City of Hope

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QUALITY OF LIFE & SURGICAL PALLIATION

Innovations in Patient-Reported Outcomes and Patient-Generated Health Data

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Disclosures

- I do not have any relevant financial relationships.

This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.

Cultural Linguistic Competency (CLC) & Implicit Bias (IB)

STATE LAW:
The California legislature has passed Assembly Bill (AB) 1195, which states that as of July 1, 2006, all Category 1 CME activities that relate to patient care must include a cultural diversity/linguistics component. It has also passed AB 241, which states that as of January 1, 2022, all continuing education courses for a physician and surgeon **must** contain curriculum that includes specified instruction in the understanding of implicit bias in medical treatment.

The cultural and linguistic competency (CLC) and implicit bias (IB) definitions reiterate how patients' diverse backgrounds may impact their access to care.

The following CLC & IB components will be addressed in this presentation:

- Awareness of diverse perspectives in relation to the provision of Patient-Reported Outcomes (PROs) and Patient-Generated Health Data (PGHDs)
- Awareness of potential inequities in the provision of PROs and PGHDs

Patient Generated Health Data (PGHD)

- Health-related data that are created, recorded, gathered, or inferred by or from patients/caregivers to help address a health concern
  - Biometric data (wearable sensors) – i.e. physical activity and intensity
  - Patient-reported outcomes (PROs) – i.e. symptoms, QOL

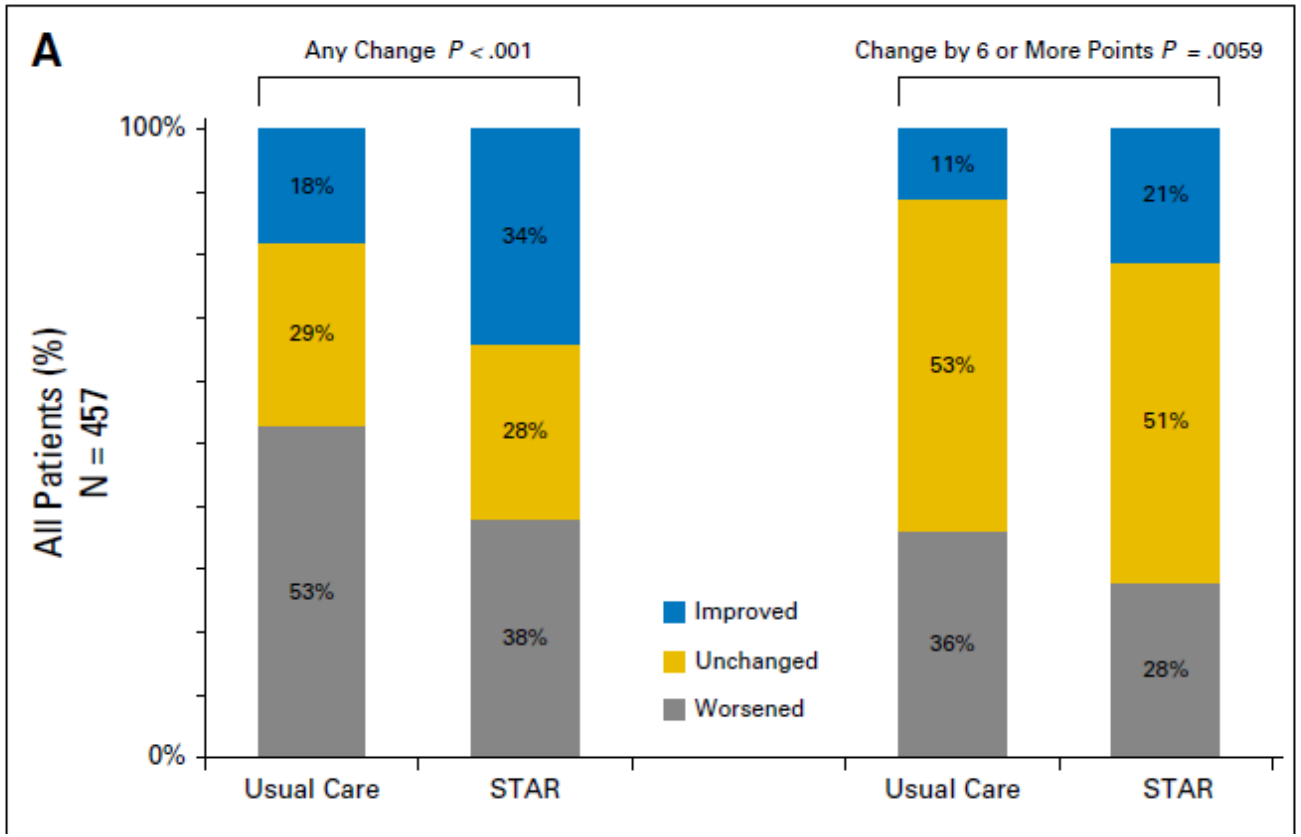
- Field in relation to research is nascent
  - Types of PGHDs most useful for healthcare systems to improve outcomes and quality of care but also most relevant/important to patients
  - Usability for patients and providers
  - Who benefits most from remote monitoring
  - Frequency of data collection, optimal timing, clinical workflow (information overload)

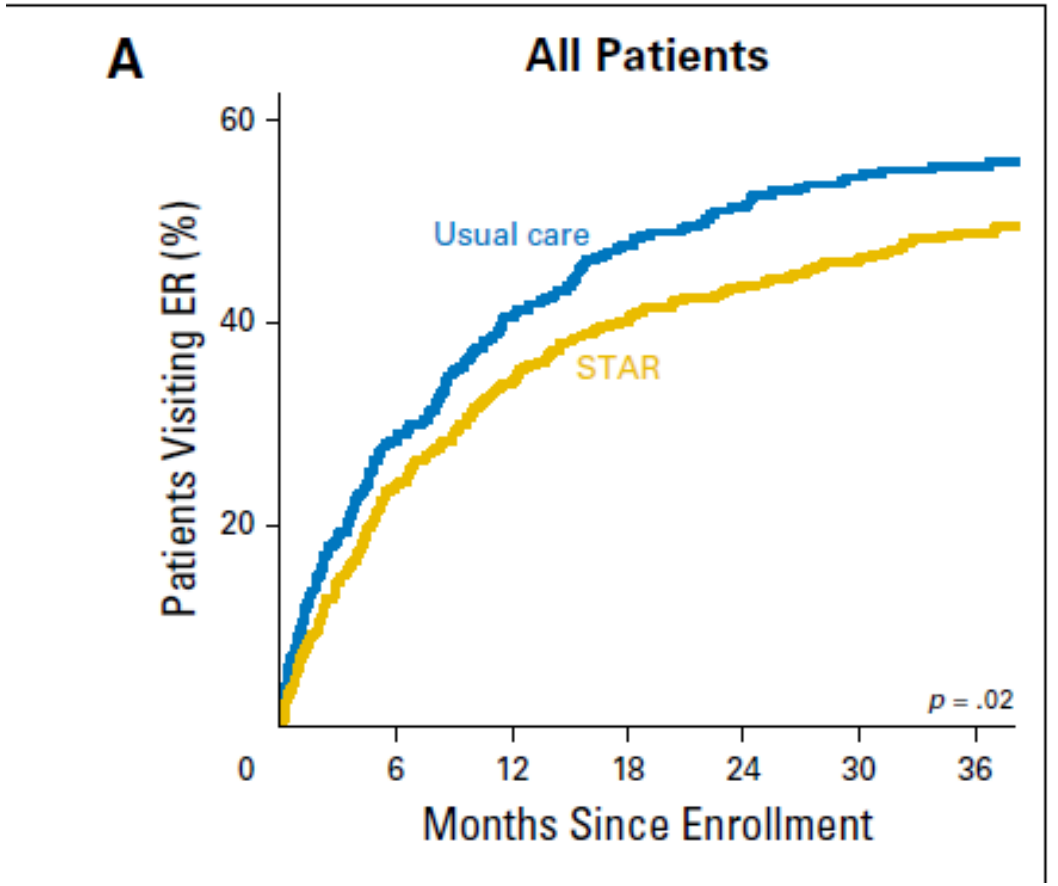
Shapiro et al., 2012. *Patient generated health data: White paper prepared for the Office of the National Coordinator for Health Information Technology*

Electronic Symptom Monitoring in Advanced Cancer

- Metastatic breast, GU, GYN, lung cancer receiving chemotherapy
- Two arm parallel RCT
  - Intervention:
    - Electronic symptom monitoring – 12 common symptoms graded on 0-4 scale
    - Predetermined thresholds – score of 3 or above or worsening scores by 2 points
      - Triggered alerts to RNs, symptom reports printed for clinicians at clinic visits
  - Usual Care:
    - Symptoms discussed with and documented in medical records
    - Patients encouraged to call between visits with issues

Basch et al., Journal of Clinical Oncology, 2016





Overall Survival at 1 year = 69% for usual care versus 75% with intervention (p=.05)

Basch et al., Journal of Clinical Oncology, 2016

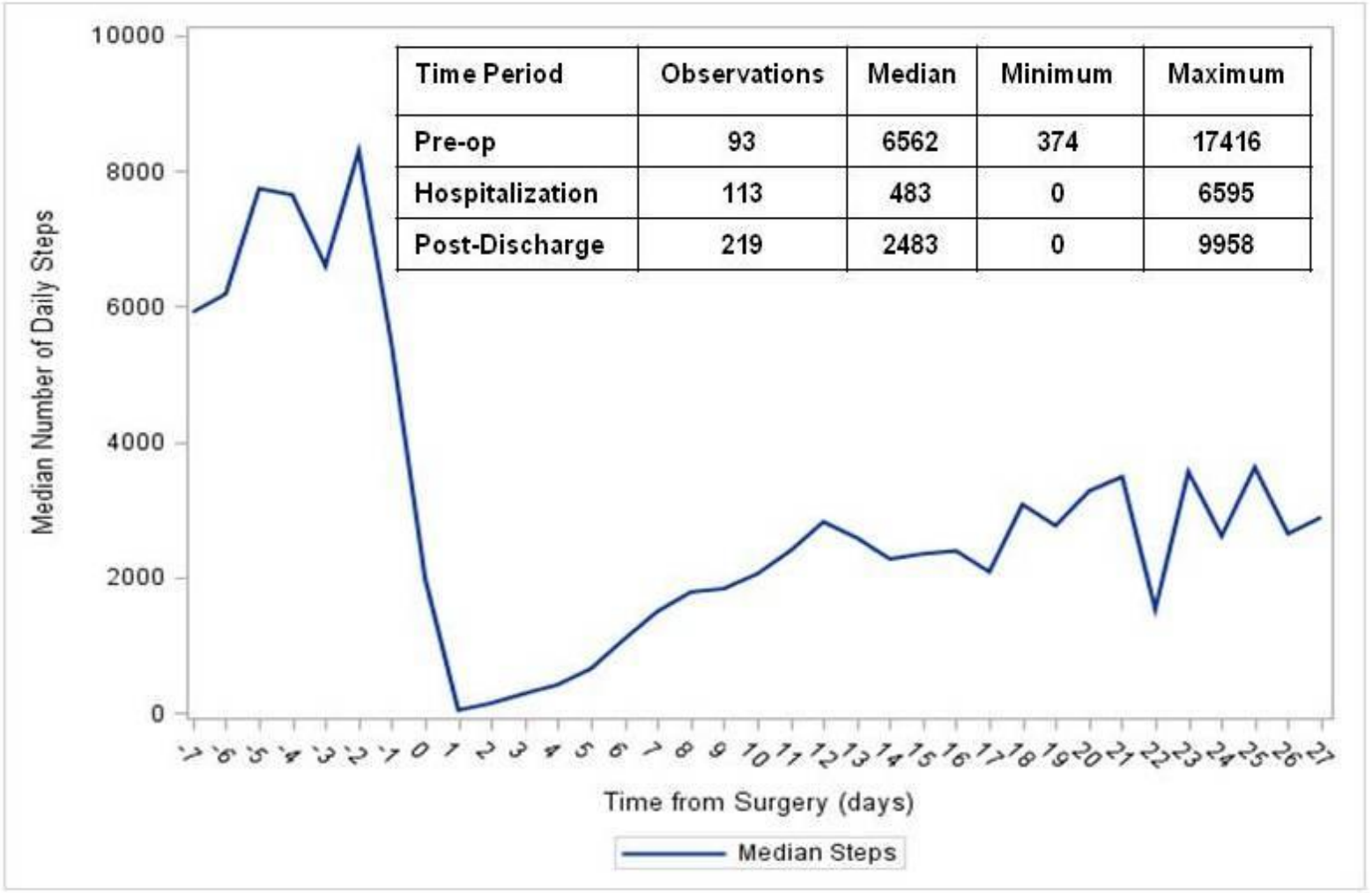
PGHD and PROs in Postsurgical Monitoring

- Challenging to monitor recovery after discharge
- Time between discharge and first postop visit offers an opportunity for symptom management, complication avoidance, readmission prevention
  - “Proactive” versus “reactive” care
- Risk stratification – identifying those at higher risk for postop issues early, allocate support and resources
- Preliminary evidence in surgical populations (cardiac, orthopedics)
  - Greater reduction in symptom thresholds
  - Feasibility and satisfaction for patients and providers
  - Improvements in outcomes

Smith and Basch, 2017 J Oncol Pract
Gunter et al., 2016 J Am Coll Surg
Van der Meij et al., 2016 PLoS One

Wearable Trackers and Postoperative Functional Status Trajectory

Median daily steps measured before surgery (pre-op), during hospitalization, and recovery (post-discharge)

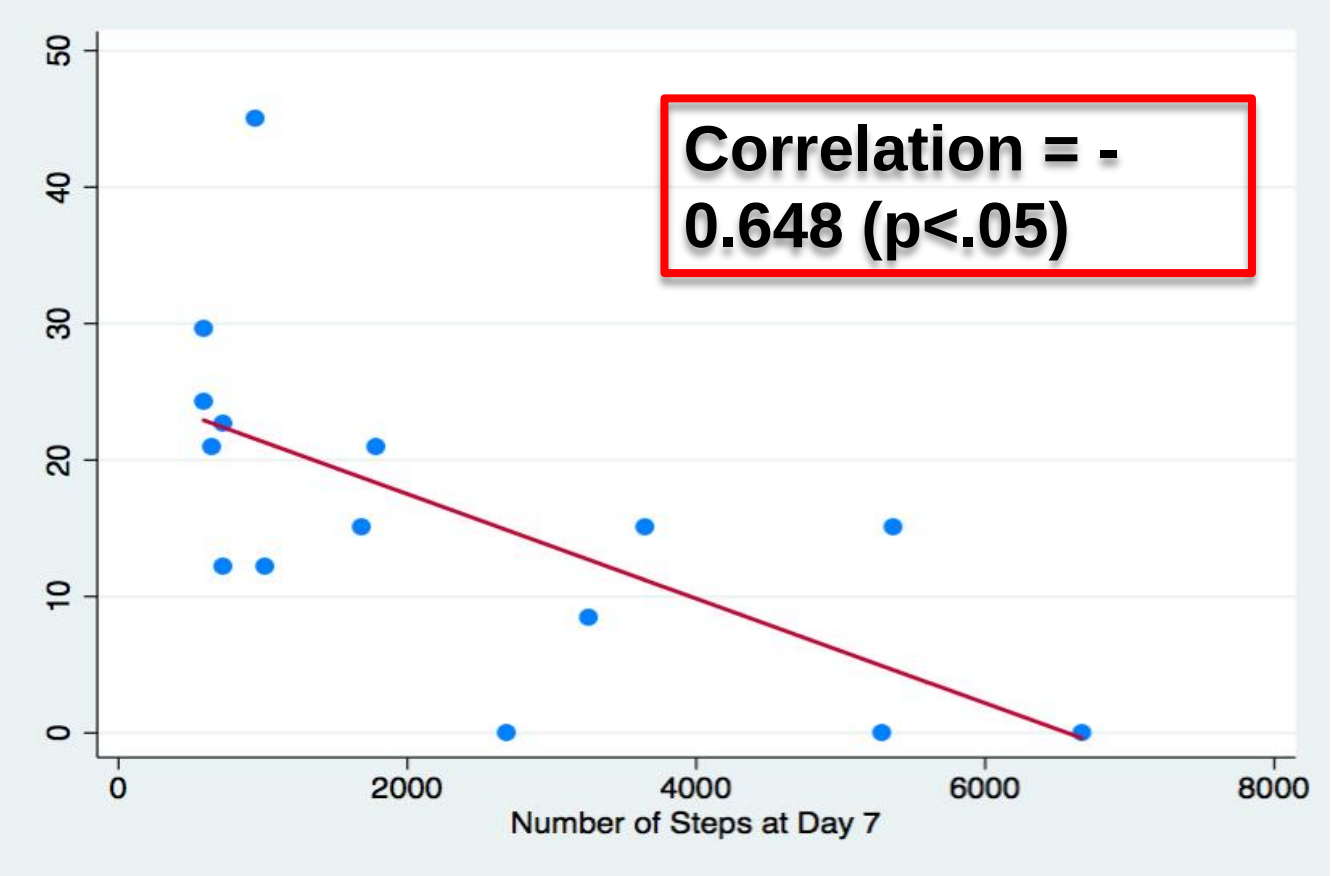


Time Period	Observations	Median	Minimum	Maximum
Pre-op	93	6562	374	17416
Hospitalization	113	483	0	6595
Post-Discharge	219	2483	0	9958

Sun V, Dumitra S, Ruel N, Lee B, Melstrom L, Melstrom K, Woo Y, Sentovich S, Singh G, Fong Y. Wireless monitoring program of patient-centered outcomes and recovery before and after major abdominal cancer surgery. JAMA Surg. 2017;152:852-859

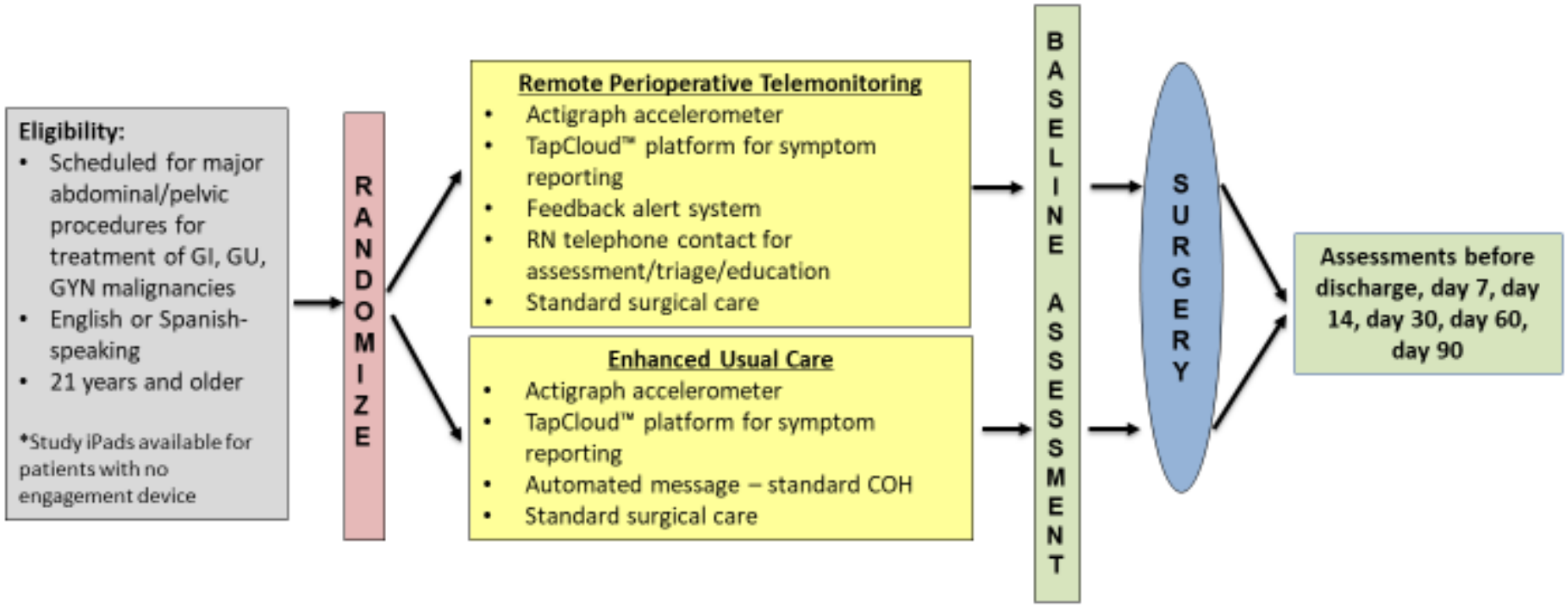
Association with Postoperative Complications

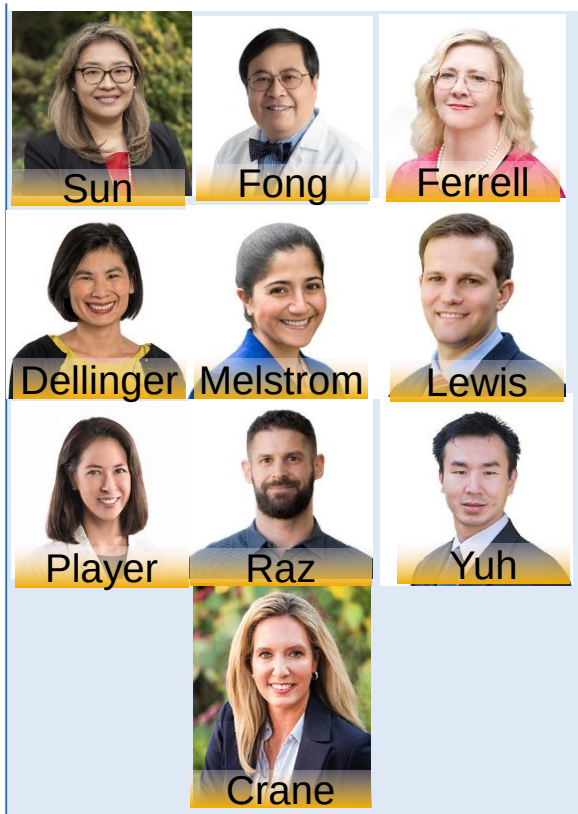
CCI
Scale of 0-100 0= no deviation from expected post-op course
100=death.



- CCI median = 15/100 (IQR: 0-22.6)
- Day 7 daily steps = 1659 (19% of baseline)
- Lower daily steps at day 7, higher risk for postop complications (higher CCI)

Comparative Effectiveness Trial of Perioperative Telemonitoring of Functional Recovery and Symptoms (2020-2023)





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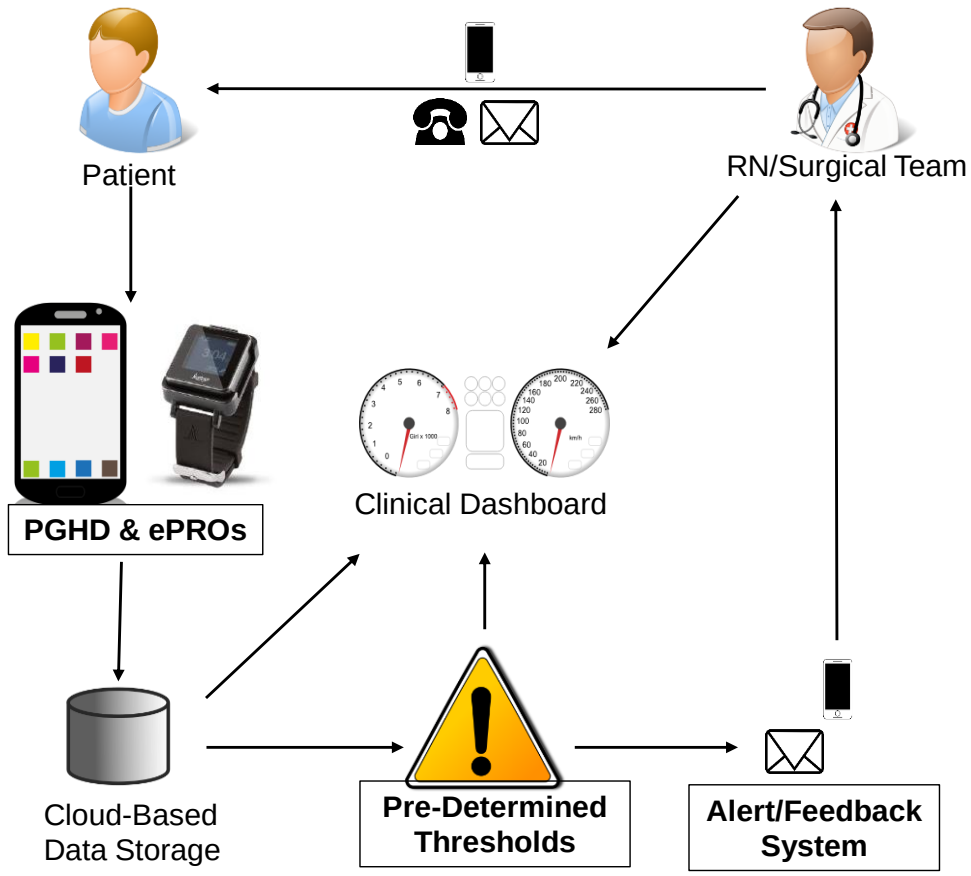
- PCORI IHS-2019C-18215
- University of Miami (Tracy Crane, PhD, RDN)

Remote Perioperative Telemonitoring: Proactive Care



- **PGHD**
  - ❑ Wristband research-grade accelerometer (Actigraph)
- **ePROs**
  - ❑ Symptoms (MDASI) – TapCloud™ platform
- **Real-time, alert feedback system**
  - ❑ Predetermined thresholds
  - ❑ Secure digital engagement platform
  - ❑ Secure alerts to RN
  - ❑ Telephone contact with further assessment/triage for data that deviates from predetermined thresholds

TapCloud: Clinician Interface (Example)

Designed for efficiency, prioritization and speed

- Care teams track patient progress and monitor for warning signs and complications
- Alerts generated based on advanced algorithms
  - Alerts for chronic patients at risk for a complication or exacerbation
  - Alerts for behavioral, emotional and quality of life issues
  - Pre-surgery alerts of potential issues which may delay or cancel surgery
  - Post-surgery alerts to complications which may lead to readmissions, infections and DVTs
- Patients prioritized based on clinical need

The most important components of remote patient monitoring all on one page for rapid decision making

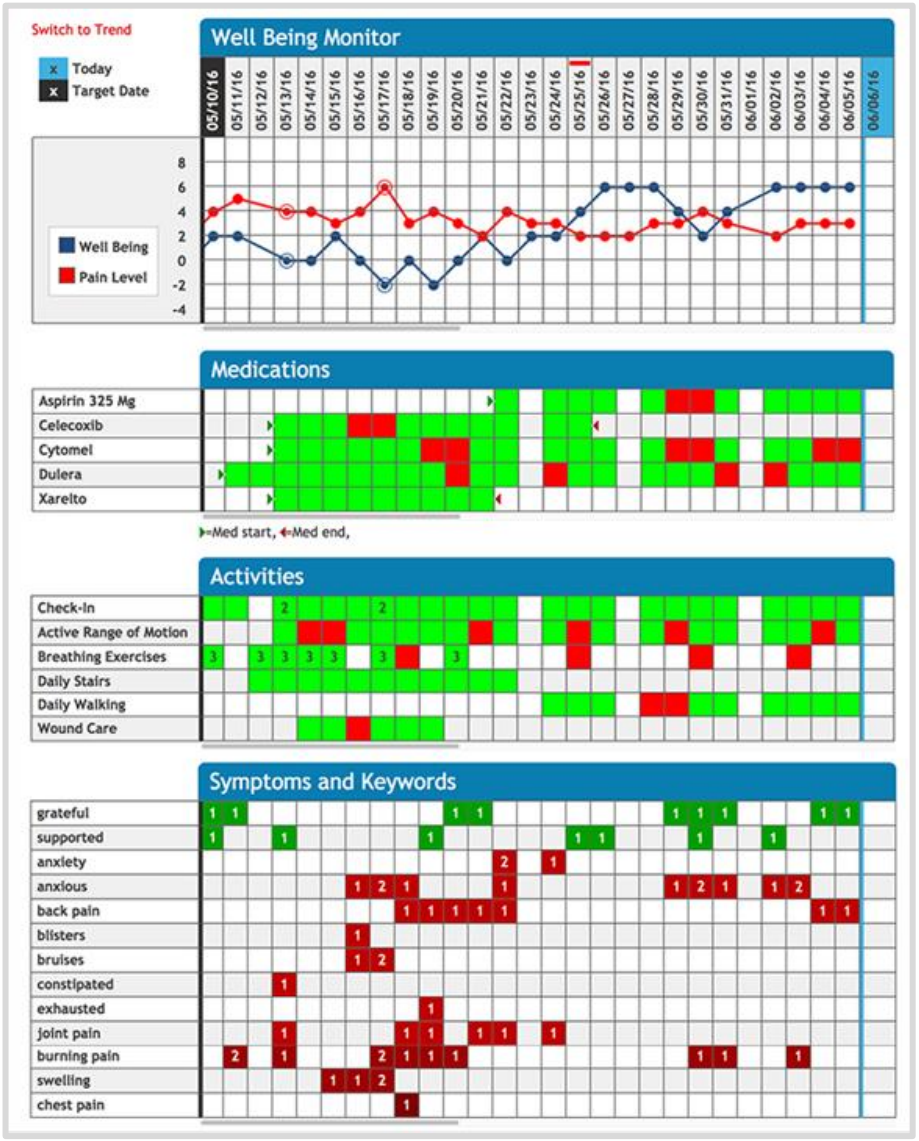
All reported data vertically lined up by date for easy tracking.

Pain and well being trajectory show patient progress.

Tracks medication compliance

Green indicates patient completed activity. Red indicates non-completion.

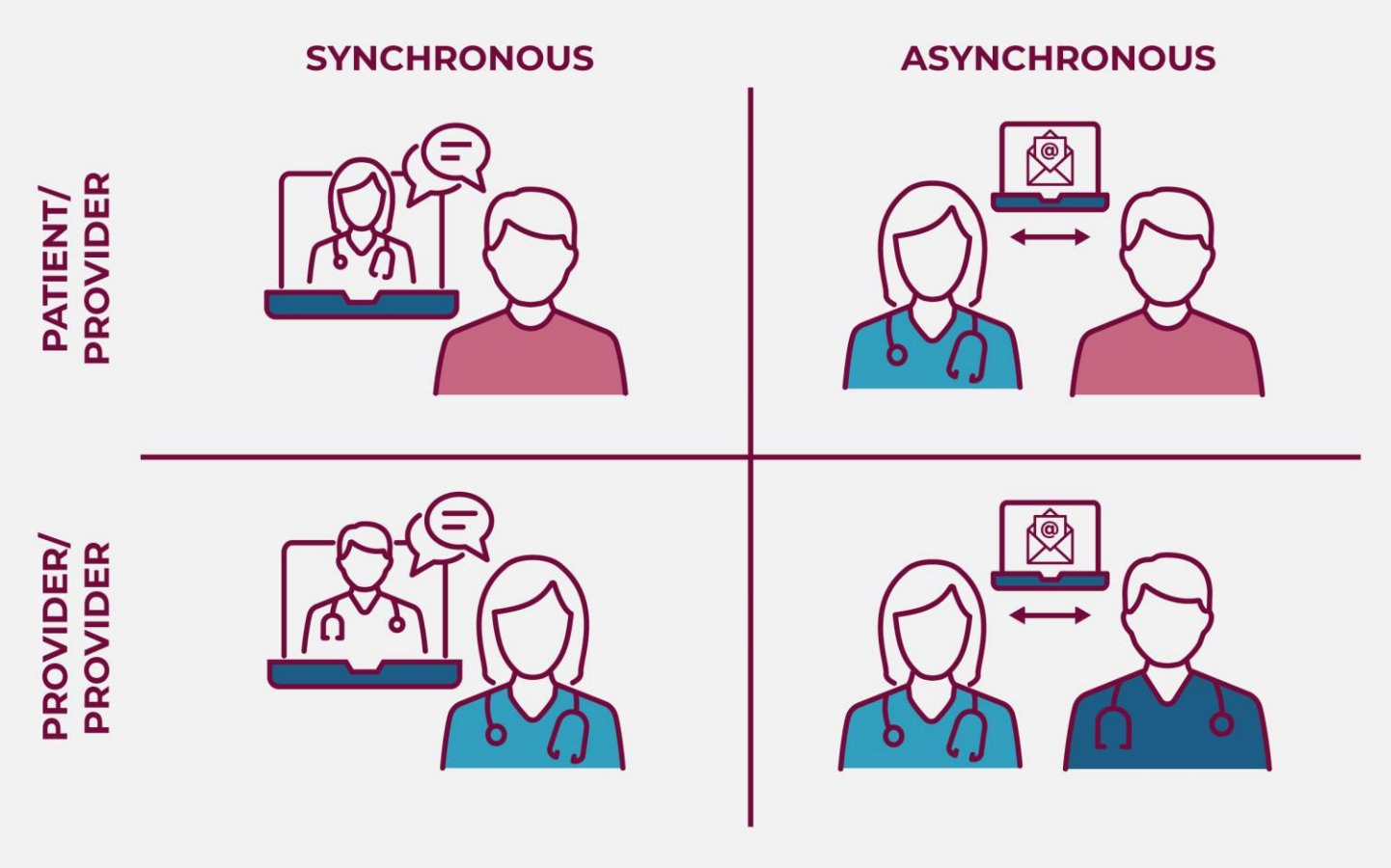
Symptom indicator enables clinician analysis. Green indicates good symptoms. Red indicates bad symptoms.



This Dashboard helps answer:

- When did the symptom or pain start? How long did it continue?
- Did a new medication help resolve a side effect?
- Are psycho-social factors impacting recovery?
- Are opioids being used appropriately?
- Are behavioral symptoms impacting compliance?
- What might be causing a set back in recovery?

Asynchronous/Synchronous Wireless Collection of PROs and PGHDs



https://healthcaredelivery.cancer.gov/telehealth/

Conclusions

- Technology driven collection of ePROs and PGHDs may provide additional data to support clinical trials in surgical oncology, including PIPAC
- Functional recovery can be tracked to observe trajectories over time
- Have potential to augment traditional subjective, QOL data with objective outcomes
- Integrating interventions to address QOL/functional recovery challenges
  - Allow patients to stay on treatment longer
- Challenges:
  - Reimbursement?
  - Burden to research teams
  - Burden to patients
  - How to interpret data and act upon the data