta, Martin Rosner, Konstantinos Makrodimitris, John Rhoads

Isabel Tejero, Michael Kirwan, Axel Wirth

Regrets: Kenneth Fuchs

Agenda / Notes

1. **General Updates**
   a. Gora gave a 1st person interview with a primary care staff - narrative for how to prep for a patient "remote" visit
      i. Preparation activities are captured in the EHR in advance
      ii. Walk patients through the app portal, prep for the actual video visit, etc.
      iii. Key Benefit: Before COVID, elderly patients didn't want to get on a portal - but now they realize the value and are learning and interacting using their primary care provider's portal

2. **Roadmap Topic**: Planning - Provider Questionnaire
2. Kenneth Fuchs led the group through a discussion of the topics and questions to discuss with providers when meetings start in a few weeks ...

b. See updated RCC slide deck for topics / notes ... starting

3. **Other Topics**

Participants

**Kenneth Fuchs** Gora Datta Raymond Krasinski

Axel Wirth, Isabel Tejero, Michael Kirwan, Greg Pappas

Regrets: Todd Cooper

**Agenda/Notes**

1. New attendees: Michael Kirwan, Raymond Krasinski
2. Greg Pappas talked about a recent presentation to FDA about Edge Computing and Analytics
   a. Distributed analytics
   b. Currently very small scale; needs standards to become large scale
   c. Recommendation we reach out to this group from Booz Allen
   d. Kosta will look into whether the presentation can be shared with us
3. Recommendation that we see if AAMI (J. Goldman, S. Weininger) would be interested in discussing their work
4. Updated the schedule on Confluence
   a. Allocated one session to discuss Acceleration
5. Worked on Jamboard (attached).
   a. Focused on Home use cases.
   b. Distinguish between:
      i. monitoring - non-specific
      ii. continuous monitoring - data is flowing continuously
      iii. episodic monitoring - triggered by an event such as a fall
      iv. scheduled monitoring - e.g. every hour
      v. intermittent / random monitoring
      vi. spot monitoring - typically a form of scheduled monitoring
      vii. on-demand monitoring - e.g. physician consult
      viii. diagnosis
      ix. therapy

![Diagram of use cases](image)

**NOTE:** Need to reverse order of the notes below ...

**Agenda**

1. Reviewed status of SES MDI RM / MH technical report project approval and development
2. Planning for technical report content development
3. New Business

**Participants**

Konstantinos Makrodimitris John Rhoads Gora Datta Todd Cooper

**Meeting Notes**

1. **General Status Review & Background** (All)
   a. Review of technical report project approvals (IHE & HL7 & TC215)
2. **Development Planning** *(All)*
   a. Starting next Tuesday *(2020.06.09)* begin 1 hour weekly work sessions; use IHE DEV WebEx;
   b. Create Project Team list on this page
   c. Include web meeting notes on this page

**Agenda**

1. General Updates on Technical Report Development & Standards Coordination & Community Engagement
2. Content Review and Development Planning
3. New Business

**Participants**

Todd Cooper  Gora Datta  Konstantinos Makrodimitris  Kenneth Fuchs  Axel Wirth

**Meeting Notes**

1. **Reviewed Status / Confluence Page Content**
   a. Kosta reviewed some of the **objectives from the quad-chart** *(above)*
2. **Reviewed "Remote Mobile Health" graphic**

![Remote Mobile Health Diagram]

   a. **CURRENT Iteration** *(Work in Progress)*:
   b. **NOTES:**
      i. Standards inside red circle are representative and not limited to the scope of the particular quadrants that they overlay
3. **Security Perspectives - Axel**
   a. First-Call Introduction - Provided professional & current background *(see LinkedIn for specifics)*.
   b. Current PROCESS FOCUSED approach: **3 Disclosure Pillars**
      i. What's supported? *(SBoM / MDS2)*
      ii. What's the vulnerabilities?
      iii. Deployment of vulnerabilities mitigation *(patches)*
   c. Security needs to be "nimble" because the attacks are dynamic - must have a pragmatic technology approach to reduce the reliance on process *(b)* above
      i. You can never patch enough to be secure enough...
      ii. In a crisis response "you go to war with the security you have"
      iii. Consider: Stockpiling med tech is important *(think ventilators ready to go)* - but is their security provisions maintained and ready for use?
4. **Remote Monitoring Scenarios / Variations - Ken**
a. Reviewed a slide with some alternatives for consideration (Work In Progress):

```
| Patient in a licensed high-acuity care facility (hospital, etc.) |
| Patient in the same hospital but outside of the Care Unit |
| Patient in an ambulance/ Helicopter |
| Patient in a licensed medium-acuity care facility (LTAC, etc.) |
| Nursing staff available to assist patient |
| Patient in a low-acuity facility (senior housing) |
| Patient in transport |
| Patient at home |
| Remotely monitored by hospital or 3rd party independent surveillance service |
| Patient reported outcome (PRO), Structured/ unstructured, Video call. |
```

b. Limited to monitoring? Or also therapies / treatment? (e.g., home dialysis)
   i. For example, you may be sending COVID-19 patients home from hospital ASAP but need to monitor and "remote" treatments
   ii. Chronic patients may also have an elevated need for RM/MH given their existing frailty / vulnerability

c. Consider also visiting nurses, nurse support, etc. vs. simple person / family care giver support
d. Add "Where is the clinician or nurse?" as another dimension

5. NEXT WEEK:
   a. Consider converting the diagram / model & "Variations" above into a table that can be used to capture various dimensions
   b. Gora will provide a briefing on primary care remote care to patients (now almost 100%)

Agenda

1. General Updates on Technical Report Development & Standards Coordination & Community Engagement
2. Topics:
   a. (Ken) Variations expanded w/ table representation
   b. (Gora) Briefing on primary care's use of RM/MH for most "visits" today
3. Document Outline Review
4. New Business

Participants

Todd Cooper Kenneth Fuchs Gora Datta Konstantinos Makrodimitris John Rhoads
Axel Wirth

Meeting Notes

1. General Updates
   a. Updated on changes to SES RM/MH
   b. ACTION: (Kosta) Invite Greg Zeller & John Garguilo
2. Topic: Review RM/MH Continuum Slides (Ken)
   a. Discussed the slides "Remote" Monitoring - Continuum
   b. Considered overlaying 4 quadrants diag (above) with the Continuum w/ "Time to Respond" vs. "Acuity" axes;
   c. Factor in geographies (implicitly / explicitly): Urban, Suburban, rural etc. + Underserved communities
   d. Factor in advanced identification of long-term acute individuals (e.g., on a ventilator at home) - and taking early action to prevent severe impact
   i. For example, often patients on vents self-position in / at an ER just in case the power goes out in a hurricane and they don't want to run the risk
   e. PURPOSE: Understand the meaning of RM - organizing current segments - in a model that can help organize the SES RM /MH guidance & strategy below
   f. NOTE: Discussed RM w.r.t. Bakul's AAMI Digital Health webinar yesterday
   g. ACTION (Ken) provide an updated version of the diagram + tabular rendering
   h. ACTION (Kosta / Gora) See if there is a nomenclature for these areas already + vet with clinical experts
3. Topic: Real-world data that can be captured from RM/MH ... especially in crisis response
   a. ACTION (Todd) add this topic as a place holder in the technical report outline below

Action Items / Task Lists

- [ ] Todd Cooper Craft sub-pages for the various sections
- [ ] Kenneth Fuchs Update "remote monitoring" graphic and table per discussion last week
- [ ] Example CMS Place of Service Codes
Konstantinos Makrodimitris Invite additional participants: John Garguilo, Dr. Gregory Zeller, Orlando Lopez, Kenneth Fuchs Update graphic & tabular version
Gora Datta Nomenclature defined somewhere for these care contexts? e.g., ATA or SNOMED etc.
Konstantinos Makrodimitris Engage some internal clinicians to review slides
Todd Cooper Finish migrating content from proposal slides + use of real-world evidence collection topic place holder

Agenda
1. General Updates on Technical Report Development & Standards Coordination & Community Engagement
2. Topics:
   a. ...
3. Document Outline Review
4. New Business

Participants
Konstantinos Makrodimitris Todd Cooper Gora Datta Kenneth Fuchs John Rhoads John J. Garguilo
Axel Wirth, Greg Zeller,

Meeting Notes
1. Introductions: Greg Zeller joined the team
2. Review of AAMI FDA Digital Health Webinar
   a. Gora & Kosta reviewed the slide deck from Bakul in the FDA for AAMI webinar last week
   b. Very little standards coordination or international coordination of Digital Health initiative
   c. Given the international standards activity in digital health and devices.
3. Review of the IMDRF SaMD Guidance
   a. Kosta reviewed the IMDRF SaMD Guidance document
   b. Includes discussion around mobile SaMD apps
   c. This is an opportunity to engage FDA CDRH via the IMDRF guidance ...
4. Reviewed the Remote Monitoring classification slides
   a. Ken reviewed his updated slide w.r.t. remote monitoring "contexts" nomenclature
      i. Slide #54 includes U.S. CMS Nomenclature for “Places of (Healthcare) Service”
         ii. These are required for CMS submissions for care delivery claims
         iii. NOTE: #02 is Telehealth facility ... patient goes to specialized telehealth facility and is "remote" - physician is in his office
a. Note: Consider **Remote Care** vs. Remote Monitoring  
  i. **(Axel)** Does "care" include treatment? Diagnosis?  
  ii. **Focus on remote care functions/dimensions:** Connectivity Displaying Transmitting Reporting Alerting  
  Controlling Analyzing Diagnosing...others?  
  iii. Treating is probably an extreme remote care scenario although it can happen: remote surgery, robotic assisted surgery, teledentistry/orthodontics, AI devices in future etc  

b. Characterizing Remote Care Contexts:  
   i. Where is the patient?  
   ii. Where is the clinician? Visiting Nurse? Coaching?  
   iii. What is the acuity? (risk analytics / risk classification / stratification)  
   iv. What is the morbidity / morbidities?  
   v. Health and wellness monitoring requirements?  
   vi. …  

c. **NOTE:** SES MDI Risk Assessment guidelines is predicated on (d) above, then across the Key Properties  
   i. What are the Quality of Information / Data ... Quality of Service ... etc. requirements  
   ii. Can "remote care" DECISIONS be made on the data received?  
   iii. Analogous to Patient Reported Outcomes  

2. U.S. HHS Hearings Energy & Commerce Committee including "telemedicine" update with COVID-19  
   a. TODAY’s hearings included statements:  
      • Coronavirus pandemic has highlighted importance of telemedicine, top doctors say From CNN's Amanda Watts  
      Top doctors told the House Energy and Commerce Committee today that telemedicine has been instrumental during the Covid-19 pandemic – and they hope it is here to stay. "Telemedicine is a very important component...as we look forward in the future, I think you're going to see a lot more of that," Dr. Anthony Fauci, director of the National Institute for Allergy and Infectious Diseases, told a House hearing today. Admiral Dr. Brett Giroir, assistant secretary for health at US Department of Health and Human Services, said with a huge increase of virtual visits, the US has "learned tremendous lessons about the utility of telemedicine."  
      • “Just to understand the uptake — the week of Jan. 15 there are only 500 telehealth visits by Medicare, the week of April 15, there was 150,000 of them,” Giroir said at the same hearing. Dr. Robert Redfield, director of the US Centers for Disease Control and Prevention, said it is very important to get the health system back up and running as soon as possible. “The introduction of telemedicine is a critical component, something that needs to stay as part of the innovation, as we work more and more to move from a disease based system to a health system,” Redfield said.

**Agenda**  
1. General Updates on Technical Report Development & Standards Coordination & Community Engagement  
2. Topics:  
   a. ...  
3. Document Outline Review  
4. New Business  

**Participants**  
Kenneth Fuchs Todd Cooper Konstantinos Makrodimitris John Rhoads Gora Datta  
Axel Wirth  

**Meeting Notes**  
1. WP Title Discussion  
   a. Should the title be modified to include "remote CONNECTED care"?  
   b. Gora researched use of the phrase "connected care":  
      i. Is increasingly used in the market place, BUT  
      ii. Not aligned with a specific company or organization  
      iii. the phrase "remote connected care" not used anywhere at this point
iv. **ACTION** (Gora) add emailed research links to this confluence page

c. Does this also require understanding / addressing non-connected care?
   i. For example, visiting nurse or someone calling the patient w/o "connected" component
   ii. Non-connected care will increasingly not be viable because who
   iii. Address this topic as part of the technical report content

d. Ken - consider "remote monitored care"
   i. Vs. actual treatment vs. monitoring
   ii. treatment is definitely increasingly in future systems and should be addressed in the technical report

e. Axel remote treatment monitoring vs. delivery?
   i. technical report would address the topic but then identify what is near / further term
   ii. See Remote Care / Remote Monitoring topic in previous meeting
   iii. See references below

2. Definitions
   a. **Remote** = not face-to-face
      i. NOTE: On the patient side of "remote" there may be a non-skilled / limited skilled caregiver "locally" working with remote clinician
      ii. For example, SNF or "remote consult"
      iii. See Remote Health graphic above
   b. **Connected** = digital information flow bi-directionally, sync and non-sync between patient & provider
   c. **Care** = Includes both "diagnosis & treatment"
      i. D&T is the regulatory medical meaning of this phrase
      ii. This includes: observation, intervention, detection, ...

3. **Topic: Digital Health**
   a. Include as a core topic in the technical report

4. **Potential Remote Connected Care Locations**
   a. Ken updated the discussion slides ...
   b. Ken will work with Gora to finalize version of the graphics ...

5. **ETSI IoT Security for Consumer Devices**
   a. Axel discussed the ETSI IoT standard (ETSI EN 303 645)
   b. Includes 13 criteria for personal health device for inclusion in scope of standard
      i. No universal default passwords
      ii. Implement a means to manage reports of vulnerabilities
      iii. Keep software updated
      iv. Securely store sensitive security parameters
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      vi. Minimize exposed attack surfaces
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      viii. Ensure that personal data is secure
      ix. Make systems resilient to outages
      x. Examine system telemetry data
      xi. Make it easy for users to delete user data
      xii. Make installation and maintenance of devices easy
      xiii. Validate input data

6. **Remote Treatment References**
   c. [https://www.kidney.org/atoz/content/homehemo](https://www.kidney.org/atoz/content/homehemo)

7. **Document Organization Discussion**
   a. How to formalize document on these confluence pages
   b. How to publish the technical report while keeping the dynamic content here (or similar)
   c. To be discussed in more detail next week

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**Action Items / Task Lists**

- Gora Datta Update the Remote Mobile Health graphic above
- Gora Datta add emailed research links to this confluence page
- Kenneth Fuchs Gora Datta 07 Jul 2020 Update the "locations" graphic

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1. General Updates on Technical Report Development & Standards Coordination & Community Engagement
2. Topics:
   a. Editorial Planning (Kosta/Ken UPDATE) 5mins
   b. Roadmap this summer-fall for the technical report (potential milestone 12-14 weeks) 20mins
      i. specific sessions (clinicians/cases, security, clinical trials/EHR & interop, NIH research/proposals, )
      ii. focus on home use? Human factors expert, patient/consumer perspective, mobile phones and apps landscape
      iii. senior population high risks case and story/geriatrics
      iv. Medical Device data/parameter and sensors need to interop with other data and algorithms(labs, AI, risk scores, drug medications...)
   c. IEEE P2933 - Discussion for how to "integrate" 10mins
3. Document Outline & Content Discussion
4. New Business

Participants

Konstantinos Makrodimitris  Gora Datta  John Rhoads  Todd Cooper  Kenneth Fuchs  Paul Schluter  John J. Garguilo

Dr. Greg Pappas, Axel Wirth

Meeting Notes

1. General Updates
   a. Dr. Greg Pappas - first meeting; public health physician at FDA; focused on RWE and the challenges around interoperability
   b. Dr. Paul Schluter - retired from GE, but continuing focus on medical device informatics standardization, especially around terminology / nomenclature
   c. Reviewed Agenda

2. Editorial Planning
   a. Kosta asked Ken to be General Editor - still waiting for final Dräger approval to take on this role, but will accept in the interim
   b. Call for Co-Editors?
      i. Gora volunteered as a Contributing Editor
   c. Roadmap Discussion
      i. Time frame
         1. ISO/TC215 WG2 is a PWI - Meaning the clock has not started; we will report out during the October meetings, at which point we can
         2. In IHE and HL7, we can go as fast or short as appropriate
         3. NOTE: Important to constrain the time to a few months to keep the document content "tight"
      ii. Outline / Topics
         1. (Pappas) Subject Matter Context: How this work connects with other related activities (e.g., to Logica Roadmap)
         2. (Pappas) Use Cases & Value Propositions - establishing relevance and benefits based on the challenges being addressed
         3. (Kosta) Pharma - looking for how to integrate device-sourced information during clinical trials
      iii. Web Discussion Sessions
         1. (Kosta) Security (Axel & Fitzgerald)
         2. Semantic (Schluter)
         3. Clinical Cases (Pappas and Goldman)
         4. Others ....
      iv. Core Care Context Foci
         1. Home health context
         2. ICU - Remote Viewing of Patient
     v. <see Agenda (2.b) above>

3. "Where's Waldo?" (the patient) Discussion
   a. Ken presented updated slides mapping out perspectives on patients, providers, care contexts, etc.
   b. Expanded sequence of slides to show the different layers and connections of the topics within this area
   c. (Kosta) Need to capture use cases that can be used to define and chart the dynamics across these models
   d. (Todd) The intersection of these models + use cases could significantly improve the productivity / value of focused discussions (mentioned above)
   e. (Kosta) Need to include a focus on the intersection between med tech "trials" and the integration / leveraging of RWE & aggregated data
   f. (Ken) these diagrams focus more on where the patient is vs. where / how the "connected" care monitoring / information systems live and network

4. IEEE P2933 - Discussion for how to "integrate"
   a. Ken provided an overview of the project
   b. Showed the project Scope diagram

   What is our Scope?

   P2933 Scope

   Health IoT

   Clinical IoT

   "research" Medical Device IoT  "approved" Medical Device IoT

   Bio-Physical Device IoT

   Environmental Device IoT

   Psychological Wellness Device IoT

   Spiritual Wellness Device IoT

   IEEE: Advancing Technology for the Benefit of Humanity

   #1: Managing Glucose Levels
   #2: Farm to Table

c. Reviewed some of the Clinical Narratives
   i. #1: Managing Glucose Levels
   ii. #2: Farm to Table
Action Items / Task Lists

No new action items.

Agenda

1. Agenda Review / Introductions / General Updates
2. Roadmap for WP in Q3/Q4, discuss 14-15 weeks, specific sessions
3. Editorial plans/updates
4. Different ICU remote monitoring approaches/examples as it affects COVID19, data analysis, trials, EHRs?

Participants

Konstantinos Makrodimitris Gora Datta John Rhoads Todd Cooper Kenneth Fuchs Paul Schluter John J. Garguilo
Dr. Greg Pappas, Axel Wirth

Meeting Notes

1. Konstantinos displayed a proposal for the ToC of the Technical Report
   a. Proposal was well accepted
   b. Some discussion related to the 3rd slide, especially around clinical trial use cases.
2. Greg supported the need for strong nomenclature guidance
   a. State of the art still seems to be faxes and pdfs for distributing lab results for Covid results
   b. Paul was requested to reserve some time for some nomenclature related sessions
3. Paul discussed the paper that Kosta distributed that discussed the situation in patient monitoring and clinical information systems.
   a. Main point was the need to support high-resolution data with low latency, also for annotation of data
4. Ken showed an update of the RCC Powerpoint deck
   a. Trying to distinguish between the "remote watchers" and the "remotely watched"
   b. Gora pointed out:
      i. We should accommodate Specialists provide remote consults to patients in PCP offices as well as in hospitals
      ii. CROs should be able to monitor clinical trials in hospitals as well as out of hospitals

Action Items / Task Lists

No new action items

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Konstantinos Makrodimitris Gora Datta John Rhoads Todd Cooper Kenneth Fuchs Paul Schluter John J. Garguilo
Dr. Greg Pappas, Axel Wirth

Meeting Notes

1. Discussed latest Interoperability Standards Advisory
2. Discussed issues with today's IT solutions and the way the pandemic is exposing our infrastructure shortcomings.
3. Reviewed Ken's slide on Connected Care Communications paths
4. Review Gora's slide on RCC & MH.
5. Adjourned

Meeting Documents
Action Items / Task Lists
No new action items

Agenda
1. Agenda Review / Introductions / General Updates
2. Editorial plans/updates
3. Different ICU remote monitoring approaches/examples as it affects COVID19, data analysis, trials, EHRs?
Meeting Notes

1. Reviewed Ken’s slides on how the Pandemic is affecting Connected Care (see attached document toward the end)
   a. New requirements
   b. Accelerating requirements
2. Kosta asked Paul about a future meeting to discuss nomenclature alternatives
   a. How would Snomed fit into our work?
   b. Paul believes that the IEEE 11073 and HL7 LOINC nomenclatures can fulfill most of my requirements
      i. 11073 and LOINC are coordinating in mapping a subset of terms to each other’s nomenclatures
      ii. Further discussion at a later date
3. Adjourned

Action Items / Task Lists

No new action items

Agenda

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Participants

Kosta reviewed the status of the technical report in ISO
a. Decision in process to decide whether this will stay with WG2 - will probably not move (Gora)
2. Kosta - introduced Isabel Tejero from FDA
3. Kosta - pending vote on AI/ML paper from TC215 WG2
4. Kosta - current goal to finish paper by end of October - but this is just a target, to be adjusted as necessary
   a. Gora - should have the structure and some content by October
5. Gora - started to discuss the provider perspectives on RCC
6. Need to start blocking dates for future discussions/presentations
   a. Brian Fitzgerald, Greg Pappas, Andrea, Axel
   b. Avoid HL7 and TC215 weeks
   c. Gora Datta and Konstantinos Makrodimitris to arrange and schedule the speakers
7. Gora - CMS to extend reimbursement for telehealth
8. Gora - IEEE Healthcare: Blockchain and AI Virtual Series
   a. Mark you calendars: Oct 7, 2020. Our work (RCC-MH) is the start presentation and will kick-off this virtual series.
   b. Multi-day conference, podcasts, technical reports - Gora Datta send out link for info
9. HIMSS21 (scheduled for Aug 2021 in Las Vegas): they want us to give a talk there on our work.
10. Kosta - Funding available in NIH and Government related to remote care and treatment
11. Gora - been speaking with providers (these are outpatient Physicians Practices) about our work and looking into the possibility of inviting them to our call and discuss their current experience of “seeing” patients at their practice. I have spoken with 4 so far (3 PCP and 1 specialist). May reach out to few more. Interesting and contrasting responses so far:
   a. “we are providing sub-optical care to our patients with this remote care” (can’t touch them, elderly, etc.)
   b. “I really don’t need (to a large extent) to see patients in my office as long as I have access to their health data”
12. Axel - Looking for 2 hours initially to cover security related topics
   a. Would like NIST participation as well
   b. Brian Fitzgerald could also participate
   c. IEEE 11073-40101; 40102 have been reviewed by FDA. 40102 went to IEEE Revcom today.
   d. Locked in for 9/1.
13. Paul - suggests sometime in September; tentative 9/22 for 1 hour;
   a. topic would be terminology related issues both PHD and Acute Care terminology
      i. Overview of breadth of devices (vents, dialysis, etc.) covered and home care relevant devices
   b. Any need to invite others such as from LOINC? Swapna would be a great collaborator.
   c. Consider Ted Klein as another contact (lab values) - not our focus
14. Gora - how about the provider dates?
   a. Shoot for 9/8; 90+ minutes; we need to work on the questionnaire for them
   b. Develop questionnaire on 8/18
15. Kosta - 9/29 and 10/6 for FDA Digital Health
16. At some point we need to address the "rapid acceleration" aspect of the paper, as well as the MH aspects
17. Adjourned

Meeting Documents

Agenda

1. Reviewed status of SES MDI RM / MH technical report project approval and development
2. Planning for technical report content development
3. New Business

Participants

Konstantinos Makrodimitris John Rhoads Gora Datta Todd Cooper

Meeting Notes

1. General Status Review & Backgrounder (All)
   a. Review of technical report project approvals (IHE & HL7 & TC215)
2. Development Planning (All)
   a. Starting next Tuesday (2020.06.09) begin 1 hour weekly work sessions; use IHE DEV WebEx;
   b. Create Project Team list on this page
   c. Include web meeting notes on this page

Agenda

1. General Updates on Technical Report Development & Standards Coordination & Community Engagement
2. Content Review and Development Planning
3. New Business

Participants

Todd Cooper Gora Datta Konstantinos Makrodimitris Kenneth Fuchs

Axel Wirth

Meeting Notes

1. Reviewed Status / Confluence Page Content
   a. Kosta reviewed some of the objectives from the quad-chart (above)
2. (Gora) Reviewed “Remote Mobile Health” graphic
3. Security Perspectives - Axel
   a. First-Call Introduction - Provided professional & current background (see LinkedIn for specifics).
   b. Current PROCESS FOCUSED approach: 3 Disclosure Pillars
      i. What's supported? (SBom / MDS2)
      ii. What's the vulnerabilities?
      iii. Deployment of vulnerabilities mitigation (patches)
   c. Security needs to be "nimble" because the attacks are dynamic - must have a pragmatic technology approach to reduce the reliance on process (b) above
      i. You can never patch enough to be secure enough ...
      ii. In a crisis response "you go to war with the security you have"
      iii. Consider: Stockpiling med tech is important (think ventilators ready to go) - but is their security provisions maintained and ready for use?

4. Remote Monitoring Scenarios / Variations - Ken
   a. Reviewed a slide with some alternatives for consideration (Work In Progress):

   * Patient in a licensed high-acuity care facility (hospital, etc.)
     * Just outside of the patient room with a view of the patient
     * e.g. isolation room
     * Close to the patient room with limited or no view of the patient
     * e.g. Central Station / Nursing Station
   * Patient in a licensed high-acuity care facility
     * In the same hospital but outside of the Care Unit
     * e.g. Common Area / Ward Area
     * In a different campus or different city in ICU
   * Patient in an ambulance / Helicopter
   * Patient in a licensed medium-acuity care facility (ERT, etc.)
   * Nursing staff available to assist patient
   * Patient in a low-acuity facility (senior housing)
     * Skilled staff available to patient and contact ambulance
   * Patient in transport
   * Patient at home
     * Remotely monitored by hospital or 3rd party independent surveillance service
     * Distinguish between caregiver role, who isn’t part of the immediate clinical care team
   * Patient reported outcome (PACE, Structured/Unstructured, Video call)

   b. Limited to monitoring? Or also therapies / treatment? (e.g., home dialysis)
      i. For example, you may be sending COVID-19 patients home from hospital ASAP but need to monitor and "remote" treatments
      ii. Chronic patients may also have an elevated need for RM/MH given their existing frailty / vulnerability
   c. Consider also visiting nurses, nurse support, etc. vs. simple person / family care giver support
   d. Add "Where is the clinician or nurse?" as another dimension

5. NEXT WEEK:
   a. Consider converting the diagram / model & "Variations" above into a table that can be used to capture various dimensions
   b. Gora will provide a briefing on primary care remote care to patients (now almost 100%)!

Agenda
1. General Updates on Technical Report Development & Standards Coordination & Community Engagement
2. Topics:
   a. (Ken) Variations expanded w/ table representation
   b. (Gora) Briefing on primary care’s use of RM/MH for most “visits” today
Meeting Notes

1. General Updates
   a. Updated on changes to SES RM/MH
   b. **ACTION:** (Kosta) Invite Greg Zeller & John Garguilo
2. Topic: Review RM/MH Continuum Slides (Ken)
   a. Discussed the slides "Remote" Monitoring - Continuum
   b. Considered overlaying 4 quadrants diag (above) with the Continuum w/ "Time to Respond" vs. "Acuity" axes;
   c. Factor in geographies (implicitly / explicitly): Urban, Suburban, rural etc. + Underserved communities
   d. Factor in advanced identification of long-term acute individuals (e.g., on a ventilator at home) - and taking early action to prevent severe impact
      i. For example, often patients on vents self-position in / at an ER just in case the power goes out in a hurricane and they don't want to run the risk
   e. **PURPOSE:** Understand the meaning of RM - organizing current segments - in a model that can help organize the SES RM/MH guidance & strategy below
   f. **NOTE:** Discussed RM w.r.t. Bakul's AAMI Digital Health webinar yesterday
   g. **ACTION** (Ken) provide an updated version of the diagram + tabular rendering
   h. **ACTION** (Kosta / Gora) See if there is a nomenclature for these areas already + vet with clinical experts
      i. Example CMS Place of Service Codes
3. Topic: Real-world data that can be captured from RM/MH ... especially in crisis response
   a. **ACTION** (Todd) add this topic as a place holder in the technical report outline below

Action Items / Task Lists

- Todd Cooper Craft sub-pages for the various sections
- Kenneth Fuchs Update "remote monitoring" graphic and table per discussion last week
- Konstantinos Makrodimitris Invite additional participants: John Garguilo, Dr. Gregory Zeller, Orlando Lopez,
- Kenneth Fuchs Update graphic & tabular version
- Gora Datta Nomenclature defined somewhere for these care contexts? e.g., ATA or SNOMED etc.
- Konstantinos Makrodimitris Engage some internal clinicians to review slides
- Todd Cooper Finish migrating content from proposal slides + use of real-world evidence collection topic place holder

Agenda

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Participants

Konstantinos Makrodimitris Todd Cooper Gora Datta Kenneth Fuchs John Rhoads John J. Garguilo

Axel Wirth, Greg Zeller,

Meeting Notes

1. Introductions: Greg Zeller joined the team
2. Review of AAMI FDA Digital Health Webinar
   a. Gora & Kosta reviewed the slide deck from Bakul in the FDA for AAMI webinar last week
   b. Very little standards coordination or international coordination of Digital Health initiative
   c. Given the international standards activity in digital health and devices.
3. Review of the IMDRF SaMD Guidance
   a. Kosta reviewed the IMDRF SaMD Guidance document
   b. Includes discussion around mobile SaMD apps
   c. This is an opportunity to engage FDA CDRH via the IMDRF guidance...
4. Reviewed the Remote Monitoring classification slides
4. 

a. Ken reviewed his updated slide w.r.t. remote monitoring "contexts" nomenclature

![Remote Connected Care - Continuum](image)

b. Slide #54 includes U.S. CMS Nomenclature for "Places of (Healthcare) Service"
   i. These are required for CMS submissions for care delivery claims
   ii. NOTE: #02 is Telehealth facility ... patient goes to specialized telehealth facility and is "remote" - physician is in his office

![U.S. CMS “Places of (Healthcare) Service” - Potential Remote Connected Care Locations](image)

a. Note: Consider Remote Care vs. Remote Monitoring
   i. (Axel) Does "care" include treatment? Diagnosis?
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      vii. Ensure that personal data is secure
      viii. Make systems resilient to outages
      ix. Examine system telemetry data
      x. Make it easy for users to delete user data
      xi. Make installation and maintenance of devices easy
      xii. Validate input data
      xiii. Consider reference and discussion in technical report

6. Remote Treatment References
   c. https://www.kidney.org/atoz/content/homehemo
7. Document Organization Discussion
   a. How to formalize document on these confluence pages
   b. How to publish the technical report while keeping the dynamic content here (or similar)
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Action Items / Task Lists
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- Gora Datta: add emailed research links to this confluence page
- Kenneth Fuchs: 07 Jul 2020 Update the "locations" graphic

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   b. Roadmap this summer-fall for the technical report (potential milestone 12-14 weeks) 20mins
      i. specific sessions (clinicians/cases, security, clinical trials/EHR & interoper, NIH research/proposals, )
      ii. focus on home use? Human factors expert, patient/consumer perspective, mobile phones and apps landscape
      iii. senior population high risk case and story/geriatrics
      iv. Medical Device data/parameter and sensors need to interop with other data and algorithms(labs, AI, risk scores, drug medications...)
   c. IEEE P2933 - Discussion for how to "integrate" 10mins
3. Document Outline & Content Discussion
4. New Business

Participants
Konstantinos Makrodimitris, Gora Datta, John Rhoads, Todd Cooper, Kenneth Fuchs, Paul Schluter, John J. Garguilo

Dr. Greg Pappas, Axel Wirth

Meeting Notes
1. General Updates
   a. Dr. Greg Pappas - first meeting; public health physician at FDA; focused on RWE and the challenges around interoperability
   b. Dr. Paul Schluter - retired from GE, but continuing focus on medical device informatics standardization, especially around terminology / nomenclature
   c. Reviewed Agenda
2. Editorial Planning
   a. Kosta asked Ken to be General Editor - still waiting for final Dräger approval to take on this role, but will accept in the interim
   b. Call for Co-Editors?
      i. Gora volunteered as a Contributing Editor
   c. Roadmap Discussion
      i. Time frame
         1. ISO/TC215 WG2 is a PWI - Meaning the clock has not started; we will report out during the October meetings, at which point we can
         2. In IHE and HL7, we can go as fast or short as appropriate
         3. NOTE: Important to constrain the time to a few months to keep the document content "tight"
      ii. Outline / Topics
         1. (Pappas) Subject Matter Context: How this work connects with other related activities (e.g., to Logica Roadmap)
         2. (Pappas) Use Cases & Value Propositions - establishing relevance and benefits based on the challenges being addressed
         3. (Kosta) Pharma - looking for how to integrate device-sourced information during clinical trials
      iii. Web Discussion Sessions
         1. (Kosta) Security (Axel & Fitzgerald)
         2. Semantic (Schluter)
         3. Clinical Cases (Pappas and Goldman)
         4. Others ....
      iv. Core Care Context Foci
         1. Home health context
         2. ICU - Remote Viewing of Patient
      v. <see Agenda (2.b) above>
3. "Where's Waldo?" (the patient) Discussion
   a. Ken presented updated slides mapping out perspectives on patients, providers, care contexts, etc.
   b. Expanded sequence of slides to show the different layers and connections of the topics within this area
   c. (Kosta) Need to capture use cases that can be used to define and chart the dynamics across these models
   d. (Todd) The intersection of these models + use cases could significantly improve the productivity / value of focused discussions (mentioned above)
   e. (Kosta) Need to include a focus on the intersection between med tech "trials" and the integration / leveraging of RWE & aggregated data
f. (Ken) these diagrams focus more on where the patient is vs. where / how the "connected" care monitoring / information systems live and network
4. IEEE P2933 - Discussion for how to "integrate"
a. Ken provided an overview of the project
b. Showed the project Scope diagram

![What is our Scope?](image)

i. Reviewed some of the Clinical Narratives
   a. #1: Managing Glucose Levels
   b. #2: Farm to Table
   c. ...
d. Ken reviewed the scenario "brainstorming" approach (Rosebud analogy)
e. Kosta mentioned that Orlando also mentioned this team reporting to the P2933 group
5. Next Week
   a. Discuss 2015 paper on different remote ICU monitoring approaches from GE and Philips
   b. ...

Action Items / Task Lists
No new action items.

Agenda
1. Agenda Review / Introductions / General Updates
2. Roadmap for WP in Q3/Q4, discuss 14-15 weeks, specific sessions
3. Editorial plans/updates
4. Different ICU remote monitoring approaches/examples as it affects COVID19, data analysis, trials, EHRs?

Participants
Konstantinos Makrodimitris Gora Datta John Rhoads Todd Cooper Kenneth Fuchs Paul Schluter John J. Garguilo

Dr. Greg Pappas, Axel Wirth

Meeting Notes
1. Konstantinos displayed a proposal for the ToC of the Technical Report
   a. Proposal was well accepted
   b. Some discussion related to the 3rd slide, especially around clinical trial use cases.
2. Greg supported the need for strong nomenclature guidance
   a. State of the art still seems to be faxes and pdfs for distributing lab results for Covid results
   b. Paul was requested to reserve some time for some nomenclature related sessions
3. Paul discussed the paper that Kosta distributed that discussed the situation in patient monitoring and clinical information systems.
   a. Main point was the need to support high-resolution data with low latency, also for annotation of data
4. Ken showed an update of the RCC Powerpoint deck
   a. Trying to distinguish between the "remote watchers" and the "remotely watched"
   b. Gora pointed out:
      i. We should accommodate Specialists provide remote consults to patients in PCP offices as well as in hospitals
      ii. CROs should be able to monitor clinical trials in hospitals as well as out of hospitals

Action Items / Task Lists
No new action items
Agenda

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Participants

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Dr. Greg Pappas, Axel Wirth

Meeting Notes

1. Discussed latest Interoperability Standards Advisory
2. Discussed issues with today’s IT solutions and the way the pandemic is exposing our infrastructure shortcomings.
3. Reviewed Ken’s slide on Connected Care Communications paths
4. Review Gora’s slide on RCC & MH.
5. Adjourned

Meeting Documents

- NYT Fax Article.pdf
- Remote Co...If1.pptx
Action Items / Task Lists

No new action items

Agenda

1. Agenda Review / Introductions / General Updates
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Participants

Konstantinos Makrodimitris Gora Datta Kenneth Fuchs Paul Schluter John J. Garguilo
Dr. Greg Pappas, Axel Wirth, Sajjad Syed, Isabel Tejero
Regrets: Todd Cooper John Rhoads

Meeting Notes

1. Reviewed Ken’s slides on how the Pandemic is affecting Connected Care (see attached document toward the end)
   a. New requirements
   b. Accelerating requirements
2. Kosta asked Paul about a future meeting to discuss nomenclature alternatives
   a. How would Snomed fit into our work?
   b. Paul believes that the IEEE 11073 and HL7 LOINC nomenclatures can fulfill most of my requirements
      1. 11073 and LOINC are coordinating in mapping a subset of terms to each other’s nomenclatures
      2. Further discussion at a later date
3. Adjourned

Meeting Documents

Remote Co...7-28.pptx

Action Items / Task Lists

No new action items

Agenda
### RCC - MH Calendar of Events

**Team Calendars**

Other related web meeting discussion notes are captured on the [SDPi+FHIR Meeting Logs & Notes](#) page.

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<th>Description</th>
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