CT Health Data Collaborative Working Group

Date: Friday, October 28

Time: 9am-12noon

Place: James Blackstone Memorial Library
758 Main Street
Branford, CT 06405
203.488.1441

Host: Todd Arnold, Mount Sinai

Agenda:

- Welcome
- Introduction: Todd Arnold
- Update on Precision Medicine Initiative:
- Murat Gunel (Yale) – Opportunities for Precision Medicine
- Opportunities for Expanding Partnerships
- Genomic Counseling: Judy Brown

  UCONN, Department of Allied Health Sciences
- Health Analytics/Informatics – Developing the Pipeline: Tom Agresta, UCHC
- Updates on Other Key Economic Development Drivers – per notes
- Other?
- Next Steps

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Presentation: The potential for a Connecticut Precision Medicine Initiative, "CT-PMI": Murat Gunel, MD
Yale School of Medicine, YNHHS, Chair and Chief, Department of Neurosurgery

- Collaboration among Connecticut healthcare data players, including the YNHHS, Yale Medical Genome Health Center, with which he is associated. Yale invested about $10 million 8 years ago for this research facility and, together with other research institutions in Connecticut, has created a platform that puts the state in the top five in the nation with the capacity for research in to whole exome sequencing. He noted that the Affordable Care Act, "Obamacare" has an express focus on personalized medicine, which he described in terms of its effect on newborn diseases, including prenatal and other chronic afflictions.
- Background: Smoking cessation and exposure to lead paint are social healthcare factors that genes do not provide markers or pathways for solutions. Yet such factors direct effects on the health of all populations, and similar diabetes, healthcare community is fully aware of these and while they are not genomic or otherwise biologically inherent in human beings, their effects great. Similarly while autism may seem like a genetic-related disease, it is presumed to be a spontaneous mutation and thus is not an inherited result from a genetic profile. Micro-encephalitis is believed to be an intrauterine infection result, and not genetic driven disease. It was also noted that from an insurance perspective, events such as car accidents leading to the grave injuries are equally important on their healthcare effects, and of course need to be accounted for in the provision of healthcare services, there is little to be done academic and practical approach.

Opportunities of CTPMI:

1) collaborations across varied and diverse institutions both in the state and across the country;
2) partnerships across all silos and areas of the state in order to facilitate new scientific discoveries;

3) in order to drive insurance collaboration, academics need to prove their theories to the insurance providers and pharmaceutical businesses that there are practical and revenue producing results possible;

4) education needs to be bolstered industry and especially within the patient population in order to develop partnerships and trust are collaborations that are possible and required to achieve positive results; and

5) the goal must be personalized health care demonstrated by the achievement of positive effects in the general population of patients.

Logical sequence for development of the initiative:

1. create as its standard of care patient support and health, based on genomic research in order to use the predisposition to diseases in order to provide early risk/screening in order to have prompt and thorough interventions.
2. by using appropriate and personalized drugs and other therapies, remedies are entirely possible. He noted that Obama care regards the patient as a partner in establishing their own health care treatment provisions, and thus that **it is imperative to get data transferring on a routine basis from the patient to the healthcare industry, and in reverse in order to best serve healthcare requirements of the patients**. It is important to recognize that there are about 59 clinically relevant variances that are required by medical ethics to be reported since they have such high genetic risk scores for patients.

Other important considerations –

- Demographic profiles of patients
- Social determinants of health;
- Addressing disparities
- Timeliness of genomic testing – e.g, A genetic sequence may predict Parkinson's disease, but it is vital for the patient to report they are experiencing shaking or other symptoms of that disease in a timely manner through regular updates.
- Experienced and professional counselors to communicate with patients; there is a growing demand for domain-expert physicians and other professional staff as this industry area develops and becomes ever more vital to the state and the nation.

CT-PMI goals may include:

- developing accurate risk assessments genetic estimates,
- identifying a wide variety of biomarkers (including inherited and environmental issues), all focused on developing a responsive and supportive platform for healthcare remedies and treatments. Whether this takes a few years or a decade or more, the work needs to begin promptly.

Potential for a BioBank: the bank would serve as database center for a precision medicine, i.e., the "database playground" that has been described by the collaborative several times. Murat's group at Yale has compiled approximately 10,000 biomedical profiles in its "exome bank." The progression is basically to start with a blood or other biological sample, further developing a more enhanced EMR, hopefully incorporating insurance (billing) records, which ultimately generates research and eventually treatments and drug therapies.

Other states investing in biobanks:

> New York State $150 million capital expenditures were of an exome bank with annual operations and maintenance expenses of $100 million per year.
>
> Indiana University, over $300 million

Connecticut does not need $100 million like New York State has already funded, especially if a full-blown collaborative emerge with the power of crowdsourcing and strength in numbers.

Opportunities in “mobile health” – capturing environmental and lifestyle data like: diet, exercise (number of steps in a day), air quality and other environmental issues perhaps based on ZIP Code. Wearables have potential for significant ROI, transparency,

CT-PMI could act as a practical and revenue-generating operation, perhaps building on the existing Yale research operation with input and partnerships with all interested parties. Computer structure for managing storage, storage eating, and analyzing the data bank is a necessary step, leading to the ultimate of analysis business opportunities.

The UK bio Bank has about 500,000 lives in its database, the United States probably has 1 million lives, while Connecticut may have as many as 200,000, but they are on organized or unified. Can the state generate a database of 2 million lives? It can, but only through collaboration and concerted effort.

Do we need our own CT Biobank? To be continued…

Counseling collaborations would allow for jointly performing bio analytics on that data in order to generate enhanced treatments and potential revenues. But who pays for testing and counseling? Currently, some insurance companies pay for blood tests in which a medical assessment is required, but they do not pay for research. Exceptions would include family history, for instance breast cancer, in which genomic sequencing is paid by insurance companies. But **there is no such payment for healthy/wellness prevention program testing**. He noted that this concept goes wrong since lives saved and hospital visits avoided due to preventative treatment of heart, stroke, or actual prevention of a potential cancer or other diseases obviously has public policy goal benefits, but not to mention financial returns to insurers or other payers of healthcare expenses. State employees may provide a good starting place for a pilot program with specific targets – e.g. breast cancer and or asthma, where the incidence is very high in CT, disproportionately high in POC. Pharma could get ROI with they had had substantive genetic type and sequencing results targeted on the effects of a particular drug produced by that particular firm. Such analytics can also satisfy corporate business plans, commercial, and healthcare in goals of a pharmaceutical company, and the collaborative would financially benefit from being the generator of data and results to substantiate their operations.

There are benefits to being an early adopter. Ultimately, we could have all of Connecticut's citizens for the direct role in developing each of them a DNA sequence that will evolve over their lifetime, and be responsive to treatments and drug therapies as they are created. This is a virtuous cycle in which patient input drives research and new treatments, and in turn cycles back to the benefit of the patients. **CT could be the first state to take a comprehensive approach to testing, counseling, analyzing and reporting, while maintaining privacy and security. We would attract other companies to come here if we become a center.**

Opportunities for entrepreneurs and grant funding would be great with an open access biobank. E.g. Yale has 1 million outpatients per year many of whom leave blood samples which wind up with remainder blood available for research purposes prior to it being discarded. While this blood can be stored for some time, perhaps as serum, the idea of sharing such specimens with other regions seems physically likely or possible, but of course the resulting data can be shared.

Patient privacy and consent: As always, obtaining patient privacy consent and involving them in future interactions will be a central, yet social, complexity in the design of the collaborative. There needs to be effort expended on forming and maintaining "interconnections" among all elements of the collaborative, with a particular emphasis on preventing or breaking silos. A unified data system may be a practical underpinning for the collaborative, there are social and political issues that need to be considered in order to unify all elements of the project.

Building the talent pipeline as an economic driver: Qualified and experienced staff of all levels is currently lacking. There is also the issue of what financial terms will be most productive in generating a revenue producing concept from healthcare data. Connecticut innovations, for instance, has an investment time horizon of roughly 5 to 10 years, while the federal CMS program is more focused on a short-term investment, probably 1 to 2-year investment cycles. In terms of federal involvement, the Obama administration has been folk focused on lifestyle risks and the use of precision medicine in order to prevent diseases before they manifest. **Employers, such as her CEO for instance, are looking for a 10-year return on investment model.** .

After Baylor University, **Yale is number two in prenatal preventative care** so there has been a focus on preventative and precision medicine with some success at Yale. Connecticut has the resources to be first in the domain, and that adequate financing it seems clear that the state can make a project like this work.

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Opportunities and Need for Genomic Counseling

Presentation: Judy Brown, UConn, Director, Health Care Genetics Professional Science Masters Degree Program http://healthcaregenetics.uconn.edu/;
Director, Diagnostic Genetic Sciences Program http://alliedhealth.genetics.uconn.edu/

Looking to the future: The need will likely be greater than the number of counselors available. This is a fast emerging market. Currently, there aren't enough jobs in CT.
Important to properly identify the competitive advantages and disadvantages facing Connecticut and the collaborative. **build a virtuous community in order to absolutely know the path forward toward creating a vibrant enterprise with the engagement and partnership of patients.** If this can be accomplished, Connecticut has the opportunity to draw in the entire world to access the data and analytics it will be possible.

The question before the collaborative today is not just structure should a bio bank take, physical or virtual. **The real issue is how to engage all the players operating in this state, that is to say all the resources and assets that are already interested in the concept, to work together.** Genomic sequencing analysis now costs $25,000, & time to perform decrease fantastically as a collaboration grows. That alone may form an incentive for further investment and involvement a very diverse and important population of industry and patients alike. This collaborative group has the human and institutional resources required to make such a comprehensive service possible. He added, however, that we need to consolidate around the concepts we developed and begin the process of digging in to the implementation stage.

- **Genomic Counseling degrees: The UConn Master's degree is the third fastest growing field in community Connecticut education and that with the in-state tuition advantage, its first class of ten students slated to graduate in the fall of 2018 enjoy a financial benefit over competitors Sarah Lawrence and BU.** UConn is exploring expanding the capacity of the program, but it is extremely difficult to launch a new degree program in any educational facility, if no other reason than the strict compliance required by national accrediting councils such as in this case. This program features internships, labs, and requires face-to-face instruction so does not provide many shortcuts.
- **Telemedicine could be a great business opportunity** (like a "shared white board") building on "comprehensive service" concept of providing genomic analysis with patient counseling, simply adding the concept of being able to remotely provide individual personalized medicine and support.
- **Challenges**: what is it practically, in terms of time and cost, and what is reimbursable? Generally speaking the scope of the sessions are 30 minutes pre-testing (exploring options for treatment, and the risks of testing) and 30 minutes post testing (explaining and responding to questions regarding the results of testing), but indicated that her

professional opinion was that this was a minimal of face-to-face discussions. Judy noted that in the event of bad news from testing, patients often “shut down” and need follow-up meetings for their comfort and for planning purposes. The time for session is generally mandated by the schedule of reimbursement**. Counseling is an insurable event in CT.**

- Doctors only spend 5-15 minutes with each patient, so in order to “change the dial on this type of treatment” it will be essential to have counselors on the team, able to respond to patient needs as they arise. As the number of tests rose and the variety of those tests will be expanding all the time such teamwork be essential to guiding patients to the best solution possible.
- Informed consents are required for such testing, it is essential for patients to “know” the potential results and consequences following testing. But this need “to know” is balanced by the need for an understanding of “what’s knowing?” In a critical field such as genomic research something that is so futuristic to most patients.

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Watson. Southern Connecticut State and IBM have collaborated on the Watson project being produced by IBM. Competitions tell us Watson is good at some things. We will be talking with IBM soon.

- Patients must be informed regarding 53 genes which are on a federal “watchlist”, including certain types of breast cancer and Huntington’s disease, of which 200 variance are possible – and this is a moving target.

- The collaboration needs to grow this program and integrate the team’s generated across all and industry segments into the practice of medicine and health care delivery to patients. If the program can deliver 1 million lives into a bio databank within the next three years it will transform medical practices, educational opportunities, and provide new opportunities for insurance companies. .

- technology becomes essential requirement for healthcare analysis and treatment

- Preventive medical care is a driver here. Need to remember “**who is our customer?”** coupled with the additional question, “do we agree that the construction of a bio bank is a critical element?” Every genomic map that a collaboration member will have sequenced in its treatment regime or research pattern will need to be attached to an individual person, repeating that “**it is the patients who own their data.”** (This is a controversial and essential piece)

Next steps:

- mapping with critical players and crowdsourcing, the status of the issues that have been opened by the dialogue among the collaborative members in order to find the path. We will continue seeking synergies, no matter how much anxiety may result from that search, but that we will all work together moving forward.

Presentation on Health Informatics

Thomas Agresta MD, MBI
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- the collaboration group needs to be practical with regard to electronic health records (EHR) since there are a many steps in a general evolution in order to move EHR are to full medical team access in the evolving fields of genomic and biome research and treatment.
- Applications are rapidly developing, apps for large population in general use are still lacking.
- it is an open commercial market for optimizing this branch of medicine, which is only in its most nascent stage.
- **Connecticut is well-suited for making rapid advances in discovering commercial opportunities for this type of research and treatment**. The state needs to develop the workforce on the highest and most staff levels to engage in improving patient treatments, developing digital applications for commercially addressing patient needs, while pursuing strategic and logical paths into the future will be required to fully embrace this field.
- Other states have largely pulled at head of the state of Connecticut by way of investment and collaboration among their resources. But many are lacking in appreciating the scale and scope of the undertaking.
- Training of medical staff of all levels by self- or vendor-trained methods and procedures is dangerous. It was commonly agreed among the group that such a training method is essentially “fumbling around in the dark” or perhaps even more insidious since there is the obvious conflict of interest with vendors being the trainers. **It was generally agreed that the states community colleges and other institutions of learning should be**

enlisted to develop IT and other healthcare support programs to at least maintain the current level of graduates, but obviously it was deemed critical that future needs be addressed in the short term.

Tools that need to be developed: health informatics, interface design, access capacity, and methods for sharing data on the highest and most complex levels. The insurance companies at this point actually receive very little real information from EHR since the focus from their perspective on the data they receive is largely limited to billing. Unfortunately, it is recognized that the insurance companies probably have the best data available in the market, and of course it is of limited use. Kaiser has a far more functional system because it owns the entire organization, thus putting them well ahead of the curve.

- A new curriculum would be very useful to pursue the goals of the collaborative and which would satisfy existing and future educational requirements for four workforce development - could be termed "clinical informatics". This could be handled as a certification program, but also could have higher level academic training programs, and should attempt to involve all institutions in the state, or a consortium of educational institutions with a focus on online courses, with "roving faculty" in order to jumpstart this program. Joe McGee added that "health informatics" was already offered at UConn, Michigan, and the Penn with great success.

A discussion ensued led by Todd Arnold as to whether or not the correct term for the collaborative should be "precision medicine," or "personalized medicine."

Computer scientists and other IT professionals should be equally trained in genomic database generation and analytics. Unfortunately, it was also recognized that UConn and other Connecticut educational institutions have explored the development of educational streams leading into this they largely not gotten off the conceptual stage.

Economic asset mapping needed: Does a Bio Bank or Genomic Center offer the best forward for this group?

- Insurance companies understand what is needed for patients and claim information, but that the best focus regarding the management offices of the insurance providers corporations is to implement value-based medicine and clinical informatics.

Next Meeting: Nov 2, 2pm-5pm at JAX in Farmington – we will start to structure the vision.

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