The Role of Clinical Research in Healthcare Technology Evaluation
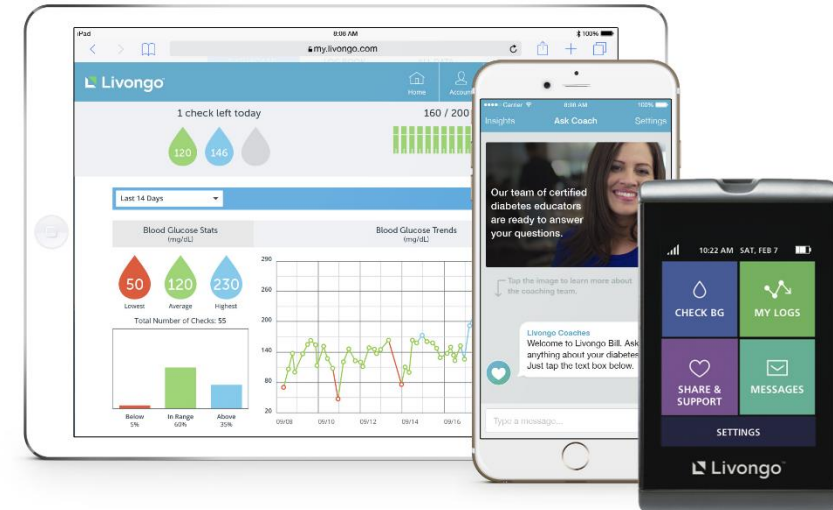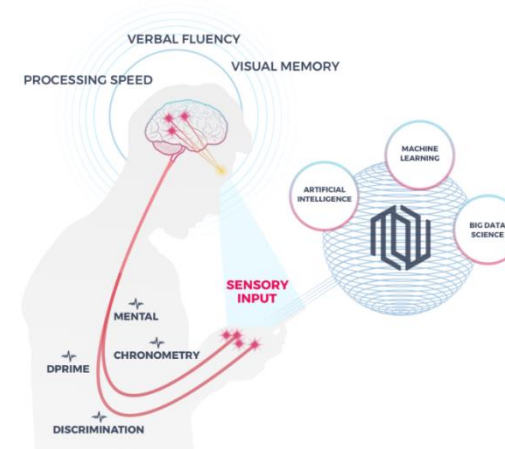
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Overview of talk

- Examples of new technology in healthcare
- How to use clinical research in evaluating these technologies
- Similarities and differences in technology evaluation vs drug trial

Some new tech innovations in healthcare

- Digital phenotype for mental health

- Diabetes e-coaching to provide immediate feedback to patients after they consume a heavy meal

Proposed Mental Health Digital Phenotype studies

Rationale & Background

High rate of relapse (~80%) within 5 years of recovery from a first episode of schizophrenia and schizoaffective disorder places a **high burden** for psychosis patients and their caregivers[2].

Rest-activity and sleep patterns disturbances have been reported as **indicators** in the early stages of relapse in schizophrenia patients. Systematic review study showed the **association of sleep dysfunction and psychosis**[3]

Continuous monitoring of digital markers presents a promising approach to *detect early signs of illness relapse* and other adverse outcomes in patients with mental illness.

Aims

Association between digital biomarkers and clinical status & health utilization outcomes

Feasibility and effectiveness of *a wide range of digital sensors* to predict:

psychiatric rating scales, relapse in schizophrenia, and various utilization measure.

Partners

Clinical sites: recruit patients and measure clinical status & health utilization outcomes

SCRI : support protocol development and data analysis.

Technology providers:

- Study 1: to bring in commercial vendors and local partners with existing technology to validate
- Study 2: with the validated technology, to study if it can intervene early and prevent outcomes like admission due to relapse

Proposed Diabetes e-coaching studies

Rationale & Background

Many of our chronic diabetes patients are on regular 3 monthly follow-up at the polyclinics, SOC and GPs with only 3 or 6 monthly HBa1C result. There is no "live" feedback for them to understand if their last meal affect their blood sugar control

Aims

To use a continuous blood glucose monitor which transmit blood glucose reading to a central office and messages via mobile phone sent to the patients to let them know if their blood sugar rises up after a meal.

Aim is to provide instant feedback to educate patients. Study aim to show patients on e-coaching have better diabetes control from HBa1C

Partners

Clinical sites: recruit patients and measure clinical status & health utilization outcomes

SCRI : support protocol development and data analysis.

Technology providers: vendor which already have the software available

Similarities and Differences in Technology vs Drug evaluation

- **Similarities:**

    1. Protocol uses the randomized control model, to study intervention vs placebo/standard of care, with similar clinical outcomes (eg HBa1c for diabetic patients)

    2. Informed consent and follow-up visits are similar

- **Differences:**

    1. Patients would need to taught how to use the new technology (eg mobile phone, home diabetes monitoring device)

    2. Currently not regulated under HSA's Clinical Trial, but under HBRA

    3. Data collected by the technology would need to be integrated and analyse with clinical data

    4. Lesser adverse events compared to drugs

Getting Ready for Future of Technology Evaluation

- **Expertise:**
  1. Principal Investigators would need to understand the IT aspect of how the technology is able to improve clinical care and its shortcomings
  2. Need to explain to patients how the study is going to be conducted and the IT support when there are problems

- **Infrastructure:**
  1. Data security issue needs to be managed to prevent data leaks (can the physical server be based in Singapore?)
  2. Integrating of the tech into our current EMR system for data collection and analysis

- **Health outcomes evaluation:**
  1. Healthcare technologies cost $$$, thus evaluation would need to incorporate health outcomes to show long term control of complications would save $$$

Thank you