Large Simple Trials: Health System & Clinician Perspective

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Large Simple Trials and Knowledge Generation in a Learning Health System

Topics

- Putting LSTs in context for health systems

- Competing priorities and illusion of the EMR as a simple solution

- Why should health systems and clinicians participate in RCTs now?

- Finding the "win-win-win-win" situations

- Where can we go next?

Putting LSTs into Context for Health Systems

✤ Affordable Care Act

✤ ↓ revenues, ↑ competition, older & sicker populations

✤ Leading health care delivery systems are already pushing the edge for efficiency and higher throughput--leaves little margin for extra

✤ Goals of health care delivery systems vs. researchers vs. sponsors vs. patients often different

Competing Priorities
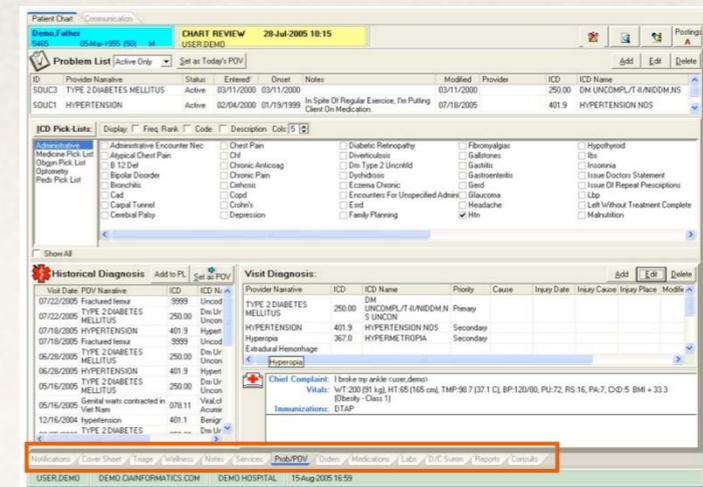
Optimize Quality of Care

Improve Patient Access

Increase Provider Efficiency

Implement & Enhance EMR

Maintain Revenues and Strategic Investments

Illusion of the EMR as Simple Solution

✤ Kaiser Permanente has one of the largest and most complex, comprehensive inpatient and outpatient EMRs based on Epic

✤ Is the EMR the simple solution for LSTs? Plenty of advantages, but..

  ✤ Each EMR is different despite a common platform

  ✤ Top 200 list of EMR priorities that never gets shorter

  ✤ Problem of "garbage in...garbage out" & 47,000+ tables on back end

  ✤ EMR-based standardized data collection for trials not ingrained in provider culture or workflow or always set up to serve dual purposes

  ✤ Need to find the right situations where EMR play key roles for LST

Why Should Health Systems and Clinicians Participate in LSTs Now?

- ✤ Given health system priorities, pressing need to know the answers to certain types of questions

- ✤ Despite advances in design and statistical methods for CER, rigorous randomized trials are complementary and needed

- ✤ Developing culture and capacity for randomization at different cluster levels can enhance health system reputation by helping find the answers

- ✤ Applications to both quality improvement and determining most cost-effective strategies for net clinical benefit

Finding the Win-Win-Win-Win
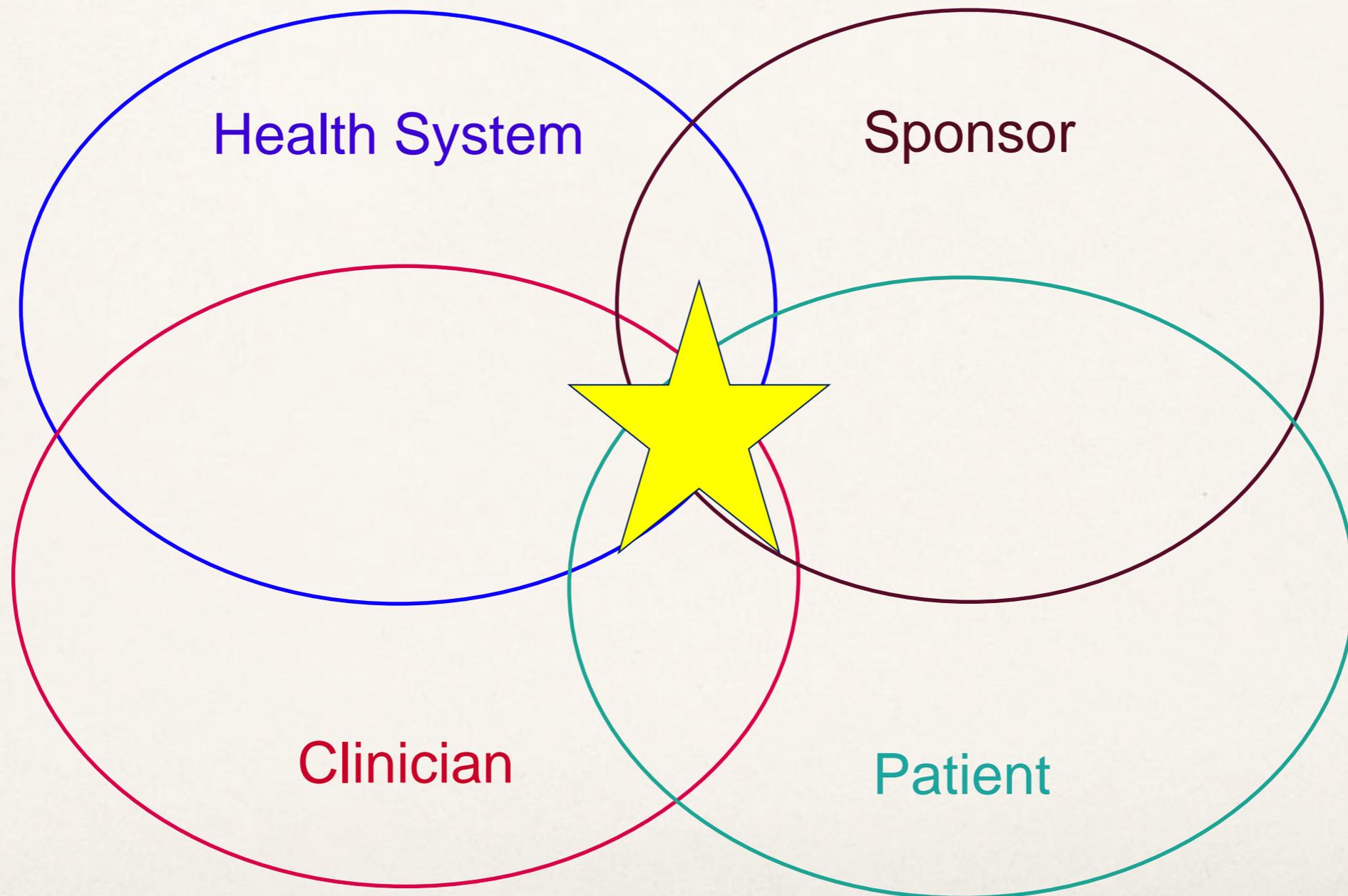
Where Could We Go Next?

✤ Research sponsors -- gather systematic input from health care delivery systems on the questions they care about -- not just what researchers propose

✤ Need to properly compensate for adding/incorporating research into systems that already provide efficient clinical care delivery

✤ Find creative ways to incentivize health systems to participate and reduce hurdles. Examples:

  ✤ Real reputational gains

  ✤ Meeting overlapping priorities

  ✤ Aligning criteria for choosing an LST, timelines, designs, consent requirements and data collection methods using the EMR and back-end databases

✤ Regional or national LST Consortia involving health systems

Finding the Win-Win-Win-Win

Health System

Sponsor

Clinician

Patient
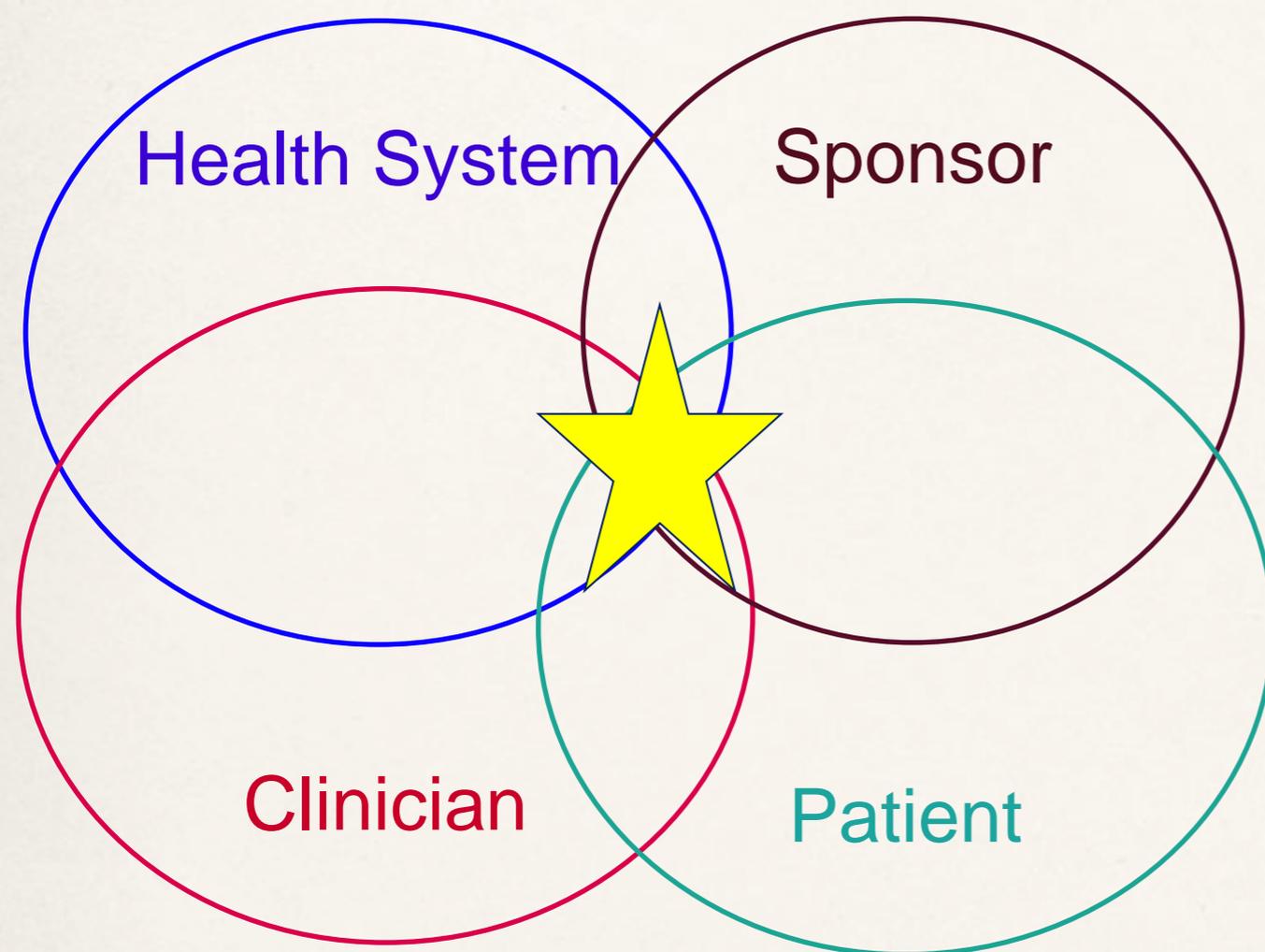
Potential Examples:

- Work up of hematuria (e.g., integrating LST with DST)

- Surgical vs. catheter-based therapies for valvular disease

- Value of different stroke and bleeding risk schemes for anticoagulation decision-making for atrial fibrillation

- Multiple diagnostic & management strategies for low back pain