How Advances in Molecular Diagnostics Will Further Drive Consolidation of All Lab Testing

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Discussion Points

• What’s driving consolidation?
• What is the relationship between Molecular and consolidation?
• Where is the consolidation focused?
• How do we play in this arena or can we play at all?
Let’s Look At Where Molecular Is Emerging

Blood Bank – Antigen identification on donor cells and patient cells.
Microbiology – Identification and sensitivity to drugs based on genetic make up.
Serology – The presence of an organism or its DNA footprint.
Clinical Trials/Personalized Medicine – Many new drugs require specialized testing that fits into this arena.
There is a moral shift away from purposely injecting incarcerated prisoners to produce antibodies that can be used for anti-sera in order to test patients.

- Can we develop a test that is able to check a patient for the presence of antigens?
  - Can this in-fact lead to the avoidance of a low-frequency antigen yielding an antibody in the population?
  - Can it be used to identify patients lacking high-frequency antigens?
    - Can this lead to fewer sensitized patients?
  - Can we identify donors lacking these antigens?
  - Can we avoid sensitizing a patient receiving long term cellular therapy (cancer patients, chronic anemia etc.)?
Yes! We can in-fact screen using molecular type testing to determine the antigenic typing of a patient in a matter of hours.

• As a result of this, we can prescreen - and since the genetic make up never changes when we need that particular genetic type we request that donor.

• A decision can be made to freeze the blood of such a donor and utilize it when requested for a particular match.

• The cost of such a test is around $90 per donor/patient.
Microbiology

Microbiology has been utilizing Molecular type testing for a while now to screen for resistance of organisms and to identify the genotype of organization to monitor their spread and predict the drugs needed to kill the organisms.

- Laboratory tests are shifting from traditional testing methods towards molecular diagnostic testing
  - Faster and more accurate
  - Better sensitivity & specificity
  - CT/NG, C-diff, MRSA, Trichomonas, Herpes (HSV), Norovirus, Rotavirus
Microbiology (cont.)

- Identification and tracking of TB is one of the earliest uses of this technology.
  - The genetic footprint tells where this organism has gone and in some cases how it got there.
  - By predicting its sensitivity (or lack of it) clinicians are able to avoid utilizing drugs that won’t work and will only create a super bug.

- Testing and screening of patients for MRSA has become very popular in the last few years.
  - Used to place patients in rooms so as not to spread the organism to other patients.
  - Invaluable in alerting clinicians to take extra precautions to prevent the spread to other patients.
• May be additional opportunities to use this technology for sensitivity and identification of organisms.
  ✓ Emerging GC Mass Spectroscopy may delay or circumvent this due to a lower cost-per-test.
  ✓ Even GC-Mass Spectroscopy will still drive consolidation!
Serology/Infectious Disease has been at the forefront of molecular testing and has been in use there longer than any other area.

- Transfusion Medicine led the charge with NAT (Nucleic Acid Testing) on all blood donors since the early 90’s.
- The high cost per test has caused creative thinking to occur.
  - Pools of donors are tested with the likelihood that none of the pool will be positive (Pre-screen questions skew this in favor of a negative test).
  - Coupled with the identification of the positive pool members only when a positive is detected has lowered the cost by at least 5x the cost of non-pool testing.
How About Blood Bank Molecular Testing?

It’s interesting; the company marketing the Molecular testing for Antigen ID for Donors and Patients is marketing to only very large hospitals, IDNs, and Blood Donor Centers, why?

- Cost is driving the market.
- Would they sell it to a community hospital if asked?
  - Yes, but only a very few are interested!
  - Might we see it come into the Community Hospitals over time?
    - Perhaps if the cost per test drops sufficiently and if the degree of automation removes any special technologist needs.
    - However, we have not seen that in either the donor centers or in the hospitals where Microbiology has been consolidated.
Clinical Trials (Clinical Research)

When new and highly expensive procedures and medications come into play, the cost of expensive testing doesn’t seem so expensive.

• Herceptin - You must have a HER2 test to determine if your cancer is HER2-positive.

• Created a need to test before treating.

• Opens up new markets for molecular/genetic type testing.
  
  • Molecular Diagnostics (MDx)
  
  • Biobanking
  
  • Clinical Research
  
  • Translational Medicine
Key Segments Found in Acute Care

• Bio-Banking (Bio-Repositories)
  ✓ Collection of patient blood & tissue specimens for future research

• Clinical Research
  ✓ Evaluates and determines safety & efficacy of therapies
  ✓ (Includes) drugs and devices as well as diagnostics

• Translational Medicine
  ✓ Applies findings in basic research to patient care
  ✓ “Bench to Bedside”
Personalized Medicine

The Harvard-affiliated Laboratory for Molecular Medicine (LMM) is a CLIA-certified molecular diagnostic laboratory.

- Operating within the Partners Healthcare Center for Personalized Genetic Medicine (PCPGM).
- Esoteric diagnostic testing.
- Designed to detect diseases before they present themselves clinically.
- Follow up DNA testing with RNA.
  - Looking for “how much” after answering the questions “is it there”.
OK.. So Why Are We Seeing Consolidation?

On one hand the answer is very simple, COST! But on the other hand it is more complicated that just cost.

- Molecular testing costs on average 10 times the cost of a non-molecular test.
  - High start-up costs of equipment.
  - High cost of reagents.
  - Relatively short shelf life of reagents compared to other testing.
  - Specialized labor requirements (skill) – not every Med Tech is trained to handle Molecular Testing.
    - This is likely to change over time.
  - Specialized environment to prevent contamination.
  - May require a PhD (Lab Developed Tests).
Annual growth of Molecular testing is 11%.

Dedicated space to Molecular testing

- Have to have the space.
- Expensive to build the Lab space to meet testing needs.
- You have to maintain the space (clean up of contamination can be very expensive).

Collection has been simplified

- Transportation of samples is safer and can travel further distances
Molecular test menus continue to expand, requiring counselor to play important role.

- Beyond the technical testing (intra-Lab) support.
  - Support the laboratory in molecular test interpretation.
  - Interfacing with clinicians.
- Leading in developing and implementing lab and hospital policy initiatives related to testing.
  - Areas that Pathologists are not always comfortable dealing with.
  - May require hiring a specialist in interpretation (PhD, MD, etc.)
In Addition...

Access to prominent researchers and physicians within the Consolidation Healthcare systems

• Provide the breakthroughs leading to next generation diagnostics.

• Major focus in specialized areas such as cardiovascular diseases, cancer, and hearing loss (Yes you “heard me”!), respiratory diseases, etc.
So Where’s The Test Case To Prove This?

Let’s Look at the Red Cross Blood Testing Centers. They set the standard for consolidation.

• 15 years ago every ARC center tested all parameters.
• They were consolidated into 5 Centers specifically because of the cost and complexity of testing.
• Blood Centers (non-ARC) often send their NAT testing to specific centers to consolidate and take advantage of the economies of scale.

✓ Cheaper to buy than to build.
✓ The results are back in the same or faster time-frame than if they were doing it themselves.
Let’s Look At Microbiology...

There has been a dramatic decrease in the number of Microbiology labs associated with hospitals in the past two decades.

• Microbiology in general has consolidated within most IDNs.
  ✓ Most send Microbiology to a Core Laboratory.
  ✓ They take advantage of the latest technology.
  ✓ Turn-Around-Time (TAT) is faster than if they were doing it themselves.

• Yes, rapid MRSA testing and Point of Care (POC) testing is being used, but the cost per test is prohibitively high and is only used when no other solution is available.
  ✓ POC tests are being performed in labs because it behaves a lot like a chemistry test without a blood sample.
What’s The Effect of “Obama Care” On Molecular?

Too soon to tell, but the push to reduce healthcare costs and improve quality with the need to have a very reliable test at the lowest cost possible is going to support consolidation.

• Reimbursement for sure will be negatively impacted.
• In other countries (e.g. Canada) we see an aversion to adopt latest technology.
• “Community” or reference labs is where it starts.
• Even in the US we have seen Molecular as the driving force to create Core Labs for an IDN with the desire to consolidate much more than just Molecular (Sutter Health System as an example).
So What Is The Conclusion Of This?

There are several conclusions to be wrestled with:

1. Look for a Molecular testing partner if you don’t already have one.

2. If you are part of an IDN and have not done so already start discussions with the other members to see how you can create a center of excellence for Molecular within your IDN.

3. Get involved with costing models of disease states in your organization and learn how you can be part of the drive to lower overall costs for your organization even if it drives your costs higher (Molecular testing).

4. Pay close attention to the literature and the Dark Report!