UC Davis Collaborative for Diagnostic Innovation

Lydia P. Howell MD
Professor and Chair, Pathology & Laboratory Medicine
Overview

- Why do we care about diagnostic tests?
- What are the problems and opportunities associated with diagnostic tests?
- How could a Collaborative address these problems?
- What unique assets and strengths could be leveraged and linked?
- What is the value? How do we get people to join to launch?
- What is the risk?
Why do we care about diagnostic tests?

- **Pivotal role** in health care:
  - Identifies and accurately characterizes disease.
  - Guides the most appropriate course of treatment.
  - Monitors disease during treatment.
  - Prevents disease development or by detecting early warning signs so that interventions can occur.

70% of all medical decisions are based on laboratory tests. Imaging tests are common and increasing in frequency.
Why do we care about diagnostic tests, con’t?

- Diagnostic tests can create cost-effective high value healthcare – if used correctly!

- **Leadership in diagnostic testing can:**
  - Improve health and lives of patients and populations.
  - Distinguish UC Davis Health from other medical schools or health systems.
But ... diagnostic test process is imperfect.

There are important problems to be solved and opportunities to be explored.

- **Problems:**
  - Diagnostic errors.
  - Misuse and over-use, particularly re: expensive tests, inflating healthcare expense and creating potential harm.
  - Lack of accuracy or stratification of findings to customize management – complications occur from generic management decisions that adversely impact many patients.

- **Opportunities:**
  - New discoveries offering solutions to problems we didn’t know we had.
  - Biomarkers, genomic info, imaging methods, and more.
- National spotlight on these issues in 2015 National Academy of Medicine report.
Problem #1: Diagnostic errors are a substantial cause of deaths from medical error.

- # of deaths from diagnostic errors similar to diabetes or flu/pneumonia.
- Diagnostic errors affect 1 in 20 Americans.
- Errors cause other complications, as well as unnecessary expense.
  - US Institute of Medicine; 2015
Problem #2: Misuse and over-use of expensive tests contributes to rise in healthcare costs

Cross-sectional imaging tests per 1000 enrollees/year


Annual imaging costs per health plan enrollee
Problem #3: Lack of accuracy/stratification of test results to “customize” management

- Need for better tests to:
  - Subclassify patients.
  - Customize decisions among many existing management or treatment strategies – or help create new strategies!
  - Improve outcomes, minimize complications.
Each of these problems provides an opportunity for innovation – but there is more!
More opportunity: Innovation $\rightarrow$ solutions to problems that we don’t even recognize now!

New knowledge, discoveries, and inventions continually emerge:

- Opportunities to improve lives in ways that we could never imagine.

- Example: The iPhone – who ever imagined that we couldn’t live without one?? Who knew we had problems that needed to be solved??
A Collaborative could link and leverage existing assets to solve problems → greater impact
Diagnostic innovation flow chart

Basic research → Target discovery or Device development → Validation
• Biomarker or technology development
• Target validation

Diagnostic test development → Clinical implementation
• Clinical trials
• Beta testing for FDA approval

Clinical implementation → Outcomes studies
• Clinical guidelines
• Quality programs
• Health economics
• Decision support tools

Health policy

Links: UCD Assets for Diagnostic Innovation – Selected examples

Biological and Clinical Technology

Animal Models

Research programs in clinical depts. (Path, Rad, others)
Mouse programs (MMRRC*)
NCI Designated Comprehensive Cancer Center
M.I.N.D. Institute
Pediatric Emergency Care Research Network

Translational research and centers

Center for Molecular Genomic Imaging
Center for Comparative Medicine
CA Nat’l Primate Research Center
Veterinary Center for Clinical Trials

Diagnostic innovation flow chart

Clinical: implementation

Health policy

*MMRRC: Mouse Mutant Research Resource Center;
Foundation: Strong existing record in diagnostic innovation at UCD

- **Diagnostic error reduction:**
  - Polage: Award-winning publication re: inaccuracy of molecular tests for C. diff; Moore Foundation-funded STOP C. diff project
  - Tran: Demonstrated inaccuracy of hand-held glucose meters in critically-ill patients, leading to FDA recall.

- **Misuse/overuse, cost-effectiveness**
  - Kupperman: NIH grant to create unique decision-support tools guiding imaging orders in the emergency department.

- **Accuracy/Customization:** Many research groups identifying unique biomarkers of disease.

- **New opportunities via newly developed tools:**
  - NSF-funded Center for Biophotonics Sensors & Systems (Chan).
  - R33-funded project for novel MUSE microscopy, beta-test in Cancer Center (Levenson).
  - $15.5M grant for 1st whole body PET (Radiol, Cherry/Boone).
  - Biobanking of remnant blood samples (Path, Tran) and microbiome samples (Wan).
Unique educational and training programs to be leveraged

- Award-winning Biomed Engineering design course led by Pathology faculty member Nam Tran
  - Challenges undergrads to provide innovative solutions to medical diagnostic challenges.

- Graduate programs in health informatics and public health

- Informatics fellowship

- UCDMC’s Quality Certificate Program

- And more!
How are we launching the Collaborative?

- **Internal seed grants:**
  - 4 themes/opportunities
    - Creation of new or better tests and test strategies.
    - Optimization of test utilization (particularly reducing underuse, overuse, and misuse of tests and imaging procedures).
    - Reduction of diagnostic errors (particularly reducing delays in diagnosis).
    - Integration of diagnostic data with other data such as clinical information, microbiome and other phenotypes, social determinants of health, behavioral medicine, and others.
  - $340,000 in the seed grant award pool, thanks to:
    - Dept/unit contributions, similar to previous inter-dept/-center grants
    - Practice Management Board contribution
    - Byers gift to Pathology
  - Seed grant networking event, 11/6/2017: MIND Auditorium, 5-7 pm.
  - **Intent:** Support pilot projects that link existing strengths and position teams for extramural funding or commercialization.
Other potential resources and programs to grow the Collaborative and link participants

- **External opportunities for support**
  - Cross-center biophotonics cluster application to NSF: Includes supplement for planning conference.

- **Networking events**

- **Services**
  - Biobank, informatics expertise, drop-in workshops, equipment, grant or IRB pre-reviews/consults

- **Educational activities**
  - Biomed engineering design course: Involve Collaborative members
  - Create educational programs re: diagnostic utilization and error reduction into Path-Rad courses for medical students, housestaff education, CME.
Collaborative for Diagnostic Innovation: Multi-disciplinary and inclusive

Center for Diagnostic Innovation

The Medici Effect:

Innovation that occurs when people of different cultures, backgrounds, disciplines and perspectives come together and interact.

Frans Johanssen

Learn more at: