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INTRODUCTION: PROMISING PRACTICE PATHWAYS™

So … Promising Practice Pathways – What are we talking about? Promising how? For what practices? And Pathways to where?

In a Nutshell
The Promising Practice Pathways describe new pathologist-driven services and programs that add clinical value outside of the laboratory by improving downstream clinical quality and outcomes, and generating downstream clinical cost savings. They span a broad range of clinical conditions and procedures, with some of the most interesting opportunities in oncology and infectious disease.

The Pathways draw upon our current capabilities as well as emerging expertise in genomics and informatics technologies. But fear not. We have numerous opportunities for delivering clinical value even without these advanced technologies. Pathology and laboratory information impact so much of clinical medicine, they are estimated to comprise 70 percent of the data in an EMR.¹

The Pathways can be used by all of us, regardless of setting or roles. The payers, providers, institutions, and increasingly the patients with whom we all interact are moving steadily toward a value-based “currency.” In other words, what is measured and compensated is quality improvement and cost savings. This has important implications for us professionally. We need to move toward delivering this form of clinical value in order to be players in this market. If not, we will become vendors, sitting on the sidelines.

These Pathways provide a number of entries into this value-based marketplace, all of which give us control of our own economic destinies in this rapidly changing marketplace.

What’s So Promising?
Let’s start with “Promising…” We don’t intend to make “promises” per se, except to say we promise you will get something valuable from reading these chapters. By promising, we mean that the future of pathology practice can be very promising, but we need to pursue a different course to realize it.

It might seem strange in the midst of economic downturns, relentless reimbursement cuts, regulatory uncertainties, and market turbulence to make such an optimistic pronouncement, but we have the wind at our backs, as you’ll see in the chapters ahead. Our promising future is not, however, our traditional business as usual; rather, it will take on new forms and leverage

new technologies. These future pathology practice scenarios derive from the critical roles pathologists can play in personalized medicine and value-driven healthcare.

These opportunities, described in our Pathways, usher in what many are calling “the golden age of diagnostics.”

Because it is not our business as usual, seizing this promising future (which is unfolding now) requires change, and change requires initiative. Make no mistake, if we do not grab these opportunities, others certainly will. In fact, as you’ll read in the upcoming chapters, other specialties, providers and companies have already begun to capitalize on molecular diagnostics, sequencing, and bioinformatics.

The wave of healthcare reform sweeping the country is creating a variety of opportunities that go beyond harnessing new technologies. For example, there are now an estimated 300 accountable care organizations (ACOs) and analysts expect 600 in 2013. We should not dread this change, as both care delivery and payment reform can be very good for pathology and laboratory medicine. These reforms free us from a cost-based compensation system, enabling us to move again to directly delivering and being paid for value-generating services.

The Pathways we’ll be describing identify many ways in which we are ideally suited for delivering clinical value. Rather than just issuing diagnostic test reports, we can leverage our unique knowledge and expertise, combine it with powerful new IT applications and create tools and services that improve clinical outcomes and generate cost savings - i.e., generate clinical value - for the patients, providers and institutions we serve.

This promising outlook is based on an economic foundation. Our projections for value-based revenues (in addition to fee-for-service testing revenues) suggest attractive returns on the time and energy spent to make these changes. In fact, we believe these revenues can more than compensate for income lost due to the expected fee schedule cuts over the coming years.

But let’s be clear, these new revenues won’t just come to us. We must take the initiative, make changes, and earn them. The Pathways in this report identify the opportunities, and the chapters that follow provide details.

Change is happening with us or without us. There will be a scramble for shares of the pie among specialties and hospitals. The search for “avoidable costs” - a shortcut to value - will be ubiquitous and relentless, and we are bound to be an easy target in this regard. Thus, we must demonstrate we can generate cost savings through the value of our services rather than through cutting our services. As many in the industry say these days, “You’re either at the table, or on the table.”

It is clear that our practices’ business models will not remain the same over the next five years. We can think of
pathology, and many other specialties, as being on a down escalator. If we exert ourselves and move up to the top, there are many promising opportunities to provide value and derive our share of new revenues. If we don’t move, we will be carried down the escalator. What will be the result of inaction? Being treated as a cost center to be marginalized by other specialties, seeing our services commoditized, suffering substantial income losses, having difficulty maintaining independent practices, and losing professional stature are likely outcomes.

Up or down. Fortunately, it is our choice and we have the Pathways to guide us.

**Promising for Whom?**
The Promising Practice Pathways are relevant to all pathologists, in all types of practices, and in all types of settings. When changes as sweeping as healthcare market reform and personalized medicine occur, they impact all stakeholders, so potential opportunities apply broadly, although not always uniformly.

The Pathways speak to how pathologists can begin offering value-generating services in order to truly participate as a peer in the value-based market. These Pathways create opportunities not just for community pathology practices, but also academic groups, hospital and healthcare system pathology employees, commercial reference labs, and specialty pathology groups of all sorts.

Three points make the universal applicability of these Pathways clear:

1. The value “food chain” will touch all of us eventually, wherever we are.

Our imperative is to begin generating value before we get eaten. “Food chain” economics are at play here. The payers are shifting financial risk to providers and patients, and, in turn, providers and patients are behaving like consumers looking for high-value services.

For example, in our practice pathway on oncology we’ll describe how bundling payment is growing. This means oncologists receive a flat fee for a bundle of services per cancer patient and determine how to allocate the money across service providers. We can see how pathologists, radiologists and anesthesiologists, in particular, become vulnerable as the food chain plays out in this value-based market. Those of us providing oncology diagnostic services will be impacted by this within the next few years, especially if Medicare adopts oncology bundling, which Medicare is pursuing, according to many experts in the field.

Whether we’re chairs of pathology departments or employees of those departments, we can use these Pathways to identify value-generating services that address the needs of our institutions’ providers, and then propose programs based on those initiatives. Demonstrating our ability to deliver clinical value moves us up the food chain.
This might result in our department averting a budget cut, pathology and lab medicine being included in ACO discussions should the institution move in that direction, or, as an employee, earning a performance bonus and the opportunity for a new position.

2. “Reform” is about value, and it is coming soon to a town near you.

It would be a mistake to think that if you do not see local ACOs or new payment models, then reform is not a concern in your market. These new delivery and payment programs are spreading quickly and reform, such as movement to a value-based market, is occurring in numerous ways that may not be visible.

Most industry leaders agree that the healthcare system is fundamentally unsustainable in its current fee-for-service, fragmented form. Thus, it is a very good bet that “value” – quality improvement and decreasing avoidable costs – will continue to take over the healthcare market and impact virtually all providers in the next several years, regardless of political drivers, because the private market momentum is too strong to stop. The changes may arrive through Medicare, Medicaid, commercial insurers, or a practice being purchased by provider organizations or health plans.

We need to be ready when value reform arrives at our practice. We must have our business case for value generation prepared in advance to seize these opportunities. We cannot wait to plan our strategy until our hospital becomes an ACO or Medicare launches bundling programs that affect us.

These Practice Pathways offer a number of different entry points for developing a value-generating program and building a business case for it.

3. There’s only a short window.

The old cliché “window of opportunity” applies to our promising future and the Pathways that lead us there. Here is yet another source of urgency, because while we are currently well positioned for a coordinated-care, population management + personalized medicine health care system, there are others who have begun to provide similar services, and they are working to diminish our competitive advantages.

When technologies such as molecular diagnostics, next generation sequencing, informatics, and cloud computing advance with exponential speed and impact broad swaths of clinical care, disruptive innovators and even business sectors often spawn from the market turbulence created.

For example, a new business sector called “genetic benefit managers,” comprised of companies such as DNA Direct (now part of Medco/Express Scripts) and Generation Health (now part of CVS Caremark) emerged to provide payers a range of services related to molecular diagnostics testing, including utilization management, patient counseling, and physician
education. Medco/Express Scripts and CVS Caremark (Pharmacy Benefit Managers, or PBMs) also employ a disruptive, innovative business model in which they proactively encourage pharmacogenetic testing for millions of patients being prescribed drugs with potentially beneficial alternatives, based on testing, and according to value-based economics.

These giant PBMs control prescription channels to a significant share of the U.S. population, with Express Scripts/Medco now covering 155 million lives and CVS Caremark 85 million. They could end up controlling pharmacogenetic testing in this country. Many others are beginning to take the initiative in the “golden age of diagnostics,” drawn by the truly historic opportunities presented by applications of personalized medicine testing.

Our Pathways are designed to capitalize on the promising prospects available during this window and to do so quickly.

Here are a few concrete examples of how these Pathways apply even in the following situations:

“Small cog in a wheel” – A pathologist who is an employee in a large department in a hospital that is part of a larger health care system can benefit by devising a way to deliver clinical value that helps the department avert a budget cut. For example, he or she could initiate a molecular antibiogram and pathogen surveillance program to tackle resistant infections. This proactive effort could earn the employee a performance bonus or an opportunity for a new position in the organization.

“Department leader” – A pathologist whose responsibilities include managing institutional budgets and negotiating with administration can communicate the department’s ability to generate value in new ways and secure a seat at the table when the institution makes key decisions, such as whether or not to move in the direction of becoming an ACO. For example, the department could launch a program to improve clinician diagnostic accuracy through test ordering, interpretation and follow-up interventions. Aversion of these diagnostic errors can be shown to generate cost savings.

“No signs of reform” – A pathologist in an area without ACO activity or other visible signs of major reform can, by becoming informed by these Pathways, recognize the tell-tale signs that reform is coming to the local area and prepare an intelligent business plan for value-generation in response. The Pathways are also relevant for those of us beginning to look toward the next phase of our careers because they are meant as a guide to the near-term future.

“Still in training” – Pathology resi-
dents and fellows now focused on finishing training and finding a job may realize that the market’s move to value and personalized medicine offers tremendous opportunities, but that those opportunities will be the most secure in a practice, department or specialty lab that is implementing the types of services described in the Pathways.

“Commercial executive” – A pathologist whose reference lab is healthy and who sees no near-term threats can recognize that many of the market forces driving current growth at reference labs, for instance, may decline or shift in the next few years, due to reform and disruptive innovation. For example, hospitals are acquiring physician practices at a rapid rate. Accenture’s report, titled, “Clinical Transformation: Dramatic Changes as Physician Employment Grows,” predicted that less than one-third of physicians would remain independent by 2013, down from 43 percent in 2009.² He or she can use the Pathways to identify new growth opportunities for the business based on value-based clients.

We cannot assume that financial health now will continue in the future when such market shifts are occurring. On the contrary, business strategists typically advise companies to seek innovative market openings as industries begin to undergo these rearrangements. Those of us in reference or specialty labs will find the Pathways valuable in identifying novel growth directions for our businesses.

And Finally, the Pathways ... Promising Practice Pathways describe new pathologist-driven services and programs that add clinical value outside of the laboratory by improving downstream clinical quality and outcomes, and generating downstream clinical cost savings. As we’ve been discussing, these value-generating Pathways offer a promising future for our profession, indeed, a “golden age.”

To better understand what the Pathways are and are not, let’s look at a True and False list:

- **True or False?** The Pathways are business models for practices.
  - **False** – They offer business cases and market analytics for a set of practice offerings, along with implementation guides (forthcoming in the full report later this fall). The Pathways do not recommend a wholesale transformation of our practices’ business models, rather a “service model” that can be initially adjunctive to our practices, and then more fully implemented over time. The Pathway does not contain all of the elements.

Promising Practice Pathways

of a business model, but rather presents the strategic rationale, market economics, description of the service model, and implementation planning guide. The College of American Pathologists plans to provide a wide range of resources to support us in implementing these Pathways over the next few years.

- **True or False?** The Pathways can be customized according to practice type, setting and resources.

- **True** – The Pathways are models that have built-in variables to tailoring them to specific practices depending on market conditions, strategic focus, and capabilities. We have developed them to be broadly applicable.

- **True or False?** Pursuing any Pathway will require a major financial investment.

- **False** – Not all Pathway variations require significant financial investments; several require minimal, or even none, at least to start. The level of investment, whether in time or money, depends on what Pathway opportunity we want to pursue and how quickly we want to pursue it.

- **True or False?** If I don’t know molecular diagnostics or informatics, the Pathways have nothing to offer me.

- **False** – First, there are offerings within the Pathways that do not involve either molecular diagnostics or informatics technologies. Second, because we recognize that these technologies are critical to our future, the Pathways provide implementation options that allow us to proceed with the Pathway while acquiring these capabilities. For example, we can partner with a molecular diagnostics specialty lab initially while we develop our services. Further, it is not necessary for each of us to learn these skills, but rather for our group or practice to have these capabilities.

The next four chapters describe the four Pathways we have identified as most “Promising.” In this abridged report, these chapters do not include details about implementing the Pathways, but rather focus on the business rationale for the Pathway, market analysis, and Pathway description.

These are brief descriptions and figures for each Pathway as a preview of what’s to come.

**Practice Pathway 1: High Performance Pathology for High-Value Oncology**

This Pathway represents the epitome of personalized medicine and one of our flagship “golden era of diagnostics” opportunities. It entails providing not just diagnostic reports but true knowledge services to enable oncologists to improve their outcomes and lower
spending, i.e., to achieve “high-value oncology.” For example, we can offer technologies and services for high accuracy initial diagnostic evaluations, tumor test panels that direct oncology care decisions along the care continuum, informatics and algorithms for predicting risk and monitoring patients to avoid complications, as well as tools for clinical trial decisions. Together, these and other sources of pathology “tumor intelligence,” when linked to the patient’s clinical context, can significantly impact the oncologist’s results, and earn us value-based compensation in the alternative-payment programs that are beginning to proliferate in oncology.

This Pathway details the tumultuous oncology market changes creating demand for our Pathway services, the market opportunity size, the Pathway services and technologies, and initial implementation considerations.

**Practice Pathway 2: High-Performance Diagnostic Services**

Many clinical diagnostic errors relate directly to clinicians’ knowledge and management of diagnostic testing. This puts pathologists in the critical position to provide a range of interventions that decrease these errors, thereby improving outcomes and decreasing costs—i.e., adding clinical value. These errors are a clinically and financially significant issue. “Medical diagnoses that are wrong, missed, or delayed make up a large fraction of all medical errors and cause substantial suffering and injury,” writes Mark Graber, Professor of Medicine at State University of New York Stony Brook.

This Pathway explains how pathologist services and IT tools can improve test selection, communications of results, interpretation of results, and follow-up/management of results, thereby generating clinical value worthy of compensation.

**Practice Pathway 3: Coordinated Population Care Services**

ACOs and other coordinated care healthcare systems deliver care using a new population health management model that holds the ACO accountable for both the health and costs of an assigned patient population. This model requires both a systematization of care with guidelines and an individualized medicine approach to ensure the use of optimal treatments and services.

This Pathway describes the multiple competitive advantages pathologists have in advancing population health management for these organizations. For example, we can marry “top down” population lab informatics applications that support systematizing care with “bottom up,” patient-specific, molecular testing tools that can individualize those guidelines in a way that preserves the art and complexity of medicine. We also bring expertise in other areas critical to population health management, such as test analytics, instrumentation, and quality control.

The population health management
model also demands novel approaches to risk management and prevention. Because pathologists deliver the most potent of predictive tools in health care—in the form of individualized diagnostics and biomarkers—and because lab testing is performed frequently, pathologists are uniquely positioned to provide a steady supply of temporal predictive data to keep risk assessments fresh.

This Pathway includes a framework and numerous examples of services, tools, and programs for us to use in generating value in an ACO setting.

**Practice Pathway 4: Patient Diagnostic Services Center**

The value-based health care market is patient-centered, meaning high quality patient experiences are rewarded. Furthermore, a true health care consumer market has arrived, and consumers who are paying for their care are demanding high levels of service.

Diagnostic testing as structured today offers few to no patient conveniences—patients who need multiple tests must travel to different locations, juggle schedules, and take time off of work for each test, for example. Further, radiology and laboratory medicine/pathology are segregated, which can negatively impact the accuracy of the final diagnosis.

In short, there are a number of market factors that provide the opportunity for a disruptive diagnostic testing center model that combines excellent patient services; integration of pathology, lab and imaging testing to improve efficiency and accuracy; and LEAN operations and an ambulatory setting for cost savings.

This Pathway describes the market needs for a new diagnostic testing center, the market opportunity, examples of integrated diagnostic testing centers, and a potential workflow plan.
Figure for Practice Pathway 1: “High-Performance Pathology for High-Value Oncology”

Oncologist Treatment Continuum

High Performance Pathology Pathway 2014-2016

1. Diagnosis
   - Onc work up - staging

2. 1st line therapy decision
   - Test panels for Rx selection
   - Use granulocyte growth factors or Erythro Stims?

3. Evaluation response
   - Patient complication > Hospitalization
   - Monitoring for toxicity, anemia, clotting, etc.
   - Testing algorithms for risk-benefit of stimulation factors
   - Analysis of test results - recommend when to switch to palliative care

4. Monitoring for efficacy/patient adherence
   - Digitally reviewed for high accuracy + comprehensive report

5. Monitoring for toxicity, anemia, clotting, etc.

6. 2nd line therapy decision
   - Clinical trial options

7. Progression
   - 3rd line therapy decision
   - Clinical trial options
   - Palliative care

8. Palliative care

Clinical trial options
- Clinical trial recruiting - tumor profiling matching (2016)
- Clinical trial options
- Palliative care
Figure for Practice Pathway 2: “High-Performance Diagnostic Services”

Sources of Dx error:
- Ordered wrong tests
- Test results not interpreted correctly
- Test results delayed/“handoff” problems
- Next steps in diagnostic work-up incorrect

Pathway interventions:
- Test ordering guidance - tool or service
- Comprehensive, interpretive reports, services
- Abnormal test results communication system + leverage patient
- Targeted follow-up monitoring

Figure A for Practice Pathway 3: “Coordinated Population Care Services”

Lab Informatics
+ Pathology Expertise
+ Molecular Testing

Guidelines, Algorithms, EMR Tools, Risk Predictions
Figure B for Practice Pathway 3: “Coordinated Population Care Services” - Our Competitive Advantage - The Dual Approach

Population-Based: Lab Informatics
- Patterns for identifying risk
- Algorithms inform guidelines
- Statistics for performance management

Individualized: Molecular or Biomarker Testing
- Results and algorithms identify risk
- Results individualized guidelines/interventions

Guidelines systematize care

Molecular individualizes care
Figure A for Practice Pathway 4: “Patient Diagnostic Services Center” – How the Center’s Design Addresses Market Needs

- Integrated Dx service modalities
- Interpretive reporting
- Six Sigma

- Ambulatory setting
- LEAN operations
- Algorithmic optimization
- Economies of scale

Clinical Quality

Cost Savings

Patient Experience

Health Care Consumers

- Co-location and scheduling conveniences
- Patient-centered
- Rapid results

- Community setting
- Retail-level services
- Low prices and financing
- High quality
Figure B for Practice Pathway 4: “Patient Diagnostic Services Center”

Phase 1: Apply Diagnostic Testing Algorithm and Develop Testing Plan

Phase 2: Patient Testing Flow Integration

Phase 3: Evaluation, Cross Review, Interpretation and Integration of Results

Phase 4: Report Integration

Scheduling and Reception – “Retail” Level Services
PROMISING PRACTICE PATHWAYS™:
HIGH-PERFORMANCE PATHOLOGY FOR HIGH-VALUE ONCOLOGY

COLLEGE OF AMERICAN PATHOLOGISTS
As the pioneering clinical specialty in personalized or “precision” medicine, oncology may offer pathologists more high value and high growth opportunities than any other specialty or market area. Because genomic, proteomic, and other profiling techniques will, in combination with traditional pathology diagnostics, be directing clinical cancer decisions in highly prescriptive ways, we have the prospect of partnering with oncologists to manage care in a manner warranting significant compensation. Many industry analysts and investors reflecting on this next decade of personalized oncology care have opined that a power shift is occurring, from therapeutics to diagnostics, and that we are entering a “golden age of diagnostics.”

This oncology diagnostic services opportunity is ours to lose, as there are others who are already entering what they see as a sentinel new, long-term market. Driven both by science and value-based market reforms, oncologists have an increasingly long list of new molecular and diagnostic testing service needs. If we can help them translate this information into achieving better outcomes more cost efficiently, we can be compensated on value rather than as a vendor.

Pathology groups that deliver knowledge services enabling “high-value oncology” – i.e., improvements in quality and decreased spending – will likely have tremendous long-term growth and control of their financial futures. Other groups who offer only basic diagnostic testing to oncologists will likely see shrinking, low-cost testing revenues.

The “High Performance Pathology for High-value Oncology” practice pathway is designed to capture this opportunity. The pathway comprises, for example, technologies and services for high accuracy initial diagnostic evaluations, tumor test panels that direct oncology care decisions along the care continuum, informatics and algorithms for predicting risk and monitoring patients to avoid complications, and tools for clinical trial decisions. Together, these and other sources of pathology “tumor intelligence,” when linked to the patient’s clinical context, can significantly impact the oncologist’s results and hence compensation in value-based payment programs.

Fortunately, there are a number of related roads to becoming a high performance pathology practice pathway for oncology. Hospital, academic, and community pathology practices can all pursue this pathway and can either build the molecular test panels and informatics systems themselves, partner with their institutions, partner with specialty/reference labs, or outsource/buy them.
Hopefully this abridged guide gives a sense of (1) the attractiveness of this practice model both professionally and financially, (2) a clear picture of what this practice model entails, and (3) the attainability of this opportunity.
CONTEXT: HOW THE PRACTICE OF ONCOLOGY IS CHANGING

Like the rest of the healthcare market, oncology is being subjected to payment and delivery model reforms by private and government payers. Having already experienced substantial financial pressures over the past few years, oncologists are reacting to these recent developments as a “last straw” requiring new types of business arrangements.

Oncology Business Review wrote in January 2011, “Before Health Reform was enacted in March 2010, community oncology was already faced with significant economic challenges, with declining payment rates and rising costs of care, coupled with a serious re-examination of potential overutilization of oncology treatment, particularly near end of life. Health Reform compounds these problems and presents new opportunities by mandating profound changes to our healthcare payment and delivery systems. It marks the beginning of a transformation in the way that cancer care services will be paid and delivered in the future.”

Oncologists Consider Costs

Oncology leaders have begun to call for changes in management that are driven by value concerns, such as evaluating palliative end-of-life cancer care and considering the cost as well as the benefit of a new therapeutic before adopting it.

As an example, Dendreon’s prostate cancer therapeutic, Provenge, has seen slow adoption, which is being attributed by many to push back from oncologists and urologists to the poor cost–benefit offered by the drug. Provenge offers a median survival benefit of 4.1 months and costs $93,000. Based on an online survey of oncologists and urologists conducted by Sermo, most oncologists and urologists thought that such drugs should have a survival benefit of at least seven months, and 30 percent said the benefit should be at least one year.

Furthermore, 86 percent of these doctors believe that Provenge and similar therapeutics should not cost more than $60,000.1

Oncology Practices Struggle
Faced with massive reimbursement cuts to the drugs that represent the majority of oncology practice revenues, and seeing the market move toward integrated delivery models, independent oncology practice groups have been switching to employment models. A number of models are being implemented – hospitals are forming oncology service lines, and collaborations such as professional service agreements are popular.

An advocacy group of oncologists trying to save the community practice model called the “Community Oncology Alliance” tracks changes in the community oncology marketplace. As of April 2012, over the prior four years, of the 1,254 cancer clinics or practices the Alliance identified:

- 19 percent had closed;
- 35 percent were struggling financially;
- 31 percent had either been acquired by or entered a contractual relationship with a hospital;
- 11 percent had merged with another practice or entity.

We estimate that the aggregate of oncologists in financially struggling or closed practices (over the past four years, according to this Alliance report) represents about a third of all community practice oncologists.

Payers Launch New Payment and Care Delivery Models
Oncology’s relatively high and rapidly growing costs, as well as projections for steeper spending increases, have made it a top target for payers. “Oncology is the service line on the top of the list for many insurers who are exploring every avenue to lower their costs,” writes Mary Lou Bowers in December 2011 in Clinical Oncology News.

Payers have begun to implement oncology-specific programs to try to curb spending. As an example, treatment pathways are a starting point for most plans because treatment variation has been tied to suboptimal outcomes and high costs. Pathways typically involve evidence-based protocols that are more prescriptive than guidelines.

Pathways prioritize treatments based on relative efficacy, toxicity, and cost, in that order. Groups of academic and community oncologists develop them and commercial companies, such as Cardinal Health’s P4 Healthcare and McKesson’s Innovent Oncology, implement them. Currently most focus only on drug decisions, but they are expanding to include diagnostic testing choices.

Oncologists are financially incentivized to adhere to the treatment pathways for a majority of their patients (higher fee schedules and bonuses, for example), and the payer benefits through

cost savings from usage of less expensive drugs and more frequent end-of-life palliative care decisions. To date, Aetna, UnitedHealth Group, and a number of state Blues are implementing oncology pathway programs.

**Oncology Bundling Looks Here to Stay**

Another popular value-based model, bundling or episode of care payments, can be implemented with or without pathways. Many industry experts predict that bundling models will be one of the long-term reform winners, as early results have shown them to be quite effective in both cost reduction and maintaining quality.

Here’s how a bundled model works:

“... a “bundled payment” or an “episode payment,” reimburses participating medical oncologists upfront for an entire cancer treatment program, rather than using the current “fee-for-service” approach that rewards volume regardless of health outcomes.”3

According to Jay Sultan, Assoc. Vice President and General Manager for Payment Reform at The TriZetto Group, bundled or “global case rate” payments per patient for cancer drugs are now extremely common.4 For example, an oncologist might receive a flat fee of $15,000 for all drug infusions for a patient over the course of two years. Sultan also reports that he is beginning to hear of complete oncology bundling programs, which include all costs – medical, surgery, pathology, etc. – in the global payment fee.

As an example of a cancer bundled payment program designed to provide value and quality to patients and oncologists at the diagnostic phase of care, Cancer Treatment Centers of America (CTCA), an employee model, integrated oncology provider network, recently launched the diagnostic services bundled offering directly to patients. Called CareEdge, the program offers a comprehensive set of pathology and radiology testing with a guaranteed five day turn-around time, set package price and personalized care plan with suggested next steps.

CareEdge is priced at $12,200 for a breast cancer patient, $11,400 for colorectal cancer, $14,500 for lung cancer, and $10,000 for prostate cancer.5 CTCA has obtained reimbursement from smaller health plans and is pursuing coverage from national carriers.

The speed with which payers are moving along this reform continuum varies with the payer and the geographic

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4Jay Sultan, Assoc. Vice President and General Manager for Payment Reform at The TriZetto Group, interview with Eleanor Herriman, MD, MBA, G2 Intelligence, on July 3, 2012

region. UnitedHealthcare is at the forefront of payers, having rolled out oncology bundling programs that include oncology services, drugs, hospitalizations and other costs – diagnostics are planned for later. In California, for example, reform is relatively far ahead of other states.

ACOs
The final phase that many payers are targeting for oncologists is a variant of an Accountable Care Organization, with value-based payment, coordinated care, and financial risk shifted to the oncologist. For example:

- The oncologist may receive some sort of “global payment” that covers managing a cancer patient over an episode of care, perhaps 1-2 years;
- The oncologist decides how to allocate that payment amongst the various services needed to care for the patient, including drugs, surgeries, radiation, labs, imaging, hospitalizations, etc.;
- The oncologist may also receive a “patient management fee” for coordinating services (this is the medical home model), such as extra office hours, round-the-clock nursing support, etc.;
- The oncologist may be rewarded or penalized according to adherence to care pathways, which would likely direct both options for therapies and testing;
- The oncologist would share in or retain all of the savings achieved if spending for the patient was lower than the fixed payment.

Payers Versus Hospitals
Aetna and several other payers are backing the oncology medical home model, in collaboration with the Community Oncology Alliance, as they see it as a means to save the community oncology practice model. In the medical home model, oncologists employ intensive care management and coordination services with the goal of reducing the use of hospitals and emergency departments. Payers’ motivation for supporting the viability of the independent oncology practice relates to curbing the tide of hospital acquisitions and avoiding expensive hospital-based oncology services.

So the payers and hospitals are in an interesting battle regarding the future of oncology practice models. Payers are hoping to safeguard private community practices through a medical home model and gain sharing, and hospitals are aiming to manage and integrate oncology through acquisition and contracting.

Medicare – The Determining Factor
The most important predictor of the timeline for new oncology payment models is Medicare. Jay Sultan predicts that by 2016 Medicare will be implementing bundled payments for oncology. This timeline begins with the Center for Medicare and Medicaid In-
innovation’s (CMMI) “Bundled Payments for Care Improvement” initiative, which begins piloting bundled programs, including one in oncology, in 2013.

CMMI has enormous powers to rapidly enact new Medicare payment reform programs without the need for Congressional approval or any type of advisory review. Assuming CMMI endures, it is quite likely Medicare will be rolling out some form of oncology bundled payment program in a few years.

Memorial Sloan Kettering has proposed a bundling model to Medicare that delivers a set reimbursement to providers for a period of care for a particular patient with a defined condition.

“As an example of our model, consider the case of non-small-cell lung cancer (NSCLC). There are currently eight combinations of chemotherapeutics that are recommended as first-line treatment for this disease, according to the National Comprehensive Cancer Network (NCCN) and a number of other practice guidelines. The costs of these regimens... vary quite substantially, however, from approximately $1,292 to $7,092 per month. If these regimens are largely interchangeable and of similar efficacy, an episode-based payment framework could result in savings without harming quality.

“For instance, imagine if the rate of reimbursement for a 1-month episode of treatment of NSCLC were set at $4,000 per month,... This would create an incentive for oncologists to choose lower priced regimens.”

Bottom Line – and Caveats – for Pathology
Both the variety of new oncology practice models being explored and the stakeholder dynamics present us as pathologists contemplating this oncology pathway with interesting opportunities and multiple “client” possibilities.

There is, however, also a cautionary side to this situation. Oncology practices under bundling contracts have another alternative – to insource the pathology and laboratory testing. This would allow them to manage the costs as well as generate revenues. The more oncologists view our diagnostic and lab testing as simply reporting results, and basically a commodity, the more likely this is to happen. However, with a high performance pathology practice oncology model that provides knowledge that directly influences decisions that save money and improve outcomes, the pathology lab is in an entirely different category.

Although this market landscape may seem a bit complicated by stakeholder power struggles, practice model variations, and evolution in payment programs, it can be distilled to a few fundamentals. Namely, whoever is being paid under these new, risk-based models, be they oncologists or hospitals/health systems, will have compensation tied to clinical outcomes and costs.

The implications are relevant for pathologists as risk-based compensation depends, directly or indirectly, upon:

- Having the highest accuracy and most precise and timely diagnosis possible;
- Utilizing the optimal (selected for efficacy, toxicity and costs) combination of therapeutics (including clinical trial drugs) at each point in the tumor’s progression; this may include the development of one’s own treatment pathway, based on evidence and experience;
- Applying the best possible information to prevent complications and hospitalizations;
- Assessing patients’ adherence to medication regimens in order to ensure therapeutic efficacy and avert complications;
- Transitioning to palliative, end-of-life care in an evidence-based manner and according to patient preferences.

**Oncologists Can’t Go It Alone**
For community oncologists and community hospital oncology service lines, possessing these “Oncology Management Capabilities” in the context of the ever-accelerating fields of cancer science and technology will be very challenging. Workforce studies are projecting shortages of oncologists, so it seems impractical to assume that an overloaded community oncologist will have sufficient time to keep current with all the necessary therapeutic and diagnostic literature needed to inform best practice management. Technology and knowledge accumulation offer only a partial solution. The combination of the spread of clinical IT and the availability of actionable oncology knowledge repositories mean that an infrastructure exists to bring academic-type oncology to community oncology practice. There are now websites that log cancer genetic variants, comparative treatment effectiveness results, and clinical trial information.

Still, because so much of cancer is driven by molecular medicine, one of the most critical pieces to equipping
community oncology for value-based payment programs is a pathology lab designed to translate testing information into clinical management decisions.

Market Opportunity for Pathologists
These market changes open up an opportunity for pathologists to provide knowledge services to enable oncologists to improve their outcomes and lower spending, i.e., to achieve “high value oncology.”

The pathology practice’s objectives for this pathway model include:

- **Ownership** - *Put a stake in the ground to begin owning this opportunity*
  - other, non-pathology/lab market entities have already begun to move into this market with various offerings;

- **Competitive differentiation** - *Create a competitively superior solution to generate value for oncology practices*
  - comprehensive, integrated testing – integrating all information for interpretation adds diagnostic power; plus it is critical to have all testing done at one lab, due to differences in reference ranges, methods, assays, etc.;
  - disease expertise – only pathologists can integrate the histopathology with the molecular genetics and understanding of disease processes;
  - informatics and IT systems – access to LIS and oncology clinical data for data mining, algorithm development and bioinformatics analysis;

- **Diagnostics in pathways** - *Work at the local level with your oncologists to integrate testing into treatment pathways*
  - treatment pathways are a key tool of payers for managing oncology costs and will likely continue to be used in bundling;
  - diagnostics should be increasingly driving cancer treatment decisions, so pathology groups have an opportunity to both codify this with oncologists and payers and tie it to value-based payment by integrating testing into pathways.

- **Business case** - *Develop an evidence-supported business case quantifying the value delivered by the pathology care management services;*
  - this is especially critical for gain-sharing and bundled payment contracts that become more prevalent after 2016;
  - for those practices that want to aggressively expand in this market, and/or contract early with payers, investing early in such a business case will provide powerful ammunition.
• **Perceptions** - Reframe the oncologists’ view of the pathologist from a provider of diagnoses to a knowledge partner who is critical to care decisions.

Importantly, this pathway enables us to be compensated fairly as oncology moves away from fee-for-service towards value-based payments. Without a set of services that demonstrate we can participate directly in improving quality outcomes and generating savings, we will be a cost line item that will become part of those savings.

The practice model we are proposing, then, is a new one. It involves pursuing revenue services that come from new payment models tied to value, and thus often based on bundling, shared-savings, global payments/capitation, and the like. Our compensation will be determined by a business case built on evidence that the services we provide result in improved quality and lower costs.

**Sizing the opportunity: initial target market and clients**

The likely, initial target market will be community oncology groups and community hospitals, given that they will have the greatest need for help. An additional, and immediate, market opportunity is contracting with payers to offer these oncology service solutions.

The size of this market opportunity can be estimated in several ways:

- It may represent the majority of the available community oncology market within 6-10 years.
- We control how big an opportunity this is for pathologists, because if we don’t pursue this course, others will, including oncologists themselves by insourcing laboratories.
- The opportunity size will vary geographically, due to differences in the adoption rates of payment reform in oncology.
- We need to compare this opportunity to projections for our fee-for-service (FFS) oncology testing market.

In Figure 1 we take a macro level, national view of the potential pathology markets in oncology in both the traditional, FFS model, and the emerging, value-based model. For an explanation of the market revenue definitions and the methodology used, see “Methodology” under the Figure.

What comes out of this model exercise is that the potential value-based oncology market for pathologists based only on a proportion of cost savings is substantial - about 23 percent of the entire FFS revenue market (this assumes testing including molecular, Flow, FISH). This does not include compensation for the testing itself. When that is included, the total value-based estimate is about 13 percent higher than the FFS market.
No doubt these projections are only directional and thus not to be taken with specificity, but the general conclusion that the oncology value-based market is an attractive, relatively large market opportunity for pathologists seems valid.

**Figure 1: Potential Value-Based and FFS Pathology Markets in Oncology**

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Potential Value-Based Oncology Services Market for Pathologists</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Oncology costs – U.S. (NCI projections of population cancer increases)</td>
<td>$137</td>
<td>$140</td>
<td>$143</td>
<td>$146</td>
<td>$149</td>
<td>$152</td>
<td>$155</td>
<td>$158</td>
</tr>
<tr>
<td>Potential market – gainsharing savings, assumes 15 percent of costs</td>
<td>$21.5</td>
<td>$21.9</td>
<td>$22.3</td>
<td>$22.8</td>
<td>$23.3</td>
<td>$23.7</td>
<td></td>
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</tr>
<tr>
<td>Potential pathologist gain-sharing revenues – assumes 10 percent of savings</td>
<td>$2.1</td>
<td>$2.2</td>
<td>$2.2</td>
<td>$2.3</td>
<td>$2.3</td>
<td>$2.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathology labs – all cancer testing excluding skin (at 10 percent discount)</td>
<td>$8.5</td>
<td>$8.0</td>
<td>$8.0</td>
<td>$8.8</td>
<td>$8.8</td>
<td>$9.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total – Value-Based Market</td>
<td>$10.6</td>
<td>$10.2</td>
<td>$10.3</td>
<td>$11.1</td>
<td>$11.2</td>
<td>$11.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Potential Fee-For-Service Oncology Testing Market for Pathologists</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathology labs – Tissue, Molecular, FISH, Flow, etc. for cancers excluding skin, prostate, uro, cervical</td>
<td>$9.9</td>
<td>$9.4</td>
<td>$9.4</td>
<td>$8.9</td>
<td>$8.9</td>
<td>$9.8</td>
<td>$9.8</td>
<td>$10.3</td>
</tr>
</tbody>
</table>

Source: Eleanor Herriman, MD, MBA, G2 Intelligence

1Since the “Oncology cost” estimates in this model were derived for all non-skin cancers, and thus include cancers that non-oncologists (like GynOncs and urologists) treat and cancers that mainly require surgery, they may not all be applicable to our oncology pathway. Thus, we conducted a second cancer costs estimate using a different methodology. This generated a very similar costs estimate, as shown in the Appendix “Cancer Cost Estimates 2.

**Figure 1 Methodology:**

The fee-for-service market estimates are based on testing revenue projections for tissue, stains, IHC, FISH, Flow, molecular, cytogenetics, and related cancer assays. The “AP only” represents practices only performing tissue-related testing. Assumptions regarding Medicare and commercial payer cuts to reimbursement rates are applied to the projections.

The value-based estimates start with the total and projected costs of cancer care in the United States, according to the National Cancer Institute. Based on reports that pathways and bundling programs can generate savings ranging from 10 to 20 percent, we assumed that by 2015 bundling programs might be effective enough to achieve 15 percent in cost savings. Next, we assumed that if a pathology lab was partnered with the oncology team and delivering documented value, they could receive a 10 percent share of these savings in some form of compensation. A 10 percent share is about double that of path and lab testing’s oncology cost share.

2Assumes reimbursement cuts to TC, IHC, MDx, FISH, etc. of 5 percent in 2014, 5 percent in 2016, net of volume increases.
Challenges and Tremendous Opportunity Ahead
While there will be many phases in the evolution of this pathway, the launch phase, which spans approximately 2014 through 2016, is perhaps both the most challenging and the most critical. It involves risk taking, initiating cultural and governance shifts, financial investments, and learning curves.

But it also offers tremendous opportunities to control our futures. This pathology pathway is an opportunity to provide knowledge services, driven by diagnostic testing and informatics + algorithms, that enable oncologists to improve their outcomes and lower spending, i.e., to achieve “high value oncology.”
A MODEL FOR HIGH-VALUE ONCOLOGY SERVICES

The high-value oncology practice model has the following characteristics:

- Services are knowledge-based, not test reports, and address clinical decisions throughout the care continuum.

- Superior clinical decision-making is enabled by:
  - Expertise and evidence-review – continuous development of test panels and protocols;
  - Pathologists integrating information across multiple types of tests – tissue, molecular, Flow, etc.;
  - Advanced tumor profiling using sequencing;
  - Risk analysis to mitigate complications – e.g., pharmacogenetic testing;
  - Informatics, mining of lab data, and algorithms; and
  - Digital pathology for expert review and quantitative analysis.

- Clients include community oncology groups, hospital oncology services lines and cancer centers, payers, ACOs, and companies developing pathways or managing oncology care.

- Payment models may initially be fee-for-service but will transition to some component of service contract, gain-sharing through bundled payments or global payments.

**Applying the Model: High-Value Oncology Services in Action**

Knowledge services in a high-performance pathology practice support oncology decision making and improve performance along the care continuum (See Figure 2).
Figure 2: High Performance Pathology for High-Value Oncology Practice Pathway

Oncologist Treatment Continuum

High Performance Pathology Pathway 2014-2016

- Monitoring for efficacy/patient adherence
- Digitally reviewed for high accuracy + comprehensive report
- Evidence-based diagnostic testing pathway
- Re-profiling of recurrent tumor + Test Panels for Rx selection
- Test panels for Rx selection
- Clinical trial recruiting - tumor profiling matching (2016)
- Testing algorithms for risk-benefit of stimulation factors
- Analysis of test results - recommend when to switch to palliative care
- Monitoring for toxicity, anemia, clotting, etc.

- Progression
- 2nd line therapy decision
- Clinical trial options
- Progression
- 3rd line therapy decision
- Clinical trial options
- Palliative care
- Progression
- Clinical trial options
- Palliative care

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
Core Service Offerings of High Performance Pathology for High-Value Oncology Pathway

In addition to a complete menu of oncology pathology and laboratory testing (not all of which needs to be in-house, though rapid turn-around is important), testing services will include:

- **High accuracy and timely, high-precision diagnostic testing services**

This need is driven by the fact that medical diagnostic errors from all causes are believed to occur at a rate of 15-23 percent. Cancer diagnostic accuracy can be suboptimal in terms of delays, misinterpretations, pre- or post-analytic errors, or clinician cognitive or system errors. Further, pathologist interpretation error has also been found to be important: “In a CAP multi-institutional study of a variety of secondary review practices, the self-reported mean and median discrepancy frequency of 74 laboratories was 6.7 percent and 5.1 percent, respectively. **Forty-eight percent of all discrepancies were due to a change within the same category of interpretation** (e.g., one tumor type was changed to another tumor type). **This change in diagnosis has a major impact on the clinical management of patients in many fields of oncology, such as lung cancer.**”

There are multiple ways to increase diagnostic accuracy:
- Conducting multiple, digital reviews of cancer cases;
- Integrating all testing into a single, interpretive case report;
- Providing services to direct test ordering;
- Utilizing “high precision” molecular testing to sub-classify and ensure diagnosis; and
- Implementing more intensive systems for tracking report follow-up.

- **Test panels for clinical decisions and pathways**

The heart of our high performance practice is the test panels and related services. These are what can drive care decisions toward better outcomes and lower spending, as we can leverage the rapid advancements in molecular and "-omics" sciences in cancer.

In our high performance practice context:

- A “test panel” is loosely defined as a suite of tests that can be comprised of different assay types (e.g., molecular, IHC, Flow, FISH, tissue, clinical lab) and are selected to address a specific clinical question for a specific cancer type.
- A test panel is dynamic – it is routinely reviewed by the pathologist and the test selection updated as the science and evidence evolve.
- A test panel may have an accompanying algorithm that quan-

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tifies risk, prognosis or treatment efficacy probability. A risk estimate algorithm, for example, may also include clinical factors. Panels may also involve a “mini pathway” with further testing.

- A test panel results in an integrated report with an interpretation and decision recommendation. It will likely frequently entail a call with the oncologist – hence the “knowledge service” moniker.

Example test panel applications:

- Deciding between treatment regimens for 1st, 2nd or 3rd course of therapy;
- Predicting prognoses;
- Determining level of risk for toxicity or complication – direct interventions;
- Evaluating treatment response or tumor resistance;
- Deciding whether to use stimulating factors (e.g., Erythropoietin, Granulocyte colony stimulating factor(G-CSF)) or other supportive therapies;
- Identifying options for clinical trial agents;
- Deciding whether to enter palliative care, based on marker profiling indicating lack of effective therapies/poor prognosis; and
- Tumor profiling to support patient consulting for palliative care decisions.

End-of-life care is an area that the American Society of Clinical Oncologists, among others, has targeted for improvement in care. Oncology leadership is communicating that chemotherapy is being administered far after it should be in terms of benefits versus harms. Moreover, patients’ wishes are not being considered in the treatment decisions. Finally, a significant proportion of cancer costs occur in the last year of life, so these therapeutic courses mostly represent unnecessary spending.

This presents an opportunity for pathologists to provide a valuable service. By mapping the evolution of the tumor’s molecular profile across a panel of markers as it develops resistance to various therapies, we can provide an objective means of assessing when further therapeutic interventions may no longer be effective. This data can be used by the oncologist for palliative care/end-of-life discussions with patients.

A key technology platform needed for tumor profiling throughout the course of treatment is next-generation sequencing (NGS). NGS of cancer markers is already being used routinely for clinical care of some cancers at many major academic medical centers, and many predict that by 2016 it will be routinely used for at least one major cancer throughout the community.

We will likely need NGS of marker panels for our high performance testing services in particular applications, such as evaluating recurrent tumor’s pro-
files, and by a particular time period – about 2016-2017. Although adopting NGS seems daunting, the technology is maturing very quickly, so bench-top instruments, sample prep and bioinformatics software are becoming more accessible every month. Our practice pathway goal should be to have either built, or arranged through a reference lab or partnership for NGS tumor profiling services with less than a two week turnaround time and the ability to sequence ~200 markers by ~2016-2017.
MAKING THE TRANSITION TO HIGH PERFORMANCE PATHWAY SERVICES

A pathology practice need not think that this pathway requires a complete practice conversion to oncology, or a sudden transition to a new business model. First, the pathway envisions a gradual transition in business revenues switching to the new model, so the practice would likely have a mix of business for a few years. Second, a high performance pathology pathway for oncology can operate within a more general practice group if it is of sufficient size.

Figure 3, “The High Performance Pathology for High Value Oncology Practice Pathway Solutions, Early Years,” provides an overview of the type of knowledge services our practice pathway model might use to support “high value” oncology in the beginning years. Keep in mind that these services may be developed through buying, building or partnering.

In addition, our pathway guide anticipates a phased acquisition of the technologies and offerings (see Figure 4, “Phased Acquisition of High Value Oncology Pathway Solutions”).

One pathway requirement that needs highlighting concerns accessing clinical oncology data. This is essential in order to formulate our clinical decision applications. In addition, it would be helpful to have access to claims data for cost analysis purposes, although in a bundled payment setting this will be automatically calculated by the payer.

Laboratory access to clinical data can be challenging, depending on the practice setting. However, with care delivery reform integrating providers, and our new practice pathway model involving us more directly in care management, we have an excellent case for accessing this data. Further, as part of our business proposal to the oncology group, hospital, ACO, academic medical center, or payer, we simply make it clear that without this data we cannot execute the program.

There are a number of ways we can access the data. In an ACO, for example, they likely have already integrated lab, clinical and other data, so it is a matter of accessing that network or database. In the case of a hospital cancer center, it may also be straightforward, as the data is likely concentrated in an EHR. For community oncology groups, we either analyze their EMRs, if they contain all the pathology and lab data we need, or build sufficient interfaces to enable two-way data exchange and work with our LIS systems.
Choosing a Path Forward
The path forward will vary depending on many factors including timing, size, resources and geography. It is possible even for small pathology practices in regions early along in reformation to begin implementing this model. Figure 5, “Spectra of Practice Pathway Service Offerings,” shows variations of some of the key pathway services along three dimensions:

- Time – 2014 to 2022: all groups will be developing the offerings to some extent incrementally;
- Size and resources: from small (e.g., five pathologists) on the left side to large or well capitalized with assets/CLIA lab on the right side.
- Geography: from regions early in reform (not many ACOs, for example, and no oncology pathway programs) on the left side to regions far along in oncology reform on the right.

The left side of the graphic shows each core service offering as a more basic version compared to the right side. “Version A” service offerings might then reflect either being early in development (2014-2015), or a small group’s offering for a number of years, or where a region without much reform would start. On the other hand, a large reference lab targeting a payer with an oncology bundling program might start developing a mix of “Versions B and C” offerings as early as 2014.
## Figure 3: The High Performance Pathology for High Value Oncology Practice Pathway Solutions, Early Years

<table>
<thead>
<tr>
<th>High Value Oncology Solution</th>
<th>Pathology Lab Service</th>
<th>Example</th>
<th>Technology</th>
<th>Potential Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High accuracy, timely and precise diagnosis</strong></td>
<td>Services to decrease chances of diagnostic errors – pre, interpretive and post, and molecular subtyping for precision</td>
<td>Cases reviewed digitally prospectively by multiple pathologists</td>
<td>Digital pathology system and Web portals</td>
<td>2014</td>
</tr>
<tr>
<td><strong>High accuracy diagnosis - 2</strong></td>
<td>Integrated reports - all testing, clinical data, possibly imaging</td>
<td>Diagnostic report incorporates tissue, molecular, sequencing profiles, IHC, cytogenticis, Flow, etc., as well as clinical information into report with recommendations</td>
<td>Next generation sequencing (NGS), bioinformatics, LIS with advanced reporting</td>
<td>NGS by 2016-2017</td>
</tr>
<tr>
<td><strong>Optimal therapy selection</strong></td>
<td>Testing panels designed for selecting drugs at every therapy line based on tumor profile, patient genetics and risks</td>
<td>At the 3rd line therapy decision point, tumor sequencing of 100 markers indicates mutations during progression best treated by a clinical trial agent</td>
<td>Next generation sequencing (NGS), bioinformatics, clinical trial database</td>
<td>NGS by 2016-2017</td>
</tr>
<tr>
<td><strong>Avoid complications/hospitals</strong></td>
<td>Lab testing protocols and algorithms to assess risk, and detect problems early through tracking results</td>
<td>Testing to weigh risks and benefits of erythropoietin stimulating factors in patients - coagulation and bleeding risks</td>
<td>US database with oncology clinical data, informatics + data-mining + algorithms</td>
<td>2014</td>
</tr>
<tr>
<td><strong>Adherence to Rx regimens</strong></td>
<td>For some tumors and therapies, tests can be used to monitor therapeutic response</td>
<td>QRT BCR-ABL testing is being used in CML to monitor response to therapy; Circulating tumor cell counts may be a future tool</td>
<td>Molecular testing, connectivity with pharmacy (optional), Circulating tumor cells in future</td>
<td>2016</td>
</tr>
<tr>
<td><strong>Switch to palliative, end-of-life care</strong></td>
<td>Profiling of recurrent tumor to demonstrate lack of adequate therapies; patient counseling to report results</td>
<td>Pathologist analyzes genetic variants in tumor recurrence and correlations with drugs; Tumor analysis regarding susceptibility to therapies supports decision for end-of-life care</td>
<td>Next generation sequencing (NGS)</td>
<td>2016-2017</td>
</tr>
</tbody>
</table>

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
### Figure 4: Phased Acquisition of High-Value Oncology Pathway Solutions

#### Launch Phase 2014-2016

**Core Offerings**
- High accuracy and high precision initial diagnostic service
- Test Panels/Services for
  - Selecting therapies
  - Predicting complications
  - Monitoring tumor response
- Tumor profiling for patient counseling for palliative care decisions

**Payment Models**
- Payers – service, subscription, PMPM
- Oncologists/Hosps – FFS + bonus, service revs or gain share

#### Evolution Phase 2017-2019

**New Offerings**
- Diagnostic Service – Integration with imaging
- Tumor profiling using next gen sequencing
- Clinical trial recruitment with tumor profiling using next gen sequencing

**New Payment Models**
- Oncologists/Hosps – Testing at per patient “case rate” (capitated) + gainsharing or other bonus

#### Expansion Phase 2020-2022

**New Offerings**
- Direct to patient – treatment and clinical trial recommendation services based on tumor profiling and case review

**New Payment Models**
- Patients – fee for service
- Oncologists/Hosps – Part of bundling revenues

Source: Eleanor Heniman, MD, MBA, G2 Intelligence
**Figure 5: Spectra of Practice Pathway Service Offerings**

**2014 ... 2022**

and/or

**Smaller Path Groups ... Larger/ Better Capitalized**

and/or

**Regions Early in Reform ... Deeper into Reform**

<table>
<thead>
<tr>
<th>Version A</th>
<th>Version B</th>
<th>Version C</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Diagnosis</strong></td>
<td>2nd pathologist read + &quot;standard&quot; markers for subclassification</td>
<td>Digital pathology-enabled review by multiple pathologists + subclassification + integration with imaging</td>
</tr>
<tr>
<td><strong>Test Panels for Rx Selection</strong></td>
<td>MDx test panel of cancer markers</td>
<td>Next gen sequencing (NGS) marker profiling + diagnostic pathways</td>
</tr>
<tr>
<td><strong>Testing to Avoid Complications</strong></td>
<td>Monitoring lab data + alerts</td>
<td>Protocols targeted for specific complications + integration with nursing</td>
</tr>
<tr>
<td><strong>Tumor Response and End of Life</strong></td>
<td>Use MDx panels to assess tumor mutations and likely response to Rx</td>
<td>NGS profiling of recurrences to compare mutations and predict resistance + tests that allow Rx monitoring - e.g., CTCs</td>
</tr>
<tr>
<td><strong>Clinical Trial Recruitment</strong></td>
<td>Use MDx panels and clinical data to assess candidacy for clinical trial</td>
<td>NGS profiling for clinical trial markers + interface to clinical trial database</td>
</tr>
</tbody>
</table>

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
Variations in Developing the Offerings

There are three options for developing the portfolio of test panels needed for this high performance pathology practice, and they can be used in combination with one another for different individual services and will likely evolve over time.

- **“Build”** – the build approach involves the pathology group developing the test panels within its lab; this does not necessarily mean each test is a “laboratory developed test” (LDT). The panels may be comprised of In Vitro Diagnostic (IVD) kits or LDTs. But the pathologist will be designing the selection, conducting the validation, and developing any algorithms and systematic interpretations for the panel.

- **“Buy”** – this option entails utilizing a reference lab for individual tests, or perhaps test panels. A relevant example is next-generation sequencing for tumor profiling. Given the level of expertise required to perform this testing, most community pathology groups will likely want to outsource this in the early years until the technology matures. Another example of “buy” for a larger pathology group might be acquiring a molecular lab with special expertise in tumor markers and profiling.

- **“Borrow”** – in the borrow approach the pathology group partners with another entity, such as a reference lab, for access to its technology, capabilities and tests. This might take a number of forms – a joint venture, a licensing arrangement, a service contract – but the general objective would be to enable a pathology group to rapidly launch into the market with a full program of services. A borrow strategy would most likely be designed to phase into the pathology practice building its own testing capabilities over time.

A Variety of Ways to Fund the Pathway

The issue of managing capital needs is as much a strategic as a financial one. There are several ways to plan the development of the pathway and the client-selling strategy that will increase the capital requirement’s flexibility. We have options to partner to access testing and even capabilities and services initially.

For instance, pathology labs already engaged in a contract or partnership with a hospital can partner with a hospital to provide high value oncology services. In fact, hospitals and academic medical centers may be excellent funding sources as they are looking for ways to diversify their revenue streams as services move to outpatient settings in efforts to lower spending.

Figure 6 illustrates some of these options.
Figure 6: Spectra of Practice Pathway Service Offerings

**Market Entry Strategy for High Performance Pathology Practice that Needs Capital**

- Enter market rapidly with a full service solution
  - Own a CLIA lab or other high cap asset?
    - Yes
      - Obtain equity or debt capital based on CLIA lab
    - No
      - Partner with another lab: For example reference lab like ARUP - for initial testing and informatics services; Raise remaining capital through private (wealthy individuals - "angels" or venture capital)

- Enter market more slowly and/or in phased, incremental way
  - Raise seed capital from either private "angels" or venture capital if no CLIA lab owned
  - and/or
    - "Bootstrap" - Develop and sell individual services on contract revenue basis and use $ for further development

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
Seldom are there opportunities in business in which multiple forces align needs and capabilities as well as the high value oncology diagnostic services opportunity presents for pathologists. The convergence of oncologists’ financial pressures, their needs for new approaches to improve clinical outcomes and achieve cost savings, the switch to episode-based and global payment programs and the advent of personalized oncology treatment management, create an unprecedented entry point for personalized medicine testing services.

At the same time, pathology faces its own challenges. We are also soon going to be struggling with the transition from fee-for-service to value-based payment. As well, we are in danger of being relinquished to a cost center to be managed like a vendor, squeezed and commoditized by our provider colleagues who are soon to be allocating fixed fee payments for episodes of care.

The answer seems obvious, but it will not be simple to execute. Our “High Performance Pathology for High Value Oncology” practice pathway offers us a roadmap for seizing this unprecedented market opportunity.

By providing evidence regarding how our tools and services generate value for oncology care by improving diagnostic accuracy, improving treatment selection decisions, helping to avoid complications and admissions, supporting end-of-life decisions, and advancing entry into clinical trials, we can participate in the emerging, next generation of payment models.

Although we do need molecular testing and informatics capabilities, as well as access to clinical data, this pathway can be navigated from a number of starting points, with variable speeds and using either buy, build or borrow resourcing.

We believe that, in the medium to long term, many of us have little choice but to move to a value-generating oncology service model such as this practice pathway. The value generation requires in expanding beyond our offices and laboratories, beyond reporting test results, and moving into the clinics with decision support services for oncologists.

The stars are aligned for us, though, and this future is a very bright one.
# APPENDIX - CANCER COST ESTIMATE NUMBER 2

<table>
<thead>
<tr>
<th>Cancer Costs - Estimate Number 2</th>
<th>Cancer Prevalence</th>
<th>Citation</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Sites</td>
<td>7,380,309</td>
<td>SEER, 2009, 0 to 10 yrs since Diagnosis</td>
<td></td>
</tr>
<tr>
<td>Cervix</td>
<td>73,001</td>
<td></td>
<td>Eliminate cancer patients treated by other specialists - GynOncs</td>
</tr>
<tr>
<td>Uterus</td>
<td>281,408</td>
<td></td>
<td>Eliminate cancer patients treated by other specialists - GynOncs</td>
</tr>
<tr>
<td>Prostate</td>
<td>1,764,269</td>
<td></td>
<td>Eliminate cancer patients treated by other specialists - Urologists</td>
</tr>
<tr>
<td>Bladder</td>
<td>329,276</td>
<td></td>
<td>Eliminate cancer patients treated by other specialists - Urologists</td>
</tr>
<tr>
<td>Cancer patients seen by oncologists</td>
<td>4,932,355</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients on chemo represent 22 percent of all with cancer diagnosis</td>
<td>1,085,118</td>
<td>Benchmarks for Value in Cancer Care: An Analysis of a Large Commercial Population; SEPTEMBER 2011 • jop.ascopubs.org</td>
<td>Limit cancer patients to those on chemo because that's who our pathway most applies to</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Estimated Costs</th>
<th>Citation</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg annual cost for patients on chemo is $111K</td>
<td>$111,000</td>
<td>Benchmarks for Value in Cancer Care: An Analysis of a Large Commercial Population; SEPTEMBER 2011 • jop.ascopubs.org</td>
</tr>
<tr>
<td>Total Cancer Costs for Patients on chemo - 2009</td>
<td>$120,448,109,100</td>
<td>Estimate in Original Model 2013 = $137 M (Figure 1)</td>
</tr>
<tr>
<td>Total Cancer cost patients on chemo 2019 - 30 percent increase in costs projected by NCI over 10 yrs</td>
<td>$156,582,541,830</td>
<td>Estimate in Original Model 2019 = $155 M (Figure 1)</td>
</tr>
</tbody>
</table>

Source: Eleanor Herriman, MD, MBA, G2 Intelligence

This cancer cost estimate uses a different methodology and is used to support the cost estimate in Figure 1.
PROMISING PRACTICE PATHWAYS™:
HIGH-PERFORMANCE DIAGNOSTIC SERVICES

COLLEGE OF AMERICAN PATHOLOGISTS
An under-appreciated “epidemic” of clinical diagnostic errors is creating a need for new approaches to elevating clinical diagnostic accuracy, opening up an opportunity for pathologists to deliver high-performance pre- and post-laboratory testing services. Clinical diagnostic error rates average 15 percent, three-fold higher than pathology, laboratory or radiology mistakes. Estimates suggest these errors contribute to 15–20 percent of all “adverse events.” While industry experts agree that these errors have received relatively less public or scientific attention, compared with other types of adverse events, this is starting to change.

At the same time, these errors do not appear to be declining. Increasing clinical complexity and rising clinician pressure may be increasing the likelihood of clinical diagnostic errors, and strengthening the case that it is pathologists who are best able to provide an answer. Aggravating factors include a wave of aging Baby Boomers with multiple chronic conditions that are challenging to diagnose, a significant shortage of primary care physicians and an exponentially rising number of diagnostic tests. Clinicians who provide direct patient care need expert diagnostic services to meet these challenges.

A significant number of clinical diagnostic errors are due to physicians’ knowledge, communication, synthesis, interpretation and management of diagnostic testing. If pathologists can help clinicians order, interpret and follow up on the right results in an accurate and timely manner, they will improve not just diagnostic accuracy, but also outcomes that translate into value warranting compensation.

This Practice Pathway, “High-Performance Diagnostic Services,” describes a promising opportunity for entering the value-based marketplace by addressing clinically and financially significant issues. The practice model entails deploying pathologist services and IT tools that improve test selection, result communications, result interpretations and result follow-up/management.

We’re offering this pathway guide because we believe that these errors are receiving increasing attention and that there is a rising interest in services aimed at reducing clinical diagnostic errors. Pathology groups that deliver high-performance diagnostic services that improve quality and decrease spending will likely have more robust growth opportunities compared with groups who offer fee-for-service testing alone.
There is a cautionary note to add here, too. Although we are the logical profession to seize this opportunity for value generation – particularly given our long-standing expertise with quality control and assurance programs and analytics of all kinds, including the College’s Q-PROBES program – if we do not take action others may usurp us. Others in health care, particularly in the quality and safety areas, have expertise in Six Sigma and can acquire other capabilities needed to design interventions to address the problems we’ll be describing.

While pathologists hold the strong competitive advantage of being able to apply much of our successful intra-lab quality work to the pre- and post-clinician testing phases, as well as holding a unique understanding of laboratory and pathology testing, we should not count on this giving us more than a great head start.

This pathway is accessible to pathologists across practice types, settings, resource levels and capability portfolios. The guide does not present a “how to” for every practice, but it does offer models applicable to several types of practices. Hopefully it gives you a sense of (1) the market demand for this practice model, (2) the attractiveness of this practice pathway both professionally and financially, and (3) the attainability of this opportunity.

The guide is structured as follows:

- Introduction: The Under-Appreciated Epidemic
- The Market Opportunity: How Improved Diagnostic Accuracy Generates Value
- Defining the High-Performance Diagnostic Services Pathway
INTRODUCTION - THE UNDER-APPRECIATED EPIDEMIC

The high-performance diagnostic services practice pathway uses the pathologist’s expertise and laboratory information to tackle a serious “epidemic” – that of clinical diagnostic errors.

As defined here, clinical diagnostic errors are cases in which the clinician misdiagnoses, misses making a diagnosis or experiences a clinically significant delay in making a diagnosis. The majority of these cases are not due to pathology, laboratory or radiology mistakes, where error rates are typically about 5 percent, but to diagnostic errors by clinicians, where the error rates average 15 percent.1

“Medical diagnoses that are wrong, missed or delayed make up a large fraction of all medical errors and cause substantial suffering and injury,” writes Mark Graber, Professor of Medicine at State University of New York Stony Brook.2 The inpatient mortality burden alone is alarming: “Diagnostic errors probably cause 40,000-80,000 preventable deaths annually in U.S. hospitals alone, and these estimates fail to account for mortality from ambulatory misdiagnosis and non-lethal morbidity due to diagnostic error.”3

These errors are “under-appreciated” because other than in the malpractice arena, where diagnostic errors have represented the leading cause of medical malpractice for the past decade,4 they have received relatively less attention versus other sources of medical errors.

Wachter, Professor of Medicine at University of California San Francisco, writes in Health Affairs, “The topic of diagnostic errors has been strangely absent from the flurry of patient safety activity over the past decade. This absence is particularly noteworthy given the frequency of these errors.”5

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1Mario Plebani, Clinica Chimica Acta 404 (2009) 16–23
3AS Tehrani et al. “20-Year Summary of US Malpractice Claims for Diagnostic Errors from 1985-2005.” Diagnostic Error in Medicine, 4th International Conference, October 25, 2011, Chicago, IL
“Despite their major public health implications, diagnostic errors have received relatively little public or scientific attention, including from the patient safety community,” reports Newman-Toker in JAMA in 2009.

Diagnostic errors are also considered by many a concerning “epidemic” because of their prevalence and apparent increasing frequency. A study commissioned by the National Patient Safety Foundation found that one in six people had personally experienced a medical error related to misdiagnosis. Further, the authors of an AHRQ-funded review reported “Thus, while these studies view the problem from varying vantage points using heterogeneous methodologies (some nonsystematic and lacking in standardized definitions), what emerges is compelling evidence for the frequency and impact of diagnosis error and delay.”

The gold standard for diagnostic error evidence is autopsy research, and these studies have repeatedly documented high rates. One report reviewed extensive autopsy studies and found major diagnostic errors occurred with a median rate of 23 percent. The errors are clinically quite consequential. “Roughly five percent of autopsies reveal lethal diagnostic errors for which a correct diagnosis coupled with treatment could have averted death.”

Furthermore, the error rates do not appear to be declining with time, “Despite the introduction of more modern diagnostic techniques and of intensive and invasive monitoring, the number of missed major diagnoses has not essentially changed over the past 20 to 30 years.”

Concerns regarding rising error frequency arise from the growing complexity of care. Chassin and Loeb of the Joint Commission wrote last year, “Along with some progress, we are experiencing an epidemic of serious and preventable adverse events. … Moreover, the available evidence suggests that the risk of harmful error in health care may be increasing. As new devices, equipment, procedures, and drugs are added to our therapeutic arsenal, the complexity of delivering

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7Golodner L. How the public perceives patient safety. Newsletter of the National Patient Safety Foundation 2004;1997:1–6


Promising Practice Pathways

College of American Pathologists

Effective care increases. Complexity greatly increases the likelihood of error, especially in systems that perform at low levels of reliability.”

Multiple studies indicate that a significant share, from 15-20 percent, of the “adverse events” referred to by Chassin and Loeb can be attributed to diagnostic errors. And other investigations point to diagnostic errors being relatively more dangerous among these adverse events. For example, a study that examined adverse events among inpatients that resulted in some type of patient harm found that diagnostic errors were significantly more dangerous, with a mortality rate of 29.1 percent versus 7.4 percent for non-diagnostic error adverse events.

Research has indicated that the majority of diagnostic errors contain a component of clinical decision making – so-called “cognitive errors.” “Three-fourths of all diagnostic errors (74 percent) involve some cognitive deficiencies.”

Enter Pathology and Lab Medicine

What does all of this have to do with us? Simply put, a significant number of these errors are attributable to clinician problems selecting, tracking, understanding, synthesizing and following up on pathology and laboratory testing. Epner and Astion have dissected the root causes of clinician diagnostic errors as they relate to pathology and laboratory medicine, and developed the following taxonomy to categorize the sources of errors:

1. Inappropriate test is ordered.
2. Appropriate test is not ordered.
3. Appropriate test result is not used properly.
   - Knowledge deficit – Clinician doesn’t know the meaning of the result.
   - Failure of synthesis – Clinician inappropriately integrates the result with other findings.
   - Misleading result – Clinician is misled by normal test limitations.
4. Appropriate test result is delayed.
5. Appropriate test result is wrong.

---

14“Adverse events” can be defined as “unintended patient harm caused by medical management rather than by a disease process, which results in a prolonged hospital stay, morbidity, or mortality.” Annu. Rev. Med. 2012. 63:447-63
17Paul Epner, MBA, MEd, and Michael Astion, MD, PhD, “Focusing on Test Ordering Practices to Cut Diagnostic Errors.” Clinical Laboratory News: Reducing Diagnostic Errors, July 2012
Category 5, “Appropriate test result is wrong,” relates to laboratory errors, which while certainly contributory to clinical diagnostic errors and addressable by pathologists, is not the subject of this pathway, so will not be included in our subsequent analyses.

For the purposes of our pathway guide, we have translated Epner and Astion’s framework into a testing chain of “Pre- and Post-Laboratory Diagnostic Errors,” shown in Figure 1, as follows:

- **Step 1: Ordered wrong tests** – corresponds to “Inappropriate test is ordered” and “Appropriate test is not ordered” in Epner and Astion;
- **Step 2: Test results not interpreted correctly** – corresponds to “Appropriate test result is not used properly” – Knowledge deficit, Failure of synthesis and Misleading result;
- **Step 3: Test results delayed/“handoffs” problems** – corresponds to “Appropriate test result is delayed;”
- **Step 4: Next steps in diagnostic work-up incorrect** – corresponds to combinations of the above.

Again, these pre- and post-laboratory testing errors are clinically significant. Michael Laposata, Pathologist-in-Chief, Vanderbilt University Hospital, entitled a presentation last year, “Errors in Test Selection and Result Interpretation: A Major Source of Poor Patient Outcome.” His abstract states “It has long been thought that errors in laboratory test selection largely result in the performance of additional, inexpensive, and automated laboratory tests. Similarly, errors in test result interpretation have been widely regarded as relatively harmless, and primarily related to a delay in achieving the correct diagnosis. However, recent information has demonstrated that the consequences of errors in test selection and results interpretation can produce outcomes with significant morbidity and mortality.”

A review of results from the College of American Pathologists’ (CAP) Q-PROBES studies shows that inaccuracies in test ordering are another common source of errors. One large study in 660 institutions looked at errors in computer entry of outpatient test orders. Novis reports that “Half the participants reported the occurrence of one or more test-ordering errors on 6 percent of requisitions, and 10 percent of participants reported the occurrence of errors on at least 18 percent of requisitions.”

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18Michael Laposata, MD, PhD, Edward and Nancy Fody Professor. Executive Vice Chair of Pathology, Dept of Pathology. Pathologist-in-Chief, Vanderbilt University Hospital, Nashville, TN, “Errors in Test Selection and Result Interpretation: A Major Source of Poor Patient Outcome.” Diagnostic Error in Medicine, 4th International Conference, October 23, 2011, Chicago, IL
The other major contributor to diagnostic errors pertains to missed test results, potentially resulting in delays in diagnosis, treatment or complete failure to diagnose the condition. These missed cases can result from failures in communicating, transmitting or attending to the results.

The frequency and magnitude of the problem are surprising. One review of the frequency of missed testing found:

- 6.8 percent (79/1163) of missed abnormal laboratory results displayed as alerts through a computerized provider order entry system were not followed-up within 30 days;
- 62 percent (125/202) of abnormal glucose tests not followed-up;
- 11 percent (131/1196) of critical radiology imaging alerts were not followed up;
- Inpatient abnormal test follow-up failures ranged from 20 percent to 62 percent.

A CAP Q-PROBES’ study supports the missed test results problem from a different standpoint – that of laboratories trying to convey critical lab values.21

The study of 623 institutions found that 5.4 percent of approximately 13,000 critical calls had to be abandoned due to failure to reach a responsible provider to receive the results. This was despite the fact that laboratorians spent, on average 46 minutes trying to reach outpatient providers, and from 9 to 25 minute averages (depending on the shift) trying to reach inpatient providers. The critical value calls in this study were also found to be clinically important, with more than 45 percent reportedly unexpected by the clinicians, and 65 percent resulting in a change in therapy. This suggests that the cases in which the critical value results were not communicated might have resulted in errors.

Wahls et al. reviewed the clinical burden from missed test results, writing, “The investigators found that clinically important missed results occurred in 0.9 percent of patient discharges [14]. In another study, this one of primary care ambulatory practices, clinicians’ documented test results were missing, often causing clinical delay, for one out of ten patients in clinic [15]. Also serial surveys of primary care providers, documented nearly [half] of the clinicians had encountered patients having clinically significant missed results in

prior two weeks of clinic [16].”

Also, a study at Duke University Medical Center found: “Data from this study show a substantial proportion of patients in whom the diagnosis of diabetes is suggested by laboratory data, but for whom there is no evidence, either from billing data or medical records, that the condition was recognized. These patients may represent at least 9 percent and as many as 18 percent of all patients with diabetes, and nearly 1 percent of adults covered by the MCO.” The problem was identified as unrecognized or “missed” abnormal laboratory results, perhaps, the investigators suggest, because the ordering clinician focused on other tests in a standard panel or the ordering physician was a specialist that does not manage diabetes.

Also significant are studies showing that EMRs and other computerized alert systems are not necessarily an answer. Singh et al. found that even using a sophisticated EMR in the integrated Michael E. DeBakey Veterans Affairs Medical Center, missed test results were a significant problem, and that alerting two providers actually increased the delays in follow-up.

Experts nonetheless advocate for a computerized system on needed intervention, but the system must be designed with diagnostic error prevention functionality. For example, considerations for signal-to-noise issues, follow-up tracking, and audit and feedback need to be made.

Figure 1: Source of Pre- and Post-Laboratory Diagnostic Errors

<table>
<thead>
<tr>
<th>Sources of error</th>
<th>Ordered wrong tests</th>
<th>Test results not interpreted correctly</th>
<th>Test results delayed/“handoffs” problems</th>
<th>Next steps in diagnostic work-up incorrect</th>
</tr>
</thead>
</table>

Source: Eleanor Herriman, MD, MBA, G2 Intelligence

22TL Wahls et al. “The frequency of missed test results and associated treatment delays in a highly computerized health system.” BMC Family Practice 2007, 8:32


24H Singh et al. “Timely Follow-up of Abnormal Diagnostic Imaging Test Results in an Outpatient Setting.” Arch Intern Med. 2009;169(17):1578-1586
The Market Need Grows Stronger
There is an additional, compounding set of factors impacting health care that both increase the need for a diagnostic error solution and strengthen the case for pathologists as the answer. These dynamics include a wave of aging Baby Boomers with multiple chronic conditions, a significant shortage of primary care physicians, and an exponentially rising number of diagnostic tests. Paul Epner has discussed the impact of these factors on diagnostic errors and the opportunities for pathologists and laboratorians to offer solutions.25

Figure 2 shows how these aggravating factors apply to the chain of diagnostic errors. This combination is a recipe for complexity, clinician pressure and, therefore, likely also for increased diagnostic errors.

Above age 65, almost two-thirds of Americans have multiple chronic conditions.26 Patients with multiple chronic conditions can be more challenging to diagnose and present more opportunities for errors in a number of ways. Illnesses interact with one another in complex ways, and the process of aging adds a further dimension that can distort the typical clinical presentation with which a physician is familiar.

Furthermore, although health care delivery reform is moving toward coordinated care and medical homes, hospitals and other provider organizations are often organized around therapeutic or condition area service lines, such as cardiac and cancer. This inevitably leads to specialists focusing on one of the patient’s conditions or cluster of conditions, and “locking in” on these areas, which can lead to errors.

Figure 2: Health Care Trends Potentially Driving Increases in Diagnostic Errors

Source: Eleanor Herriman, MD, MBA, G2 Intelligence

25Paul Epner, “Impact of Laboratory Services on Diagnostic Errors.” Clinical Laboratory Management Association, ThinkLab, May 24, 2011

26CA DuBard, “Moving Forward with the Medical Home: Evidence, Expectations, and Insights from CCNC.” NC Med J May/June 2009, Volume 70, Number 3
Rouse has aptly described health care as a "complex adaptive system' that includes many different players and forces, and therefore cannot be thought of as a hierarchical function. This observation is vividly true in the arena of geriatric care and chronic illness, where focusing on single conditions can neglect others, where focusing only on known conditions can lead to missed diagnoses...."27

The other risk that accompanies an aging population with multiple chronic conditions is the increase in clinical “handoffs” between providers. Given that these patients will need to see a number of different specialists, and may experience periodic hospital admissions, these handoffs, also known as “care transitions,” are inevitable and known to be a major source of medical and diagnostic errors. This factor is particularly likely to exacerbate the problem of missed test results.

Aggravating the diagnostic challenges associated with an aging, chronically ill population is the primary care physician shortage crisis. The Association of American Medical Colleges estimates that the country will be short 29,800 primary care physicians in 2015, growing to 65,800 by 2025.28 If a wave of tens of millions of formerly uninsured Americans also enters the system as a result of the Affordable Care Act, primary care will be stretched beyond the break point.

Finally, as we know, genomics and molecular medicine are producing a variety of new laboratory tests at an unprecedented rate. Clinicians, especially primary care physicians, cannot be expected to keep current with these ever-growing test menus, to know what tests might be optimal in a given situation, and to understand how to interpret results from these new tests. Without addressing this knowledge gap, diagnostic accuracy will likely decline further.

Taken together, these trends suggest an increase in clinical diagnostic error rates. When considered in the context of providers being increasingly compensated based on clinical outcomes and costs, the market demand for solutions to diagnostic inaccuracies is bound to rise.

THE MARKET OPPORTUNITY — IMPROVED DIAGNOSTIC ACCURACY GENERATES VALUE

In a value-driven marketplace, services that can improve quality, e.g., by raising clinical diagnostic accuracy, and lower health care costs, e.g., by avoiding the spending associated with diagnostic errors and adverse events, can translate directly into financial compensation. As payers advance toward “alternative payment models,” i.e., value-based or non-Fee For Service (FFS) — providers are becoming increasingly focused on quality measures, avoidable complications and meeting spending benchmarks.

Our opportunity, then, is to generate value by elevating clinical diagnostic accuracy through “high performance” pre- and post-laboratory testing services.

The “High-Performance Diagnostic Services Pathway” that embodies this opportunity entails pathology lab services and tools that improve test selection, result communications, result interpretations and result follow-up/management. Many of the interventions have reported evidence of effectiveness.

Pathway Overview and Value Proposition

The overarching principle upon which the High-Performance Diagnostic Services Pathway operates is pathologist involvement in the pre- and post-laboratory clinical testing processes to decrease errors and introduce advancements that improve diagnostic accuracy.

Example services that we might provide as part of this pathway, as shown in Figure 3, include:

- Service line/condition targeted test ordering guidance — guidelines/clinical pathways, algorithms, computer decision support, collaborative services.
- Pathologist as diagnostic specialist — integrates diagnostic testing (radiology, pathology and laboratory) with clinical data and creates narrative report with recommendations; can include collaborative teams with specialty physicians and regular meetings.
- Specially designed abnormal test result communication systems to mitigate handoff and missed result problems — computerized, or multimedia, also can include engaging patient given new ruling...

29Paul Epner, “Impact of Laboratory Services on Diagnostic Errors.” Clinical Laboratory Management Association, ThinkLab, May 24, 2011
regarding patient access to test results.

- Pathologist monitoring for missed or erroneous cases - lab test tracking by the pathologist using informatics.

- Collaboration, measurement, feedback, iteration - pathology, radiology and clinical specialists meet regularly to review reports, results and outcomes; outcomes and costs are measured and evidence collected; continuous process improvement is employed.

Because pathologists have the diagnostic testing expertise that can inform many diagnostic missteps, as well as ownership of the pathology and laboratory data that are critical to clinical decisions, as evidenced by estimates that these data comprise 70 percent of EMR content, developing such a program is not as challenging as it may seem. In fact, because it can be implemented in a targeted, modular way, the pathway should be accessible to most pathology groups with access to basic informatics capabilities, as well as clinical pathology expertise.

Figure 3: High-Performance Diagnostic Services Pathway - Example Interventions

Sources of Dx error

- Ordered wrong tests
- Test results not interpreted correctly
- Test results delayed/ “handoff” problems
- Next steps in diagnostic work-up incorrect

Pathway interventions

- Test ordering guidance - tool or service
- Comprehensive, interpretive reports, services
- Abnormal test results communication system + leverage patient
- Targeted follow-up monitoring

Source: Eleanor Herriman, MD, MBA, G2 Intelligence

Providers, ACOs and payers would derive value from this practice pathway in direct and indirect ways, to wit:

- Lowering diagnostic errors could help improve a wide variety of quality performance measures such as readmission, complications and mortality rates. Scoring high on quality measures is important to variable compensation payment programs being rolled out by Medicare and others.

- Higher clinical diagnostic accuracy translates into cost savings from, for example, shorter length of stay, avoidance of unnecessary treatments and services, and averted malpractice expenses. Diagnostic errors are, indeed, costly – one study found them to be in the top three most expensive of all medical adverse events.31

- Improving patient confidence and satisfaction: Patient experience measures are a key component of many value-based payment programs, and surveys show patients believe diagnostic errors are common and concerning.32 Furthermore, health care is now a consumer market, and “hospital leaders have overwhelmingly agreed that patient experience will drive referrals and volume as much as clinical quality.”33

**Pathologists Are an Excellent Fit**

Why are we ideally suited to address this issue?

- Diagnostic specialist – First and foremost, a major cause of the diagnostic errors made by clinicians has to do with ordering, identifying and interpreting tests. Although some of these tests are radiology tests, pathologists may be in a better position to coordinate the integration of testing across modalities given our knowledge of the disease processes. Furthermore, digitization is driving a convergence between radiology and pathology, and as clinical laboratory informatics and molecular informatics become increasingly important the pathologist seems the natural integrator and interpreter of information, in collaboration with radiologists.

- Information nexus point – More than any other service, we can serve as a clinical information nexus point within a provider network, hospital system, medical home, ACO or similar setting. This value has not yet been tapped at all. Leveraging our lab data in conjunction with clinical data, we can connect, track and monitor patient health status throughout provider and facility settings, and

in a time frame that enables clinical action. Services based on this knowledge could improve the diagnostic accuracy of care transitions and help ensure providers in acute care settings like the emergency room do not miss a potentially critical diagnosis.

Pathologists Louis et al. recently advocated for a new vision for “next generation pathology and laboratory medicine” that encompasses many of the above points regarding our role in improving diagnostic accuracy through comprehensive test integration, supporting test ordering and analysis, and clinician collaboration. They write:

“In a value-oriented health care system, the pathologist will then become the integrator of large, complex data sets to continue to fulfill the classic central role of determining diagnosis, prognosis, and appropriate therapy. Furthermore, with this increase in clinical data, pathologists can extend their traditional roles in the appropriate use and integration of laboratory information. ... A greater need for pathologist involvement has thus arisen at the interface of the laboratory with the clinic. The pathologist can no longer be solely within the laboratory, but must be positioned at the door, able to look both into and out of the laboratory.

For instance, the growing number of different laboratory tests creates a challenge for the typical physician to remain appropriately informed. ... Given that "shotgun" approaches to laboratory test ordering lead to wasteful over-ordering and affect quality outcomes adversely through delays in diagnosis and pursuit of false-positives, the laboratory diagnostician will need to define ordering practices... and integrate information from different platforms.

In such a model, pathology reports would become comprehensive, integrating the results of imaging, biochemical, histologic, molecular genetics, cytogenetic, genomic and epigenetic analyses into a cohesive, clinically relevant and valuable diagnostic, predictive and prognostic document.”

To sum up, pathology groups have the ingredients for an attractive business venture, as illustrated in Figure 4:

- A substantial, unmet market need with few competitive solutions being proposed.
- A client base that needs and would pay for a solution to this problem.
- A practice pathway model that holds great promise as a value-generating answer.

Market Demand and Size Estimates
Although diagnostic errors have been “under-appreciated” relative to other patient safety issues, in the past few years they have been receiving increasing national attention. First, there have been a number of papers in prominent medical journals such as JAMA, for example, “Diagnostic Errors – The Next Frontier for Patient Safety,”\textsuperscript{35} drawing attention to the problem.

Secondly, in 2007 the Agency for Healthcare Research and Quality (AHRQ) focused on diagnostic errors as an issue for special emphasis, based on its conclusion that these errors constituted a substantial and expensive share of all medical errors. They have also sponsored research through the Diagnostic Error Evaluation and Research (DEER) project. Furthermore, the “Diagnostic Error in Medicine” conference series is now in its fifth year, supported in part by a grant from AHRQ. Other organizations endorsing this conference include the Institute for Healthcare Improvement, National Patient Safety Foundation, National Center for Patient Safety, Veterans Affairs Administration and the Society of Medical Decision Making.

The diagnostic errors agenda is also being driven at the national level through a number of initiatives, namely:\(^{36}\):

- **Clinical Laboratory Integration Into Healthcare Collaborative – CLIHC\(^{TM}\);** “Seeking to break down the barriers between care providers and laboratory professionals.” Sponsored by the CDC.

- **Improvements In Test Selection And Results Interpretation (ITSRI)** – seeks to experimentally determine the effectiveness of laboratory interventions on diagnostic error reduction.

- **National conferences** –
  - **Society to Improve Diagnosis in Medicine (SIDM)** – launched 2011.
  - **Diagnostic Error in Medicine** – 5th year.

Also, there was attention drawn to diagnostic errors due to an issue with a Centers for Medicare and Medicaid Services (CMS) and Joint Commission quality measure regarding community acquired pneumonia (CAP) and time to first antibiotic dose (TMAD). Initially, the quality measure was an eight-hour target, but based on retrospective studies CMS made the measure a four-hour TFAD in 2002 for public reporting purposes, and in 2006 CMS pay for performance programs included this measure in their calculations.\(^{37}\) After implementation, the emergency medicine community began issuing complaints and publishing studies indicating that the measure was having perverse consequences, including increasing the rate of misdiagnoses of pneumonia, without producing offsetting outcome improvements.

For example, a prospective study by Welker et al. in Arch Intern Med found a significantly high diagnostic error rate: “... [D]epending on the rigor with which one assigns the diagnosis of CAP, nearly one-third to two-thirds of patients who were admitted and empirically treated for CAP seem not to have had that diagnosis at discharge.”\(^{38}\)

Not only did this episode spotlight clinical diagnostic difficulties, but also their clinical and cost outcomes. Welker et al. wrote, “The potential morbidity and mortality resulting from an increased number of incorrect diagnoses, inappropriate antibiotic therapy, and delays in establishing the correct diagnosis in patients who do not have CAP.

\(^{36}\)Paul Epner, “Impact of Laboratory Services on Diagnostic Errors.” Clinical Laboratory Management Association, ThinkLab, May 24, 2011


must be considered if a TFAD of less than four hours is considered to be a core quality measure.\textsuperscript{39}

Within months of these critical publications, in 2006, CMS revised the measure.

Employers are showing interest in companies that offer second opinions or other diagnostic accuracy services. “More employers and health plans are offering second opinions as a benefit to workers or their member companies for review of diagnoses and treatment plans. The idea is to reduce diagnostic error rates, and to save money,” reports a journalist in The Tennessean.\textsuperscript{40} One example company is Best Doctors, Inc., which provides its client corporations’ employees expert second opinions through in-depth reviews of diagnoses and treatment plans by opinion-leading medical physicians.\textsuperscript{41}

Another is called Premerus,\textsuperscript{42} a unit within radiology benefits manager MedSolutions. Premerus claims improved outcomes and decreased costs through subspecialist radiologist digital reviews of CT and MRI scans.

Regardless of the market’s awareness of the problem of diagnostic errors, the size of the opportunity and financial actualization of that business depends on the business case we can bring to the table and the results we can deliver.

Laposata’s team at Vanderbilt University has begun to build such a business case, in quantifying the impact of their coagulation diagnostic management team (DMT).\textsuperscript{43} RL Van Horn, PhD, MPH, MBA, Assoc. Prof. of Economics and Management at Vanderbilt, conducted an analysis in which “differences in total charges and Length of Stay, pre/post implementation of DMT pilot” were calculated. He concluded that “There is evidence that in coagulation sensitive DRGs an initiative is related to an observed change in LOS [length of stay]." For example, for pulmonary embolism cases, the LOS dropped from three to two days, on average.

\textbf{Getting Paid Based on Value}

In the context of our Pathway opportunity, we are defining market size as (1) the value, in dollars, of the improvement in diagnostic accuracy that our pathway might deliver, and (2) the proportion of that amount that we might retain.

\textsuperscript{39} A Welker et al. “Antibiotic Timing and Errors in Diagnosing Pneumonia.” Arch Intern Med Vol 168 (No. 4), Feb 25, 2008

\textsuperscript{40} Getahn Ward “TennCare to initiate financial sanctions.” The Tennessean, Oct 31, 2011

\textsuperscript{41} Getahn Ward “TennCare to initiate financial sanctions.” The Tennessean, Oct 31, 2011

\textsuperscript{42} http://www.medsolutions.com/services/expert_interp/premerus_radiology/index.html

\textsuperscript{43} Michael Laposata, MD, PhD, “Advising Treating Physicians on Laboratory Test Selection and Interpretation.” Presentation at Massachusetts Society of Pathologists Annual Dinner Meeting and CME Seminar, May 10, 2012
Before we proceed with the macro market estimates, we need to briefly review the value-based purchasing market in terms of provider payments. This is far too dynamic and varied a topic to adequately cover here, so we aim to just provide sufficient fundamentals to enable an understanding of this pathway opportunity. The College has a series of resources and tools planned to support members in navigating the business aspects of these new payment schemes.

At a basic/simplistic level, most value payment models assign providers a risk-adjusted (for their patient population) “benchmark” payment of some sort - it could be for a population, per patient (as for an ACO), or for an episode of care, such as for a prostate surgery, in which case it would include all physician, hospital, inpatient and outpatient, and ancillary services before and after the surgery (called a “bundled payment”). In addition, providers will be assessed based on some group of quality metrics for that period of care.

There are a number of ways that payers calculate how much money gets retained by which party, but in simple terms the result is a “gain share.” If the providers are able to deliver care for less money than the benchmarked fee, while still hitting the quality metric targets, then the providers “gain,” i.e. retain some share of the cost savings achieved (the savings being the difference between the benchmark fee and the actual spending). On the other hand, with many of these models, if their spending exceeds the benchmark fee, and the contract has them at financial risk, then they can lose income.

Currently, in most parts of the country, most providers are still being paid on a fee-for-service basis, with an increasingly large proportion of their income being transferred over to these types of “alternative payment models” – either bundling or some type of gain sharing arrangements.

How would our pathway model fit into these value payment models? First, we will need to demonstrate through an evidence-based business case, that we have a program or set of services that can impact quality outcomes and/or costs. The most commonly used study to generate this type of evidence is a pre- and post-observational model. We can take a targeted service line, such as diabetes, collect data regarding costs and quality metrics for a six-month period, for example, then compare these data to a similar six months during which we implement our high-performance diagnostic services pathway. With evidence such as this as a starting point, we are ready to negotiate with a provider organization such as an ACO or Medical Home network.

**Our revenues will be directly tied to the quantification of the clinical value we generate.** The improvement in clinical quality outcomes is clearly more challenging to translate into dollars, unless those outcomes are aligned with...
measures on a payment scorecard, in which case they will be quantifiable to provider executives.

In most cases, we will want to assess the value and negotiate a contract separately for each “program” in our pathway. A program would likely, then, roughly correspond to either a clinical service line or some other business delineation, such as the emergency room.

Fundamentally, then, if our pathway delivers services that decrease downstream clinical costs, and increase quality measures, then we will be able to negotiate with providers or payers involved in gain sharing payment contracts. We can be paid based on the value, in terms of savings and quality improvement, we generate. For example, we might have a contract with an ACO that states that we receive 10 percent of the gain share savings from a program we lead to reduce ER avoidable admissions for viral meningitis. At the end of the year, if the number of viral meningitis ER admissions has been reduced, and the target savings achieved, than our program was successful, and we would receive 10 percent of those savings, in addition to our regular laboratory testing fees.

We now turn to estimating the overall, macro opportunity.

Estimating the Market Size
Given the relative immaturity of the field of diagnostic errors, there are few economic studies that directly quantify the downstream costs related to diagnostic inaccuracies. It is a complex value proposition to quantify, given the multiple aspects of inpatient and outpatient cost savings opportunities, as well as the variety of quality outcomes improvements.

We can, however, make estimates by applying findings from diagnostic error research with other studies in the field of adverse events and patient safety to create simple economic impact models. These estimates provide a picture of the high level, or “macro,” market opportunity.
Figure 5: Market Estimates - Potential Value for High-Performance Diagnostic Services Pathway

## Market Estimate 1: Prometheus Program - Patient Safety Failures and ER Diagnostic Errors

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total costs for ‘Potentially Avoidable Patient Safety Failures’ for 21 conditions and procedures in Prometheus database of pop of 4M (over 18 yrs old)</strong></td>
<td>$235</td>
<td>Prometheus is a bundled fee payment system centered on comprehensive episode of medical care that covers all patient services related to an illness, condition, or procedures that has been adopted by Medicare for implementing bundling programs. These costs are for a one-year period. <a href="http://www.hc3.org/what_is_prometheus/framework/evidence_informed_case_rates">http://www.hc3.org/what_is_prometheus/framework/evidence_informed_case_rates</a></td>
</tr>
<tr>
<td>Scale up for U.S. population - over 18 yrs old</td>
<td>$11,750</td>
<td></td>
</tr>
<tr>
<td>Account for other conditions and procedures - assume double (costs with 21 estimated as 20-30 percent of total)</td>
<td>$23,500</td>
<td></td>
</tr>
<tr>
<td>Assume pathway interventions can mitigate 75 percent</td>
<td>$3,000</td>
<td>Projected estimate from research - personal communication</td>
</tr>
<tr>
<td><strong>POTENTIAL COST SAVINGS for Patient Safety Failures</strong></td>
<td><strong>$3B</strong></td>
<td></td>
</tr>
<tr>
<td>Emergency room visits, 2009, CDC</td>
<td>136,000,000</td>
<td></td>
</tr>
<tr>
<td>Assume pathway interventions can mitigate 75 percent</td>
<td>816,000</td>
<td>Projected estimate from research - personal communication</td>
</tr>
<tr>
<td>Avg cost per ER visit - Prometheus – $1,450</td>
<td>$1,183</td>
<td></td>
</tr>
<tr>
<td><strong>POTENTIAL COST SAVINGS for ER visits</strong></td>
<td><strong>$1.2B</strong></td>
<td></td>
</tr>
<tr>
<td><strong>POTENTIAL PATHWAY COST SAVINGS – Patient Safety - ER</strong></td>
<td><strong>$4.2B</strong></td>
<td></td>
</tr>
</tbody>
</table>

## Market Estimate 2: Investigation of Adverse Event Costs from Utah and Colorado


Reviewed 14,732 discharge records from hospitals across Utah and Colorado to estimate inpatient and outpatient medical costs of adverse events.

Estimated as percent of state’s health care expenditures for preventable adverse events.

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Projected to 2012 – assume 5 percent annual growth</td>
<td>$1,576,575</td>
<td></td>
</tr>
<tr>
<td>Diagnostic errors as percent of adverse events – 15-20 percent</td>
<td>$12,865</td>
<td></td>
</tr>
<tr>
<td>Assume pathway interventions can mitigate 75 percent</td>
<td>$9,649</td>
<td>Projected estimate from research - personal communication</td>
</tr>
<tr>
<td><strong>POTENTIAL PATHWAY COST SAVINGS</strong></td>
<td><strong>9.6B</strong></td>
<td></td>
</tr>
</tbody>
</table>

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
### Market Estimate 3: Milliman Economic Assessment of Medical Errors

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Estimate 2008</th>
<th>Estimate 2012</th>
<th>Potential Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cost of medical errors - extrapolated to U.S., for 2008</td>
<td>$19,500</td>
<td>$25,935</td>
<td>$5.8B</td>
</tr>
<tr>
<td>Projected to 2012, using Milliman Medical Index</td>
<td>$25,935</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assume percent that are diagnostic errors is 30 percent</td>
<td>$7,781</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assume pathway interventions can mitigate 75 percent</td>
<td>$5,835</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Potential Pathway Cost Savings</strong></td>
<td><strong>$5.8B</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Final Triangulated Market Estimate - Potential Value for High-Performance Diagnostic Services Pathway**

<table>
<thead>
<tr>
<th>Average of Three Estimates</th>
<th>$6.5B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Share Retained by Pathologists - assume 5-20 percent</td>
<td>$330M - $1.3B</td>
</tr>
</tbody>
</table>

These revenues are supplemental to any payment for diagnostic testing.

Source: Eleanor Herriman, MD, MBA, G2 Intelligence

As displayed in Figure 5, we used three different research methodologies to generate model estimates for the costs associated with diagnostic errors, and thus the potential value that might be generated through interventions designed to improve accuracy.

The resulting, triangulated or averaged estimate of these three estimates was an annual, U.S. market of $6.5 billion in value that might be generated by our diagnostic pathway as it relates to diagnostic errors. This would represent anywhere from ~$330 million to $1.3 billion in revenues for pathologists in value-based payments, depending on the share of savings we received. This compensation would be in addition to any fee-for-service payments for diagnostic testing.

There are a number of caveats regarding this estimate. First, it should be taken as “directional” only, as it rests upon many assumptions and estimates, by necessity. This means it is best used as an indicator of the relative size of the opportunity, rather than for specific business planning purposes.

There are aspects of these market estimates that likely overestimate the market size, but others that exclude opportunities, and numerous variables that impact both, so focusing on the details of the analysis is not likely to be fruitful.

The business opportunity for an individual pathology practice will vary, depending on, for example, the clinical setting, the focus of the services and intervention, and the degree of the provider’s need.

One interesting target market opportunity worth noting is the emergency room (ER). The largest source of ER errors that caused patient harm according to one report was diagnostic errors. Furthermore, multiple studies

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found that 20 percent of return ER visits were caused by diagnostic errors.\textsuperscript{45} Our market estimation of potential value generated by targeting this area was $1.2 billion. Given that return ER visits also drive potentially avoidable admissions, the cost escalation might be significant. Especially for hospital-based pathology practices, designing specific diagnostic accuracy improvement services for the ER could be an attractive starting point.

**Radiology Business “Proof of Concept”?**

As mentioned previously in this chapter, radiology services company MedSolutions, which serves 30 million lives through commercial, Medicare Advantage and Medicaid payers, is successfully operating a diagnostic accuracy unit called “Premerus.” Premerus uses “definitive imaging diagnoses” and focused subspecialty interpretations by subspecialist radiologists, who they describe as local to health plan members, to improve outcomes and reduce costs for payers.\textsuperscript{46}

Support for the Premerus concept emanates from prestigious sources nationwide, including Edward Coleman, MD, professor and vice chairman of the department of radiology, Duke University Medical Center\textsuperscript{47}:

> Premerus is founded upon the fundamental fact that for specific medical problems, experienced specialists provide more accurate diagnoses and better outcomes than do generalists. In the past three decades, there has been a great deal of research demonstrating the relationship between volume and patient outcome for a variety of medical conditions and procedures.”

He concludes that an accurate diagnosis mitigates downstream expenditures and minimizes emotional distress for patients that result from an inaccurate diagnosis, adding, “An early, accurate diagnosis provides the best prognosis for the patient.”

There are two points that are perhaps relevant for our practice pathway business model considerations – first, the way they are positioning their business to payers and other clients, and, secondly, the clinical and value results they are claiming.

First, Premerus is certainly making the case for diagnostic accuracy being the key to value generation. Consider their website content\textsuperscript{48}:


\textsuperscript{46}http://www.scanhealthplan.com/documents/arizona/providers/radiology/Premerus%20SCAN%20AZpdf

\textsuperscript{47}http://www.premerus.com/news/Misdiagnosis_in_America.pdf

\textsuperscript{48}http://www.medsolutions.com/services/expert_interp/premerus_radiology/index.html
“Premerus is founded on the principle that diagnostic accuracy can improve patient outcomes and reduce costs. This is because once the diagnosis is made, a cascade of costly treatments — including high-tech therapies, specialist visits, medications, biopsies and additional testing — are often set into motion. Premerus focuses on the diagnosis because it impacts all subsequent medical decisions, expenditures and outcomes.”

Secondly, the cost savings and value results they are reporting from particular health plans are impressive. "Using MedSolutions' Premerus® Diagnostic Accuracy, a proven solution to the problem of diagnostic error, one major health plan reduced ER use of services by over 50 percent, shortened hospital length of stay by 1.4 days, and decreased unnecessary biopsies and surgeries by 35 percent. ... The health plan using Premerus also reduced total health care claims by 7.6 percent, saving more than $5 per member, per month (PMPM) while improving outcomes.”

There is no way of evaluating the validity of these results, as details have not been published. However, even if the data are only directionally correct, they strongly support interventions that improve diagnostic accuracy as potent drivers of clinical cost savings.

THE HIGH-PERFORMANCE DIAGNOSTIC SERVICES PRACTICE PATHWAY

In this section, we’ll provide an overview of the practice model and interventions. The pathway model description comprises the services and tools that would be used to implement the pathway, with consideration given to key variables such as the target step in the testing chain, target condition and/or target clinical setting.

Overview – High Performance Diagnostic Services Pathway Model

The multifaceted nature of the clinical diagnostic accuracy opportunity means that there is no, one “best practices” model. This makes this pathway very accessible to a wide variety of us, across practice types, settings, resource levels and capability portfolios, because we can each design an intervention program from a matrix of potential target opportunities and services.

The first determination in defining the model concerns what the clinical focus, or target, of the pathway interventions will be. There are two primary dimensions we can use to frame this choice – clinical conditions/clinical area or the chain of diagnostic steps we’ve described earlier (previously denoted as the source of errors), as shown in Figure 6.

Figure 6: Practice Pathway Design – Diagnostic Step Chain and Potential Target Conditions

- Diabetes
- Infectious disease
- Coagulation
- Cancer
- Myocardial infarctions
- Drug reactions
- Pulmonary emboli

Source: Eleanor Heniman, MD, MBA, G2 Intelligence
Thus, our pathology group could choose to initially focus our high-performance diagnostics pathway program on interventions to improve test result communications (i.e., address the “missed test results” and handoffs problem) across multiple conditions (example 1 in Figure 6), or improve diagnostic accuracy across all steps for coagulation conditions (example 2 in Figure 6), as Laposata has done first at Massachusetts General Hospital, and currently at Vanderbilt.50

There are a number of considerations that should inform our choice, including strategic (e.g., the goals for your practice, and other business initiatives you’re pursuing), our practice’s resources and expertise, and your target client’s most critical needs in terms of diagnostic accuracy and value.

If we decide to focus on a target condition rather than a model where we design a solution for a single error step across diseases, then we next consider which disease area to select. Figure 7

Figure 7: Considerations in Selecting Target Conditions

High rate of Dx errors

Optimal area for selecting target condition for pathway is intersection of all three

Accessibility – intervention that fits practice

High avoidable costs

Source: Eleanor Herriman, MD, MBA, G2 Intelligence

50Michael Laposata and Anand Dighe, “Pre-pre” and “post-post” analytical error: high-incidence patient safety hazards involving the clinical laboratory.” Clinical Chemical Laboratory Medicine. Volume 45, Issue 6, Pages 712–719
depicts a Venn diagram of three key factors for choosing a starting condition or disease area – we should look for areas in the intersection of these three circles. The two most important are high diagnostic error rates and high health care spending. This basically equates to a large market opportunity for us and an area of probable pain for our client.

The final factor is whether the condition’s leading sources of diagnostic errors (if they are known) are amenable to an intervention that we feel comfortable developing. In other words, are we a good fit for the opportunity?

The conditions/disease areas listed in Figure 6 have high diagnostic error rates along some or all of the diagnostic steps shown.

About the Interventions
Now we turn to describing the interventions themselves. Here we will provide only a summary overview, as this requires broader scope and depth then appropriate for this report. Upcoming Practice Pathway content from the College will be covering this topic in greater detail.

For purposes of explanation, we will consider a range of intervention types aligned by the diagnostic step chain. Figure 8 illustrates a matrix of the diagnostic steps versus a range of interventions, including information technology, pathologist services, multispecialty teams and multicomponent programs.

The point of the matrix is to emphasize that we can start small with this pathway, e.g., one grid point on the matrix for one condition, and add services

Figure 8: Practice Pathway Intervention Option Matrix

![Figure 8: Practice Pathway Intervention Option Matrix](image-url)
and tools to our interventions vertically, as well as extend horizontally to address other error steps.

An individual pathology group customizes their pathway program by selecting from this type of matrix, based on the needs of their providers and payers, and what they are best equipped to provide.

For example, a pathology group could decide to start pursuing this pathway by implementing a diabetes program that uses IT tools and pathologist follow-up to identify patients with abnormal glucose and HA1c values that may have been missed.

The intervention types range from single component offerings, such as IT applications and pathologist services, to the more advanced multispecialty teams and multicomponent programs which incorporate pathologists, IT systems, and other elements.

**IT tools and applications** span a range from, for example, testing panels with algorithms, order entry with decision support, LIS data mining for disease management, and more complex clinical decision support systems. Many of us already use forms of these tools in our laboratories. By expanding their functionality and considering evidence-based design principles, these types of tools can be effective in improving diagnostic accuracy for particular applications. One review found that “The availability of automated information management systems at the point of care may significantly improve the appropriateness of test requesting. ...”51

There is evidence from various sources that different IT tools can have an impact on improving diagnostic performance. For example, a JAMA 2005 review evaluating the performance of the then very primitive computerized clinical decision support systems (CDSS) found “The CDSS improved practitioner performance in 62 (64 percent) of the 97 studies assessing this outcome, including 4 (40 percent) of 10 diagnostic systems, 16 (76 percent) of 21 reminder systems, 23 (62 percent) of 37 disease management systems, and 19 (66 percent) of 29 drug-dosing or prescribing systems.”52

**Pathologist services** go beyond the phone call for an abnormal result. They might comprise a spectrum from more structured telephone consultations, regular meetings with clinicians, collaborations with clinicians including hospital rounding, generating patient-specific expert narrative interpretive reports and establishing new roles for pathologists as diagnostic specialists at the point of care in high risk settings such as the emergency room.

**Multispecialty teams** are exemplified by the “diagnostic manage-

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51 Mario Plebani, Clinica Chimica Acta 404 (2009) 16-23
ment teams” innovated over the past several years by Michael Laposata, MD, PhD, now at Vanderbilt University Medical Center. These teams are comprised of multiple pathologists, including an attending, and often a specialist clinician, depending on the disease area (e.g., microbiology has an infectious disease specialist on the team). The team meets daily to interpret individual patient cases, considering clinical data as well as all pertinent laboratory, pathology and radiology results, and generates a patient-specific, expert-driven interpretation that “improves both the time to diagnosis and the accuracy of the diagnosis.”

Multicomponent Programs combine one or more of these services and tools into a broader “program” that might be employed by a hospital or ACO to tackle a broad problem area, major condition (e.g., diabetes) or particular care setting (e.g. the ER).

Let’s look at selected examples of these interventions along the diagnostic testing chain.

1) Test Selection - IT Tools Example

Examples include:

- Disease-specific, reflex testing algorithms – e.g., celiac disease at Massachusetts General Hospital (MGH).54

- Clinical guidelines, algorithms – have been found useful for diagnostic errors when well designed.55 These can be incorporated in order entry systems, and can be part of automated order sets. MGH has implemented a “rule-out acute myocardial infarction” as part of an admission order set.56

- Diagnostic checklists oriented around high risk conditions or care settings57 can be implemented through EMRs or hospital IT systems.

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2) Test Handoffs/Communication - Multicomponent Program Example

The test handoffs/communication step addresses a multifactorial and critical source of problems in both ambulatory and acute care settings. An example intervention would be a Multicomponent Program for an ACO to establish a system for ensuring early, more accurate diagnoses.

A recent paper that reviewed U.S. studies of missed test results in ambulatory settings found: “Missed test results in ambulatory settings are attributable to multiple factors including: the paucity of governance principles related to test management; the lack of integrated information systems around test management; the multidisciplinary nature of test management processes, and the need to consider the role of the patient in test result follow-up.”

In this example, our high-performance diagnostic services group could play a leadership role in implementing a testing communications solution program for an ACO. The pathologist group might direct the following, for instance:

- Test management procedures and governance - evidence shows that a key source of errors derives from lack of clarity regarding responsibility for abnormal results and follow-up. Studies have shown that when computer systems sent abnormal results to two providers the delay in abnormal test result follow-up was increased. The pathologist could establish procedures to address this, as well as computerized systems to support the processes. Finally, in some cases the pathologist might be the designated responsible agent.

- IT tools - applications which connect LIS and EMRs for notifications of abnormal results, then track for acknowledgement and follow-up have been shown to be effective if properly designed. Again, the pathologist can take the lead as the high-performance diagnostic expert in designing these tools with evidence from the medical literature, human factors science, as well as other safety industries such as aviation where communications are critical.

- Patient reports - given the new proposed ruling regarding lab results being accessible to patients, as well as recommendations from experts in diagnostic errors that patients can be helpful in improving accuracy, we can also develop specially designed patient reports or communications for abnormal results that include

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patients as a safety net. This intervention is exactly in line with the Institute of Medicine’s call for “patient-centered care.”

3) Test Result Interpretation - Pathologist Services and Multispecialty Teams Example

As described above, a prototypical example of a test result interpretation intervention is Laposata’s “diagnostic management teams (DMTs).” These teams provide diagnostic services for coagulation, hematopathology and microbiology disorders. They have plans in the next couple of years to add teams for endocrinology, toxicology, autoimmunity, anemia, renal and some cancers.

Geisinger has also implemented pathologist interpretative services along the lines of Laposata’s DMTs. They report:

“At Geisinger, the Department of Laboratory Medicine provides a coagulation consultation service, including 24-hour availability by one of four pathologists between two hospitals with reports generated on the same AMEDx system used by Dr. Laposata. The laboratory has supported (as part of its point-of-care testing role) the installation of six thromboelastograph analyzers for the operating rooms and intensive care units in two hospitals. The same pathologists provide consultative interpretation of the thromboelastograph histograms that have been networked and can be seen from remote sites or home. Pathologists have developed a standard interpretive algorithm for evaluation of microvascular bleeding and use it to advise clinicians on the appropriate blood components in complex cases. This approach is a significant step in the rationalization of blood component usage in difficult operative bleeding cases.”

Laposata reported that 72 percent of physicians at MGH indicated that his coagulation services helped them avoid a misdiagnosis – an impressive indicator of effectiveness. Also, 59 percent said that the services shortened the time to diagnosis.

In terms of the accessibility of this intervention to community pathology groups, it is important to note that there is evidence that patient-specific narrative interpretations that incorporate clinical data can be potent accuracy boosters even for less complex conditions than coagulation or hematologic conditions. Laposata has stat-

59Michael Laposata, MD, PhD, Professor of Pathology, Vanderbilt University Medical Center, presentation, “Advising Treating Physicians on Laboratory Test Selection and Interpretation,” 2012


ed that his clinicians have found these types of pathologist interpretive consultations valuable for a broad range of laboratory tests, including basic results like liver function tests.\textsuperscript{62}

Also, Laposata offers his program “in a box” to other institutions on a contractual basis, with revenue sharing arrangements as one possibility. His DMT program includes\textsuperscript{63}:

\begin{itemize}
  \item Test selection algorithms and test panel recommendations.
  \item Enabling software for creation of interpretations.
  \item Reliable and simple connection to Vanderbilt DMTs using Skype if possible.
  \item Billing information to collect revenue for interpretations for as long as it is available.
  \item Templates for local physician surveys of clinical benefits of the DMT service in the receiving institution – and for collection of local data on savings from use of the diagnostic service.
\end{itemize}

4) Follow-up and Tracking – IT Tools

The follow-up and tracking intervention opportunity encompasses the following types of support:

\begin{itemize}
  \item Following up with a patient-centric lens on abnormal results to ensure that appropriate clinical actions have been taken.
  \item Collaborating on care management and treatment recommendations.
  \item Leveraging diagnostic testing results to support “disease management” services.
\end{itemize}

This intervention, like the handoffs step, can have a major impact on ensuring abnormal results are not missed. Moreover, in value-centered settings such as ACOs and Medical Homes, where chronic care management is measured and tied to compensation, our role in tracking patients to facilitate optimal care will be highly valued.

For example, we can design LIS or EMR/EHR applications to provide these capabilities in a hospital, ACO or Medical Home setting. Such a tool might be comprised of alerts and reminders, perhaps also combined with test interpretations, for managing Coumadin dosage or diabetes.

\begin{itemize}
  \item The Coumadin dosing example provided in a chapter on clinical decision analysis tools for laboratory testing by JY Kim and colleagues is compelling because of
\end{itemize}

\textsuperscript{62}Personal communications - Michael Laposata, MD, PhD and G2 Intelligence’s Eleanor Herriman, MD, MBA, July 3, 2012

\textsuperscript{63}Michael Laposata, MD, PhD, Professor of Pathology, Vanderbilt University Medical Center, presentation, “Advising Treating Physicians on Laboratory Test Selection and Interpretation,” 2012
the serious impact of this common problem. They write\cite{64}: “[P]atients receiving long-term anticoagulation therapy with Coumadin must be monitored at regular intervals using a PT-INR test to ensure adequate anticoagulation therapy. If the patient’s PT-INR becomes subtherapeutic, the patient may develop a fatal clot or embolism. Excessive anticoagulation may result in bleeding or hemorrhage. Usually the physician schedules office visits for these patients at various intervals and provides a prescription for outpatient PT-INR testing at more frequent intervals. Once the patient has left the office, the physician has no way to be certain that the patient actually went to the laboratory for the regular PT-INR testing, unless the office staff periodically reviews the patient’s records to check for the results of recent testing. Noncompliance on the part of the patient can have potentially catastrophic consequences. On the other hand, if the test orders for PT-INR have been recorded in an order entry system, it is possible to implement an alert system such that the physician is made aware if the patient did not show up for testing within an appropriate time interval. Furthermore, the system could alert the physician of nontherapeutic PT-INR values, thus permitting more timely adjustments to therapy.”

A final example is a diabetes management system that monitors hemoglobin A1c, urinary microalbumin, lipids and other parameters. The system could issue reminders to clinicians when patients have not received recommended testing or abnormal results have not been followed up.\cite{65}

\begin{flushleft}

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CONCLUSIONS

Clinical diagnostic errors are not only significant, causing unnecessary harms for patients and value destruction for the health care system, but they are also increasingly being recognized as such. Many clinical diagnostic errors relate directly to clinicians’ knowledge and management of diagnostic testing, putting pathologists in a central, ideal position to provide a range of interventions that can help decrease errors and add value to providers and payers.

“In general, focusing on decreasing diagnostic errors is a good strategy for clinical laboratorians, because it de-emphasizes lab tests as a commodity and focuses on the value we add. In other words, it changes our mission from providing accurate, timely, low-cost test results to rapidly and efficiently enabling accurate diagnosis, selection of appropriate treatments and effective monitoring of health status. In addition, because many diagnostic errors related to laboratory services involve physician behavior, it motivates us to collaborate beyond our walls and show our value to our colleagues who provide direct patient care,” wrote Paul Epner, MBA, MEd, and Michael Astion, MD, PhD.

Because there are multiple sources of errors, there are many opportunities for different types of interventions, making this a pathway that is accessible to a wide variety of pathology practices, regardless of practice type, setting, resource levels, and capability portfolios. Potential interventions range widely in scope, making it possible for any group to start small and expand over time.

The pathway is also likely to be attractive to any client compensated based on value/clinical costs. Examples of market applications include:

- High-performance diagnostic services in an academic medical center may help improve outcomes in a cancer center and/or may lower costs, thus improving the AMC’s margins when under cancer bundling contracts.

- For a reference lab, the value proposition may lie in the design, development and offering of computer tools for diagnostic decision support for specific conditions.

- A pathology group with a hospital contract or within a provider institution might begin by offering

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66Paul Epner, MBA, MEd, and Michael Astion, MD, PhD, “Focusing on Test Ordering Practices to Cut Diagnostic Errors.” Clinical Laboratory News: Reducing Diagnostic Errors, July 2012
diagnostic testing interpretive services that target a particular “out of control,” high-cost DRG area.

• In an ACO setting, the high-performing diagnostic specialty team might be the “command center” in charge of ensuring delivery and follow-up of abnormal test results, perhaps initially targeting only high-risk areas, such as the emergency room, critical care units, and discharge hand-offs. With such a high profile, high responsibility program, the pathway business plan would include requirements for additional resources, IT systems and authority from the ACO.

• For a payer, a high-performance diagnostic service can implement a diagnostic accuracy improvement program for a population or a service line and contract for revenue based on performance targets or shared savings.

The possibilities are many and, overall, this pathway represents an excellent opportunity for pathologists to expand the reach of their diagnostic expertise outside of the laboratory. We can participate in a visible way, clinically with our physician colleagues, and add clinical value in this new market, enabling us to participate financially, as well.
PROMISING PRACTICE PATHWAYS™: COORDINATED POPULATION CARE SERVICES

COLLEGE OF AMERICAN PATHOLOGISTS
The new performance-based demands of healthcare delivery reform will ultimately shift compensation to “alternative,” value-based purchasing arrangements such as shared savings, bundled or global payment. These changes are driving healthcare systems and physician groups, such as Accountable Care Organizations (ACOs), toward a new paradigm called population health management, a model that holds the ACO accountable for both the health and costs of an assigned patient population.

This new care delivery model demands that ACOs perform comprehensive performance measurements, including process of care, outcomes, and patient experience metrics. To improve quality and reduce costs, ACOs need to both systematize care with pathways and embed “individualized medicine” into routine care. They also need to segment their populations and predict risks to direct interventions, improve health and avoid preventable illnesses and complications.

Population health management (PHM) is challenging because it spans three dimensions of care. As shown in Figure 1, PHM requires 1) managing populations that range from the community down to a physician’s practice, 2) managing care along the time continuum from prevention through end of life, and 3) managing across all conditions and procedures.

Pathology and laboratory medicine are competitively advantaged in having expertise and services that add value across all three of these dimensions, arguably uniquely so in medicine.

Furthermore, information technology systems and robust, thorough clinical data are critical components in this new model. But beyond IT solutions, ACOs are looking for guidelines, order sets, and other electronic medical record (EMR) applications for which pathology knowledge is a necessity. These ACO PHM needs provide an opportunity for pathology and laboratory medicine to develop services and EMR/EHR applications that go beyond supplying laboratory results.

The key to meeting these needs intelligently involves a dual approach that is unique to pathology. Pathologists can marry “top down” population lab informatics applications that support systematizing care with “bottom up,” patient-specific, molecular testing tools that can individualize those guidelines in a way that accounts for the art and variability of medicine. This is our second, critical competitive advantage in delivering PHM value to ACOs. See Figure 2.
ACOs and other providers engaged in PHM need not only our data, but our expertise and services to generate the value they need to be successful under these new payment models. But the move to ACOs has significant momentum and the models and roles supporting their needs are becoming established rapidly. Without taking action to develop these services and applications that extend beyond test results, ACOs will sideline us as providers of data.

ACOs are now estimated to number 300¹ and are projected by some analysts to double to 600 in 2013.² That implies that we will all be exposed in some manner to ACOs of some type in the near term. “You’re either at the table or on the table” is a favorite phrase among the healthcare market stakeholders immersed in reform these days.

We have tremendous value to bring to the ACO table in terms of PHM services, but we need to take action to do so. We do not need to have informatics capabilities to start this journey, for we will have resources and guides along the way to build them, and there are many services we can offer that do not require informatics.

The “Coordinated Population Care Services Practice Pathway” we introduce includes “entry options” for pathology practices without informatics expertise, which can begin by adding value in their hospitals, for example, through population health applications and services we’ll describe. Many of these are collaborative programs in which the pathologist’s expertise adds a vital component that can greatly improve the initiative’s impact.

For example, one of the leading opportunities for cost avoidance for ACOs is infectious diseases, particularly given the ubiquity of resistant pathogens, both inpatient and in community settings. Pathologists can play a significant population health, value generating role in teaming with infectious and pharmacy colleagues to develop high powered surveillance and stewardship programs, including the targeted use of molecular testing to guide antibiotic use.

There are a number of other opportunities for pathology groups who have not yet acquired informatics capabilities that rely solely on our expertise. For example, controlling glycemia in inpatients is very challenging, and suboptimal management drives high rates of avoidable costs and adverse events. One problem that contributes to this situation is that some of the hand-held glucometers widely used in hospitals have clinically significant accuracy.

¹Susan Dentzer, Editor of Health Affairs, remarks at the Third National Accountable Care Organization Summit in June 2012
problems. Pathologists could play a role in ensuring the quality and accuracy of these and other point of care testing devices throughout an ACO.

This glucometer example may seem like just a routine service, but we need to understand and quantify the tremendous clinical quality and economic value this generates and develop this one example into a population-wide program that we lead. This point of care testing program might involve strategic recommendations regarding when and where to introduce such testing (including home care), selection of instruments and certification as well as data collection of some sort. In this way, we have evolved a simple quality responsibility into a valuable population health management program that can be measured for results and compensated based on the value it generates.

This chapter is designed as an introductory guide to this population health management opportunity, offering context on population health management, explaining the population care needs of ACOs, exploring the business dynamics and opportunity size, and describing the pathway at a high level.

The guide is structured as follows:

- Market Need: ACOs Need Pathologists to Manage Population Health
- About the Coordinated Population Care Services Practice Pathway
- Planning for the Pathway
Figure 1: Population Health Management Spans Three Dimensions of Care

- **Populations:** Community to Practice
- **Conditions and Procedures:** Diabetes to CABG
- **Time:** Prevention to End of Life
MARKET NEEDS - ACOs NEED PATHOLOGISTS TO MANAGE POPULATION HEALTH

Population Health Management: A Paradigm Shift in Care Delivery
A major component of the current U.S. healthcare market reinvention is care delivery reform, and one of the primary new paradigms in care delivery is population health management (PHM). Providers being compensated under “alternative payment” programs such as ACOs need PHM by definition; they are responsible for both the health and costs of an assigned patient population.

“To cope with these new demands, healthcare systems and physician groups are moving toward an approach known as ‘population health management.’ The goal of population health management (PHM) is to keep a patient population as healthy as possible, minimizing the need for expensive interventions such as emergency department visits, hospitalizations, imaging tests, and procedures.”

To manage population care and successfully operate this business model, an ACO must be able to perform comprehensive performance measurements, including process of care, outcomes, and patient experience metrics. In order to qualify for Medicare shared savings payments, ACOs are required to meet specified thresholds on a set of 33 such quality performance measures. They also, of course, need to measure and project their costs.

When we look at the span of conditions, providers and settings that need to be measured in order to be managed by ACOs, or indeed by any provider organization that is being compensated based on an “alternative” or value-based purchasing arrangement (e.g., bundled or global payment), it is quite evident that potent information technology systems and robust, abundant clinical data are critical to success.

Information Technology: Essential for Population Health Management
A variety of electronic health record (EHR) tools and informatics database applications have become important for ACOs and Medical Homes and, so far, these applications have helped enable PHM:

• Describing his experience with a partnership ACO with Norton Healthcare, launched in 2010, Dr. Tom James, Humana’s corporate medical director, said “ACOs are really changing our work from (health) utilization management to more data and information sharing. It is more extensive than we have ever seen before.”

• The Institute for Health Technology Transformation puts it very succinctly: “Automation makes population health management feasible, scalable and sustainable.”

The majority of ACOs using IT tools in a PHM setting recognize that pathology and laboratory testing results are an important component of these databases and tools. Yet without involving pathologists in the analysis and utilization of this information, these organizations are working below full potential.

What ACOs really need are standardized and coordinated applications for implementing the insights generated by the laboratory test informatics. Particularly they need to imbed “individualized medicine” into routine care. This translates into guidelines, order sets, and other EMR applications for which pathology knowledge is a necessity.

Systematization with Intelligence

Such systematization, however, may not be immediately embraced by physicians, especially if they perceive that standardized guidelines and coordinated IT applications equate to “managed care” medicine. Yet the reality is that physicians cannot care for individuals without the collective intelligence of the entire healthcare system, from appointment management to pharmacy to laboratory and beyond. Further, ACOs cannot manage quality and costs without controlling variations in provider care.

Pathologists have a unique opportunity to contribute intelligence that transforms “managed care” medicine into astute care. The key to this transformation is a dual approach that is unique to pathology. Pathologists marry “top down” population lab informatics applications that systematize care with “bottom up,” patient-specific, molecular testing tools that individualize guidelines in a way that allows for the art and variability of medicine.

Our data, tests and knowledge enable both population-level analytics, and individualized patient-level applications. Using this dual approach (see Figure 2), we can employ informatics and molecular testing to utilize both population-based and individualized care management.

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4Steve Ivey, “Humana, Norton use information to keep employees healthier under ACO,” Business First, December 2, 2011

For example, on the population level, informatics analysis of serial antibiograms taken from locations throughout the community, as well as other nearby locations, can be used to formulate guidelines for antibiotics based on predicted pathogens and resistance patterns. At the same time, we can offer individualization of those guidelines for particularly high-risk patients using point of care molecular testing to identify the pathogens and immediately direct antibiotic treatment. A patient with COPD and heart failure, for instance, presenting with a recurrence of a pneumonia, would be a good candidate for such testing.

Another illustration of our dual population and individualization approach might be in the area of venous thromboembolism (VTE) prevention. Based on statistical data mining of an ACO database containing both lab and clinical data, we might identify particular patterns of lab test values that would inform the complex risk stratification involved in current VTE prevention guidelines. Turning to the individualized level, we might provide a personalized coagulation profiling service for challenging patients. This service might include pharmacogenetic testing to ensure proper dosing of warfarin, as well as for hereditary thrombophilias, for example.

In this way, our expertise and testing information are applied both to advancing guidelines at the population level and to individualizing care at the patient management level – a dual approach that represents a strong competitive advantage.

Any provider organization that is managing patient populations under alternative, non-fee-for-service payment programs needs a population care focused pathology group to optimize its performance. We are needed to develop applications and services directed at population health care – via informatics, molecular technologies and programs that impact care at the community, hospital or practice population level.

**Risk Management and Prevention: Central to PHM**

In addition to applications to support clinical decision making, information sharing and reporting, PHM requires a different way of looking at patients. For instance, one of the core functions that determines how effectively an organization can manage a population is population segmentation, such as risk stratification.

For example, population segmentation can be performed according to a patient or cohort’s clinical risks, testing results, demographics, lifestyle factors, and/or claims history. Since this segmentation is typically used for decisions regarding resource allocation, care management services, and provider interventions, the “accuracy” of the segmentation in terms of predicting risks and optimally matching needs with resources impacts the ACO’s quality and cost results.
Figure 2: Coordinated Population Care Practice Pathway’s Dual Approach: Population Informatics and Individualized Testing

Population-Based: Lab Informatics
- Patterns for identifying risk
- Algorithms inform guidelines
- Statistics for performance management

Guidelines systematize care

Individualized: Molecular or Biomarker Testing
- Results and algorithms identify risk
- Results individualized guidelines/interventions

Molecular individualizes care

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
Health risk stratification is the most critical type of segmentation, as it is mostly closely linked to value – i.e., costs and outcomes. It is also used in population health management to direct care management – which patients are at high-risk and need ongoing support, which have serious chronic conditions warranting an active intervention plan to prevent complications, and which are fairly healthy and just need prevention and education.

The tricky part of risk stratification is that a patient’s risk status is quite dynamic, so ACOs need recent data to continuously refresh risk stratifications. In fact, the true power comes with being able to use risk assessment to predict future healthcare spending.

Studies show that more than 70 percent of patients in the high cost category in a given year were in a lower cost category the prior year. In other words, who will be the highest cost patient mostly changes year to year.

While payers have developed predictive algorithms for risk assessment, they do not completely meet the needs of ACOs. “Health insurers use predictive modeling algorithms that can help forecast which patients are likely to have significant health costs. Some health plans are giving provider organizations these kinds of tools, which can be valuable in identifying patients who may be hospitalized or suffer complications in coming months. But, since these programs are not designed for providers and have limited utility in clinical settings, organizations must define and develop more appropriate tools.”

For example, Robert Fortini, Vice President and Chief Clinical Officer Bon Secours Medical Group, Richmond, Va., described his organization’s IT needs for population health management: “In the future, we’d like to be able to predict which patients are most likely to get sick and incur major treatment costs.”

The critical capability of population segmentation and risk prediction needed for successful ACO financial management requires pathology and lab testing more than most any other part of medicine. Why? Because we deliver the most potent of predictive tools in healthcare – molecular diagnostics and lab biomarkers. Furthermore, because lab testing is performed frequently, it provides a steady supply of temporal data with which to refresh risk assessments.


Pathology and Laboratory Medicine: At the Core of PHM

In fact, pathology and laboratory medicine are at the core of population health management, and therefore inexorably linked to its success.

Pathologists are critical to success because pathology and laboratory test data are critical to PHM:

- These data go beyond being just a component in the ACO’s EHRs and integrated databases. Lab and pathology results are one of the leading sources of information powering the IT systems so vital to population care: lab and pathology data are estimated to comprise 70 percent of EMR content.9

- Population health management requires tools that span a wide clinical breadth - few healthcare applications can rival the “impact range" of pathology and lab testing. They are performed in the diagnosis and/or management of almost all major clinical conditions.

- Population health management requires tools that cover both the population and patient care continua - again, pathology and lab medicine are among the only clinical implements with significant roles across these care continuum ranges:
  - Prevention and wellness - e.g., cervical cancer screening and HPV, hepatitis screening, lipid profiles.
  - Diagnosis - e.g., histopathology, coagulation testing, microbiology.
  - Therapeutic guidance - e.g., pharmacogenetics, molecular testing for HCV, oncology markers.
  - Chronic care management - e.g., HA1c, warfarin INR, lipid profile.
  - Acute care - e.g., microbe identification with molecular tests, perioperative glucose control.

- Care coordination is integral to population health management. Because pathology and lab testing span clinical conditions and care settings/continua (as described above), the information can be used as a coordination glue to track and manage patients, services and providers. However, this requires recognition of this resource and development of the asset into a coordination system that is managed by an expert in pathology/lab medicine. For example, because lab tests are ordered during the majority of provider visits, lab test records can be used as a proxy for clinician interactions.

• We deliver the most potent of predictive, risk assessment tools in health care: individualized medicine diagnostics and biomarkers. Furthermore, lab testing is performed frequently, so it provides a steady supply of temporal data with which to refresh risk assessments.

**Not by Data Alone: Expertise Needed**

ACOs and other providers engaged in PHM need not only our data, but our expertise and services to generate the value they need to be successful under these new payment models. Moreover, we bring the ability to infuse individualized medicine into guideline-driven care, and to merge the two - population informatics with personalized medicine testing, as shown in Figure 2.

In addition to pathology and laboratory test data, pathologists are needed to:

• Interpret this data for ACOs

  Given the complexities generated by the increasing numbers of molecular and "omics" diagnostic tests, the complexities of pathophysiology, and the complexities of the aging population with multiple chronic conditions and polypharmacy, providers and payers need pathology experts to interpret and disentangle the interrelationship of test results. This is essential when conducting data mining and developing predictive algorithms. For example, without knowing a patient’s albumin levels, one cannot properly interpret calcium levels.

• Select the correct diagnostic data to analyze

  Pathologists are needed to identify the new evidence regarding tests with predictive power that can serve as clinical biomarkers.

• Assure that data is used correctly

  Pathologists’ expertise in laboratory analytics can identify issues that can influence the degree of validity of informatics analyses. For example, a little-appreciated problem with potentially significant consequences on a population management level is that of mixing test results from different labs, as they often use different reference ranges for the same tests. Thus, problems can occur when trying to interpret test results for one patient from a variety of labs.

• Assure that diagnostic data is leveraged optimally

  Pathologists can have a tremendous impact on the effectiveness of PHM because there are many opportunities to utilize pathology and laboratory testing in the reduction of downstream clinical costs and improvement of outcomes, but they necessitate pathology/laboratory expertise. For example, by applying informatics-determined cohort-specific test
reference ranges, we can often detect early signs of pathology in what would otherwise be considered “normal” lab results. Laboratories have used data repositories to set analyte-specific reference ranges based on gender, age groups, and pediatric Tanner development stages.

**Population Health Management: A Clear Opportunity for Pathology and Laboratory Medicine**

Taken together, the superior value of pathology and lab medicine for population health value seems clear. Yet this value cannot be fully realized unless pathologists are engaged in applying the information to population health management.

In the “Coordinated Population Care Services Practice Pathway” our pathology group plays a key leadership role by applying laboratory informatics, molecular testing and pathologist expertise to produce applications and services for optimally managing care that are used by the ACO providers, hospitals, and community.

But we need to move quickly to secure our role and prove our value in these ACOs. They have significant adoption momentum behind them, with an estimated 300 ACOs in existence today, so the models and roles are becoming established rapidly. Without taking action to develop these services and applications that extend beyond test results, and to present a business case, ACOs will sideline us as providers of data.
OUR MARKET OPPORTUNITY - ADVANCING POPULATION HEALTH MANAGEMENT

The emergence of value-based payment models and coordinated, population care have created a tremendous opportunity for our profession. The information contained in the myriad of clinical pathology and laboratory tests performed on patients every year is essential for efficient and effective population care and it is waiting to be fully unlocked. Pathologists are one of the primary key holders.

This information, in conjunction with molecular testing applications and services we provide, can advance population care through, for example:

- **Predictive informatics, biomarkers** - lower costs and better outcomes through avoided complications and admissions.

- **Guidelines that systematize “individualized medicine”** - protocols that implement value-based determinations of when to use pharmacogenetic testing for selecting therapies and/or dosing.

- **Lab informatics for care coordination** - e.g., IT systems to track and analyze lab results for Medical Home management of provider referrals, and facilitation of patient transitions between care settings.

- **Lab informatics for managing service utilization** - e.g., blood products, provider test ordering variations that impact downstream costs.

- **Hospital and community pathogen programs.**

There are abundant opportunities for us to add value in advancing PHM given the wide array of provider organizations managing populations and their diverse needs in carrying out that management. The challenge may be in selecting the best area to begin.

Like all businesses, the answer rests with the customer’s needs, so that translates into understanding your local ACO, integrated delivery network or Medical Home.

**Target Client: Focus on the ACO**

We can start with a high-level analysis of the needs of a typical ACO in terms of population health management. Managing the health of the population for an ACO translates into achieving the value-based outcomes defined by the payer who developed the ACO program.

As background, an ACO has essentially three levels of populations on which it is measured and hence needs to
manage. To give a sense of population scope, the ACO program offered by the Center for Medicare and Medicaid Services (CMS), requires a population of at least 5,000 beneficiaries.

The largest population level is the community, which likely includes healthy people and might be demarcated by a geographical region, depending on the rules of the ACO. The mid-level is the provider setting, such as a practice group or a hospital population. And finally, the smallest population unit is a clinician’s panel of patients.

**Figure 3: Medicare’s Quality Measures for Tiered Population Levels**

Source: Adapted from graphic in presentation: “Quality Metrics as a Foundation for Value-Based Care” Shari M. Ling, MD. Deputy Chief Medical Officer, Center for Medicare and Medicaid Services, Office of Clinical Standards and Quality, 9th Annual World Health Care Congress, Washington, DC, April 16-18, 2012
To reiterate, ACOs need to manage care along all three population levels, both to meet quality performance targets and to lower costs.

On the quality side, most ACO contracts dictate specific quality measures for which performance is tied to ACO compensation. These measures typically span all three ACO populations. For example, a quality measure regarding what percentage of the community population is receiving a vaccination or preventive screening, a measure at the hospital population level regarding 30-day readmission rates, and a measure at the physician practice level regarding diabetic patients’ HA1c levels.

ACOs’ management of cost savings also involves all three population levels, as well as a focus on improving quality, because decreasing poor outcomes means cost savings. The cost equation for ACOs is essentially a capitated benchmark based on historical claims for the population. In other words, if the ACOs can decrease the average spend per person based on the prior few years for their patient population then they receive a share of the net savings.

To manage costs, an ACO needs to use a number of tactics – e.g., coordinating care across the community population, using pathways to minimize provider variations, reducing adverse events in facility populations, focusing on predicting risk amongst chronic conditions within physician patient panels in order to intervene early, investing in prevention and wellness at the community level, etc.

Revisiting our Figures 1 and 2, let’s start to look at how our competitive advantages involving 1) a dual approach of top down population informatics and bottom up, individualized molecular testing, and 2) value to all three dimensions of care can bring us front and center to the ACO PHM table.

Given that ACOs are essentially our clients, in that we are delivering value to them and looking for value-based compensation from them, we need to begin by understanding how they are being measured and where they are looking for cost savings. Let’s start with quality.

ACO Analysis: Measuring Quality

CMS’s ACO program, the “Medicare Shared Savings Program,” measures 33 nationally recognized quality assesses in four domains. In 2013 the measures will be implemented as pay for reporting, meaning they must be reported in order to earn bonuses, and in 2014, they will go into effect in a pay-for-performance mode, meaning ACOs will need to meet certain performance levels on these measures in order to get payments.

Further, an ACO must meet a quality performance standard for at least 70 percent of the measures within each of the four domains, or else Medicare places the organization on a corrective action plan. If the ACO continues to underperform, Medicare terminates...
the agreement. The quality measures are also used for calculating points that impact their shared savings payments.

The quality measure domains are as follows (bolding indicates measures of particular interest for our pathway):

- **Domain 1: Patient/caregiver experience** – 7 measures; e.g.:
  - “Health promotion and education”; “how well your providers communicate”

- **Domain 2: Care coordination/patient safety** – 6 measures; e.g.:
  - All condition 30 day readmissions;
  - Ambulatory sensitive conditions admissions – congestive heart failure (CHF)
  - Ambulatory sensitive conditions admissions – chronic obstructive pulmonary disease (COPD)

- **Domain 3: Preventive health** – 8 measures; e.g.:
  - Colorectal cancer screening; mammography screening

- **Domain 4: At-risk population:**
  - **Diabetes (6 measures); e.g.:**
    - percent of Diabetics with HA1c below 8 percent
  - Hypertension (1 measure)
  - **Ischemic Vascular Disease (2 measures)**
  - Heart Failure (1 measure)
  - **Coronary Artery Disease (2 measures)**

Looking at how we might support ACOs meeting these quality measures, major opportunities might include managing diabetes and chronic cardiovascular diseases and predicting and preventing readmissions.

The need to predict and prevent readmissions is a high profile opportunity applicable to all hospitals, regardless of ACO status, because of Medicare’s “Readmissions Reduction Program,” which starts in 2013 with acute myocardial infarction, heart failure and pneumonia. It targets 30-day readmissions.

One study of readmissions among 11,855,702 Medicare beneficiaries found that across all medical and surgical cases, the most frequent cause of a readmission was heart failure, and the second pneumonia. Postoperative infections and septicemia were also among the top four most frequent reasons in the majority of the surgical procedures analyzed.

A potentially promising opportunity for pathology to impact preventable

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10[http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html/](http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html/)

30-day readmissions is to tackle the resistant pathogen problem. With the emerging maturity of rapid molecular testing for identifying microbes, and powerful informatics for integrating surveillance data across laboratories, microbial surveillance programs are advancing to the point where they might be able to help meaningfully reduce resistant pathogen levels and hospital acquired infections.

**ACO Analysis: Reducing Costs**

To understand how an ACO might approach reducing costs, we can reference an influential and vetted source, the Prometheus Payment model, which was recently adopted by CMS as the engine behind its bundling programs. The Prometheus model bundles all care services for specific conditions and procedures, called “evidence-informed case rates (ECRs),” into base payments with severity adjustments (“potentially avoidable complications (PACs)” (what should be done) and “potentially avoidable complications (PACs)” (what should not happen).

The developers write, “We separated the costs attributable to patient-related factors from those attributable to providers’ actions. These latter costs are critically important in terms of accountability. In Prometheus, these potentially avoidable costs are called PACs and are recognized as the result of “care defects” – problems necessitating technical care that are under the professionals’ control and that, with the best professional standards, could have been avoided. PACs might include the cost of hospitalization of a patient with uncontrolled diabetes or the readmission for a wound infection of a patient who had recently been discharged after cardiac bypass surgery.”

The Prometheus model has been developed for 21 ECRs, together comprising about 30-35 percent of total spending. These 21 do not include any oncology related conditions, other than colonoscopy and colon resection procedures. HCI3 is currently developing ECRs for the majority of major conditions and procedures, and for the Medicare population.

Because PACs represent the costs that are in providers’ control and have been deemed “potentially avoidable” by groups of expert physicians who advised on the development of the program, these dollars and areas should be good targets for ACO cost reduction, and therefore for our PHM services.

HCI3 has made available the results of an analysis of a privately insured population of 4.7 million adult beneficiaries for the starting set of 21 conditions and procedure ECRs and their associated PACs. Using these data, we have analyzed the share of PAC dollar opportu-

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12Developed by the Healthcare Incentives Improvement Institute (HCI3) – see [http://www.hci3.org/what_is_prometheus](http://www.hci3.org/what_is_prometheus)

Promising Practice Pathways

The following summarizes the share of PAC dollars for this commercial population – in other words, what percent of cost reduction opportunity does each area have:

By conditions and procedures:

**percent of PAC dollars**
- Chronic Medical = 61 percent of PAC dollars
- Outpatient procedural = 21 percent
- Inpatient procedural = 12 percent
- Acute medical = 6 percent

By setting/charge area:

**percent of PAC dollars**
- Inpatient = 57 percent of PAC dollars
- Outpatient = 27 percent
- Professional = 15 percent

The top 10 conditions or procedures (in order of highest share): percent of PAC dollars
- GERD (gastroesophageal reflux) = 17 percent of PAC dollars
- Diabetes = 15 percent
- COPD = 9 percent
- Hypertension = 6 percent
- PCI (Percutaneous Coronary Intervention) = 6 percent
- Asthma = 5 percent
- Colonoscopy = 5 percent
- CHF = 5 percent

Prometheus also provides a detailed analysis of the types of PACs that drive these costs. Some of the most costly PAC areas as a percent of all PAC dollars include:

- Emergency room visits = 15 percent of PAC dollars
- Gastritis, Ulcer, GI Hemorrhage = 7 percent
- Pneumonia = 7 percent
- Sepsis, meningitis, hepatitis = 5 percent
- Fluid and electrolyte disorders = 5 percent
- DVT and pulmonary embolism = 4 percent
- Stroke = 4 percent
- Diabetic emergencies – hypo- and hyper-glycemia = 4 percent
- Urinary tract infections = 3 percent

What can we take from these data to inform a starting roadmap for our PHM applications and services? A few observations:

- Inpatient and chronic conditions areas dominate the opportunities for savings.
  - This is driven in part by admissions for chronic conditions that are deemed avoidable.
- Diabetes also offers an oversized share of avoidable costs.
- Infections and coagulation disorders comprise a large share of PAC dollars.
**Figure 4: Potentially Avoidable Costs (PACs) from Prometheus Payment Model - Example for Commercially Insured Population of 4.7M Adults**

<table>
<thead>
<tr>
<th></th>
<th>INPATIENT</th>
<th>OUTPATIENT</th>
<th>PROFESSIONAL</th>
<th>TOTAL</th>
<th>PAC Share</th>
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</thead>
<tbody>
<tr>
<td><strong>Chronic Medical</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>61 percent</td>
</tr>
<tr>
<td>Diabetes</td>
<td>$73,146,717</td>
<td>$87,177,569</td>
<td>$61,949,863</td>
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<td>CAD</td>
<td>$31,968,633</td>
<td>$16,277,081</td>
<td>$14,382,656</td>
<td>$62,628,370</td>
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<tr>
<td>CHF</td>
<td>$34,567,824</td>
<td>$19,283,541</td>
<td>$15,871,551</td>
<td>$69,722,916</td>
<td>5 percent</td>
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<tr>
<td>GERD</td>
<td>$138,623,866</td>
<td>$70,787,277</td>
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<td>Asthma</td>
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<td>$35,084,926</td>
<td>$21,845,902</td>
<td>$79,169,669</td>
<td>5 percent</td>
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<td>$43,771,418</td>
<td>$29,970,775</td>
<td>$128,050,036</td>
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<td>6 percent</td>
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<td>Pneumonia</td>
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<td>$0</td>
<td>$39,949,528</td>
<td>3 percent</td>
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<td>Stroke</td>
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<td>$0</td>
<td>$0</td>
<td>$19,308,490</td>
<td>1 percent</td>
</tr>
<tr>
<td><strong>Inpatient Procedural</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12 percent</td>
</tr>
<tr>
<td>CABG</td>
<td>$53,230,340</td>
<td>$0</td>
<td>$0</td>
<td>$53,230,340</td>
<td>4 percent</td>
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<tr>
<td>Bariatric surgery</td>
<td>$26,735,367</td>
<td>$0</td>
<td>$0</td>
<td>$26,735,367</td>
<td>2 percent</td>
</tr>
<tr>
<td>Hip replacement</td>
<td>$14,669,590</td>
<td>$0</td>
<td>$0</td>
<td>$14,669,590</td>
<td>1 percent</td>
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<tr>
<td>Knee replacement</td>
<td>$33,552,754</td>
<td>$0</td>
<td>$0</td>
<td>$33,552,754</td>
<td>2 percent</td>
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<td>Colon resection</td>
<td>$33,552,754</td>
<td>$0</td>
<td>$0</td>
<td>$33,552,754</td>
<td>3 percent</td>
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<td><strong>Outpatient Procedural</strong></td>
<td></td>
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<td>21 percent</td>
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<td>PCI</td>
<td>$75,885,702</td>
<td>$7,935,749</td>
<td>$0</td>
<td>$83,821,451</td>
<td>6 percent</td>
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<td>Low-risk pregnancy and delivery</td>
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<td>$1,767,581</td>
<td>$0</td>
<td>$54,534,615</td>
<td>4 percent</td>
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<td>Knee arthroscopy</td>
<td>$5,994,561</td>
<td>$5,078,196</td>
<td>$0</td>
<td>$11,072,757</td>
<td>1 percent</td>
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<td>Gall bladder</td>
<td>$44,106,893</td>
<td>$8,844,822</td>
<td>$0</td>
<td>$52,951,715</td>
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<td>Hysterectomy</td>
<td>$21,367,938</td>
<td>$4,495,240</td>
<td>$0</td>
<td>$25,863,178</td>
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<td>Colonoscopy</td>
<td>$16,315,169</td>
<td>$61,955,282</td>
<td>$0</td>
<td>$78,270,451</td>
<td>5 percent</td>
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<tr>
<td><strong>TOTALS</strong></td>
<td>$848,778,733</td>
<td>$405,849,974</td>
<td>$224,890,196</td>
<td>$1,479,518,903</td>
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<tr>
<td>PAC Share</td>
<td>57 percent</td>
<td>27 percent</td>
<td>15 percent</td>
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</table>

The ACO Movement: Growth and Distribution

As of August 2012, there are 154 ACOs in the Medicare Shared Savings program. Almost half of the most recent group of 89 ACOs announced this summer is physician-led ACOs with fewer than 10,000 beneficiaries, indicating that this model is being adopted beyond the major, integrated health systems.14 Physician ACOs may be advantageous pathway customers for us, because they might have greater laboratory testing informatics and coordination needs than hospital system ACOs.

In addition to the 154 Medicare ACOs, there are an estimated 150 ACOs in the private sector, bringing the current total estimate to about 300 ACOs.15

In terms of geographic distribution, the 154 Medicare ACOs are spread across 40 states and the District of Columbia and cover 2.4 million beneficiaries. Figure 5 shows the regional service areas for about 200 ACOs that Leavitt Partners was tracking as of May 2012.16 The East and Midwest have a greater concentration of ACOs compared to the South, Great Plains and Mountain West regions. Since Leavitt’s May 2012 update, ACOs have been reported in Idaho and West Virginia, leaving only two states without ACOs.

How fast might the ACO movement grow? That depends, of course, on how successful the model is in generating cost savings, which won’t be known for likely two years. Jonathan Blum, principal deputy administrator and director of the Center for Medicare, reported that an estimated $940 million over four years might be saved by the Medicare Shared Savings Program.17

Indicators of near-term interest include Medicare’s comment that it has received about 400 notices of intent from provider groups regarding the ACO program at the next start date of January 1.18 Furthermore, a recent, national survey of 1,070 executives in provider organizations (66 percent hospitals or health systems and 14 percent physician orgs) found that 53 percent indicated their organization would join an ACO within the next five years.19 These and other market signs point to a brisk growth in the number of ACOs over the next few years, barring any

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15 Susan Dentzer, Editor of Health Affairs, remarked at the Third National Accountable Care Organization Summit in June 2012
16 David Muhlestein et al. “Growth and Dispersion of Accountable Care Organizations: June 2012 Update,” Leavitt Partners, June 2012
18 “Blum: Diversity, Number Of ACOs Shows Program Is Spreading Fast,” Inside Heath Policy, July 11, 2012
In fact, some analysts are projecting about 600 ACOs, a doubling in number, for 2013. It is important to note that even if the Affordable Care Act were to be repealed, the private market momentum behind ACO-like models is sufficiently strong that analysts predict it would have little impact on the commercial insurance side.

**Figure 5: Numbers of Private and Medicare ACOs by State, May 2012**

Source: Adapted from Leavitt Partners, “Growth and Dispersion of Accountable Care Organizations, June 2012 Update.”

Note: Leavitt Partners’ tracking of ACOs, current as of May 2012; their total at that time was 221 ACOs in 45 states. This map shows the 198 ACOs for which they were able to define geographic limits.

Fitting Into the ACO Market
There are a multitude of business flavors among ACOs, as many are implemented in the private payer market. Even within the Medicare Shared Savings program, there are ACOs that are run and owned by physician organizations, others by hospitals, and others by payers partnered with either physician groups or hospitals. It is beyond the scope of this chapter to review the contractual options available to pathology groups across various ACO models. In most circumstances, a pathology group that was already contractually tied to either an ACO hospital or ACO physician organization for diagnostic testing services will be the best candidate for this pathway.

Figure 6 illustrates how the Medicare Shared Savings “one-sided” program works in terms of payment flows, in a simplified depiction.

Figure 6: Medicare ACO Shared Savings Payment Mechanism – Simplified Illustration

Benchmark spending for ACO based on prior 3 years CMS claims data

Savings 15%

Actual Spend 85%

Source: Eleanor Heniman, MD, MBA, G2 Intelligence
No matter how it is contractually configured, the business arrangement we seek with ACOs is compensation based on value payments—e.g., ACO shared savings bonuses. We will demonstrate the value of our Coordinated Population Care Pathway to the ACO in terms of a business case that documents opportunities for cost savings and for achieving quality measures. Based on this business case, our goal will be to negotiate a share of the ACO’s net savings.

According to Milliman, the savings pool is generally allocated between three provider pools, primary care, specialty and hospital (when a hospital is part of the ACO). As an example methodology, the report provides the table in Figure 7 as a starting point that shows how an ACO might divide the providers’ pools first against service line dollars, according to that pool’s level of responsibility for that service line. Thus, in their example, hospital has no responsibility for PCP service costs.

The exact share can be determined using one of several other methods it details. For example, for hospitals, it describes incorporating important cost savings measures into the determination of the hospital’s allocation, including:

- Length of stay
- Readmission rates
- Infection rates
- Preventable events
- Admissions through the emergency room
- Intensive care unit days
- ER visits (top five diagnoses)
- Utilization of high-cost or frequently overutilized interventions—e.g., MRI, CT, PET and endoscopy

In a scenario in which the hospital’s allocation of the savings pool is being determined based on the cost savings measures listed above, we may have another negotiating approach: Some of our pathway interventions can improve measures such as readmission rates, infection rates, length of stay or intensive care unit days. If our pathology group is already aligned or part of the hospital, we can build a case that by using our new services and applications we can position the hospital to capture a greater share of the ACO bonus pool, and that we therefore deserve a share for our group.
Sizing the Potential Market Opportunity

To model the five-year pool of potential ACO revenues from our “Coordinated Population Care Services Practice Pathway,” we projected the growth in ACOs, the average number of beneficiaries per ACO, the average expenditures per beneficiary, and the average cost savings achieved on by ACOs.

In order to model what share of the ACO pool our pathology pathway group might receive, we considered that we would likely be negotiating from the hospital pool, given that most of our groups will be affiliated closely with an ACO hospital if they are pursuing this pathway. Most commonly, according to Milliman, the hospital receives about 50 percent of the total ACO bonus pool. Although there are numerous variables concerning the health system, politics, hospital and pathology group size, etc., we assumed for modeling purposes a range of 2 percent to 8 percent of the hospital’s share of savings could be paid to our group if we make our business case.

The rationale is that 2 percent to 8 percent of the hospital pool translates to 1 percent to 4 percent of the total savings pool. Given that laboratory and pathology charges comprise about 3 to 4 percent of all spending, and that some providers allocate savings based on the percent of charges, we reasoned that the negotiation could be supported on this basis.

We also assume that these shares can increase over time as we prove our value to the system and increase the number of services and applications provided.

Using these projections and assumptions we can project revenues for 2013 to 2017 for a potential, total Coordinated Population Care Services Practice Pathway ACO market, as seen in Figure 8. The caveats are that models such as these are to be taken as directional only, given the imprecisions.

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inherent in dealing with such complex and highly uncertain systems.

Our model estimates that in 2014, for example:

- The average payment per pathology group from a CMS ACO covering 15,000 lives is ~$472,000.
- The average payment per pathology group from a private ACO covering 30,000 lives is ~$416,000.
- This is due to the fact that Medicare patients have double the per cap expenditures versus private populations.
- The total, potential ACO market opportunity in 2014 is estimated at $332 million.

In 2017 the model estimates the potential total market for pathology groups to be $739 million.

Again, these payments are in addition to diagnostic testing service payments and Medicare Part A revenues. It is also true, however, that many are predicting that our fee-for-service testing revenues will be declining over this time period, especially hospital lab test volume.

The model directionally supports an attractive opportunity from a financial perspective.

More importantly, however, if we do not pursue demonstrating our value with ACOs, the risk of our becoming a commodity vendor is real and possibly permanent.
### Figure 8: Market Estimates for Medicare ACOs

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medicare ACOs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated number of CMS ACOs</td>
<td>154</td>
<td>350</td>
<td>450</td>
<td>500</td>
<td>550</td>
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<tr>
<td>Estimated number of covered lives per ACO</td>
<td>15,000</td>
<td>15,000</td>
<td>15,000</td>
<td>15,000</td>
<td>15,000</td>
</tr>
<tr>
<td>Estimated per capita medical expenditures for Medicare beneficiaries in 2013</td>
<td>$11,000</td>
<td>$11,440</td>
<td>$12,012</td>
<td>$12,613</td>
<td>$13,243</td>
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#### Conservative Scenario

<table>
<thead>
<tr>
<th>Assumed percent cost savings retained by ACO (assumes Medicare gets 50 percent under Track 1 program)</th>
<th>5 percent</th>
<th>5 percent</th>
<th>5 percent</th>
<th>5 percent</th>
<th>5 percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assumed shared of net cost savings earned by pathology group</td>
<td>1 percent</td>
<td>2 percent</td>
<td>3 percent</td>
<td>3 percent</td>
<td>3 percent</td>
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<tr>
<td>Total potential Medicare ACO market for pathology pathway – conservative scenario</td>
<td>$12,705,000</td>
<td>$60,060,000</td>
<td>$121,621,500</td>
<td>$141,891,750</td>
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<td>Estimated potential Medicare market per ACO – conservative</td>
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#### Aggressive Scenario

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<th>9 percent</th>
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</thead>
<tbody>
<tr>
<td>Assumed share of net cost savings earned by pathology group</td>
<td>4 percent</td>
<td>5 percent</td>
<td>6 percent</td>
<td>6 percent</td>
<td>6 percent</td>
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<tr>
<td>Total potential Medicare ACO market for pathology pathway – aggressive scenario</td>
<td>$91,476,000</td>
<td>$270,270,000</td>
<td>$437,837,400</td>
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<td>Estimated potential Medicare market per ACO – aggressive</td>
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<td>Total potential Medicare ACO market for pathology pathway – average</td>
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<td>Potential Medicare ACO market for pathology pathway per ACO – average</td>
<td>$338,250</td>
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Source: Eleanor Herriman, MD, MBA, G2 Intelligence
### Figure 9: Market Estimates for Private Market ACOs

<table>
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<tr>
<th>Private Market ACOs</th>
<th>2013</th>
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<td>300</td>
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<tr>
<td>Estimated number of covered lives per ACO</td>
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<td>30,000</td>
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<td>30,000</td>
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<tr>
<td>Estimated per capita medical expenditures for commercial beneficiaries</td>
<td>$4,800</td>
<td>$5,040</td>
<td>$5,292</td>
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**Conservative Scenario**

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<tr>
<th>Assumed percent cost savings retained by ACO (assumes payer gets 50 percent)</th>
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<th>5 percent</th>
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<th>5 percent</th>
<th>5 percent</th>
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</thead>
<tbody>
<tr>
<td>Assumed share of net cost savings earned by pathology group</td>
<td>1 percent</td>
<td>2 percent</td>
<td>3 percent</td>
<td>3 percent</td>
<td>3 percent</td>
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<tr>
<td>Total potential private ACO market for pathology pathway – conservative scenario</td>
<td>$21,600,000</td>
<td>$60,480,000</td>
<td>$119,070,000</td>
<td>$137,525,850</td>
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<td>Estimated potential commercial market per ACO – conservative</td>
<td>$72,000</td>
<td>$151,200</td>
<td>$238,140</td>
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**Aggressive Scenario**

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<tr>
<th>Assumed percent of cost savings retained by ACO (assumes payer gets 50 percent)</th>
<th>9 percent</th>
<th>9 percent</th>
<th>9 percent</th>
<th>9 percent</th>
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</thead>
<tbody>
<tr>
<td>Assumed share of net cost savings earned by pathology group</td>
<td>4 percent</td>
<td>5 percent</td>
<td>6 percent</td>
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<td>6 percent</td>
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<td>Total potential private ACO market for pathology pathway – aggressive scenario</td>
<td>$155,520,000</td>
<td>$272,160,000</td>
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<td>$495,093,060</td>
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<td>Estimated potential commercial market per ACO – aggressive</td>
<td>$518,400</td>
<td>$680,400</td>
<td>$857,304</td>
<td>$900,169</td>
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<td>Total potential private ACO market for pathology pathway – average</td>
<td>$88,560,000</td>
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<td>$273,861,000</td>
<td>$316,309,455</td>
<td>$362,318,103</td>
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<td>Potential private ACO market for pathology pathway per ACO – average</td>
<td>$295,200</td>
<td>$415,800</td>
<td>$547,722</td>
<td>$575,108</td>
<td>$603,864</td>
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<tr>
<td>Total, estimated, potential ACO market for pathology pathway</td>
<td>$140,650,500</td>
<td>$331,485,000</td>
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<td>Estimated, potential pathology pathway payment per ACO – average</td>
<td>$316,725</td>
<td>$443,850</td>
<td>$584,672</td>
<td>$613,905</td>
<td>$644,600</td>
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</table>

*Source: Eleanor Herriman, MD, MBA, G2 Intelligence*
ABOUT THE COORDINATED POPULATION CARE SERVICES PRACTICE PATHWAY

The Coordinated Population Care Services Practice Pathway offers one model for becoming an ACO population care management center. As we’ve been describing, there are a number of dimensions along which we can generate value, including:

- The population level – either community, hospital or provider’s patient population.
- The application areas – including population informatics for risk prediction, individualized medicine guidance, utilization management, quality programs, and coordination programs.
- The provider group users – primary care providers, hospitalists and ER clinicians, surgeons/proceduralists and ACO executive leadership who manages the population.

The primary inputs for our practice are our pathology expertise, lab informatics, and molecular testing. The “outputs” – i.e. our pathway’s offerings – take the form of guidelines, algorithms, EMR applications, and risk prediction reports, for example (See Figure 10).

In pursuing this pathway, we can choose to target only a particular population level or provider user group, especially to start out and prove our ability to generate value. For that reason, we will describe the pathway applications, services and programs in a matrix fashion across “provider user groups” and “application areas,” as shown in Figure 11, “Pathway Offerings Matrix.”
Figure 10: Coordinated Population Care Pathway: Key Inputs and Outputs

Lab Informatics

Pathology Expertise

Molecular Testing

Guidelines, Algorithms, EMR Tools, Risk Predictions

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
**Figure 11: Coordinated Population Care Practice Pathway Offerings Matrix**

<table>
<thead>
<tr>
<th></th>
<th>INFORMATICS-BASED RISK PREDICTION</th>
<th>INDIVIDUALIZED MEDICINE GUIDANCE</th>
<th>UTILIZATION MANAGEMENT</th>
<th>QUALITY AND COORDINATION PROGRAMS</th>
</tr>
</thead>
</table>
| **Primary Care Providers** | • Reports on patients at high risk  
• Tests to order based on elevated risk | • Tools – MDx for rapid, targeted antibiotic selection  
• Tools – PGx for statins, anticoag, SSRIs, – Rx selection and adherence ... | • PCP test ordering variations for tests with high downstream costs | • EMR apps – changing Rx, ordering Rx levels, ordering LFTs, protocols for referrals to specialists  
• High risk patient reports – triage care management services |
| **Hospitalists and ER** | • Reports on in-patients at high risk – e.g., daily; protocols with reflex testing based on risk  
• Early detection based on labs-alerts  
• Suggested meds and tests based on risk in certain settings | • Tools - MDx for rapid, targeted antibiotic selection  
• Programs for preventing ER admissions using MDx – e.g. enterovirus | • Specialist test ordering variations for tests with high downstream costs | • Glycemia control and glucometer accuracy problems |
| **Specialists - Medical Specialties, Surgeons, Proceduralists** | • Reports and protocols for patients at high risk – anticoagulation, fluids and electrolytes ... | • Tools - MDx for rapid, targeted antibiotic selection  
• PGx tools – e.g. Clopidogrel  
• Oncology – see Oncology pathway | • Blood products/ transfusions  
• Specialist test ordering variations for tests with high downstream costs | • Lab testing protocols for referrals between providers |
| **Population-wide Management/ ACO Leadership** | • Subpopulation reference ranges for more precise disease detection  
• Prediction of next year’s high cost patients  
• Identification of high adverse event areas | • Development of guidelines for PGx and MDx testing by risk status and cost-effectiveness modeling | • Blood products utilization program  
• Lab-Pharmacy – decision free for antibiotics based on cost-effectiveness + antibiograms | • Pathogen surveillance  
• POC testing validation and data networking  
• Home testing – glucometers, etc.  
• Lab phlebotomy network  
• Digital pathology |

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
**PGx** = pharmacogenetic testing; **MDx** = molecular (e.g. DNA) testing

This Matrix is not an exhaustive accounting of the potential solutions we can offer for ACO population health management, but provides a range of examples that illustrate the model and its value.

**Below we describe specific application examples and, for some, their potential value generation in terms of either quality or cost reduction for each practice category.**

**Offerings for Primary Care Providers (PCPs):**

**Informatics-Based Risk Prediction** for PCPs – Reports on patients at high risk and recommended tests to order.

Example: EMR report on high risk diabetics. Based on trends in glucose, HA1c, and levels of biomarkers such as CRP, lipid profiles, etc. We produce an EMR report that identifies particular diabetes patients in a PCP’s practice as very high risk for thromboembolic events. If we have a program linking us to pharmacy data, we can check on statin or other anticoagulation prescriptions and apply protocols that consider adherence and resistance questions. Test recommendations could include both other biomarkers, such as hs-CRP, and perhaps pharmacogenetic tests for aspirin or Plavix resistance, for example.

• Value generation potential: when the Prometheus model’s PAC costs for diabetic stroke, AMI, DVT and pulmonary embolisms are scaled up from the commercial population to the nation, they represent $1.2 billion in potentially avoidable costs. Each avoided myocardial infarction admission is estimated to be worth ~$13,600. If, using our lab data/biomarker algorithm informatics we can identify high risk diabetics, and thereby direct more intensive interventions and therapeutics, we might help prevent some of these adverse events.

Example: Reports alerting PCP of patients with even low levels of hyponatremia, as these have been associated with risks of falls, hip fractures and osteoporosis. This is especially risky in patients’ CHF, cirrhosis and renal failure, as it portends a worse prognosis. Also, thiazide diuretics and SSRIs can worsen the condition.

• Value generation potential: by intervening, hospital admissions, adverse events like falls or fractures while in the hospital, and poor outcomes might be averted.

**Individualized Medicine Guidance** for PCPs – MDx tools for rapid, targeted antibiotic selection. EMR guidelines or decision support for using point of care or near care molecular testing to identify resistant pathogen strains and select targeted antibiotics. Guidelines will be based on informatics indicating patient risk and antibiograms determining local resistance patterns. The resistance problem is impacting
the empirical treatment of all types of infections, and significant proportions of patients are not effectively treated based on empirically directed antibiotics. Molecular testing for rapid identification of the pathogen and thus more specific antibiotic selection has been shown to significantly improve treatment – i.e., more rapid recovery for more patients, and thus cost savings and better outcomes.

Example: an EMR application or guideline for using rapid molecular infectious testing to guide antibiotic selection for pneumonia. This might be cost effective, for example, in populations at high risk for adverse events with pneumonia, such as patients with multiple chronic conditions. In addition, in the ER, this might allow for avoided admissions if molecular testing confirms a viral versus bacterial etiology (an estimated 20 percent to 30 percent of community-acquired pneumonias).

- Value generation potential: multiple studies show that delays in effective treatment of resistant pathogens in pneumonia increase hospital lengths of stay for several days, typically five to seven, representing a difference of at least $20,000 per patient in costs.

**Individualized Medicine Guidance** for PCPs – PGx tools for anticoagulants, statins, SSRIs, adverse reactions, etc. – pharmacogenetics (PGx) is beginning to gain both clinical and payer traction, and our ACO population practice center should take the lead in answering all the major questions regarding how these tests are implemented for population care in an ACO setting. An important data point here is that the two leading pharmacy benefit managers (PBMs), Medco and CVS Caremark, are currently operating major PGx testing programs for millions of their client payers’ beneficiaries. The PBMs have publicly stated that these programs are economically attractive for their clients. Thus, PGx testing should have a value generating role to play in an ACO population. For a list of drugs with PGx tests included on their FDA drug labels see [http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm](http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm)

Example: Program (EMR applications, testing and customized patient report) to increase patient adherence to statin therapy using data on their KIF6 carrier status as a motivator.

- Medco reports 50-90 percent of patients stop taking their prescribed therapies at end of first

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23 For example, SE Cosgrove, “The Relationship between Antimicrobial Resistance and Patient Outcomes: Mortality, Length of Hospital Stay, and Health Care Costs,” Clinical Infectious Diseases 2006; 42:S82-9
year—this includes depression, diabetes, cholesterol, and hypertension. For statins, at one year the difference between high and low adherence translates into almost a 10 percent difference in patient survival rates.\(^{24}\)

Medco trial with Celera just published—”The AKROBATS trial demonstrated that 6-month statin therapy adherence and persistence are significantly improved by providing the patient with KIF6 genetic information. This study provides the first prospective evidence that pharmacogenetic testing has utility in modifying patient adherence.”\(^{25}\)

**Utilization Management** for PCPs—Identification of lab tests that have high PCP ordering variations and also high downstream cost consequences, using data-mining of LIS systems. Provide feedback to PCPs of their test ordering relative to peers, along with explanation of optimal use of test, and test menu decision support for EMR/CPOE as available.

Example—A program to reduce variations in ordering of CA 125 testing. This testing has a high false positive rate and generates high downstream costs due to imaging testing.\(^{26}\)

**Quality and Coordination Programs** for PCPs—There are a number of applications that we can deliver for supporting chronic care management based on analysis of an individual’s lab testing results, especially if we link our data with the pharmacy database. Needless to say, we also need access to the ACO’s clinical database/EMRs and EHRs.

Example—guidelines implemented into the EMR for when to either refer diabetics to an endocrinologist or start them on insulin based on lab values.

- Value generation potential—studies show improvements in HA1c levels and complication rates when diabetics are started on insulin early, yet many PCPs are reluctant to do so.

Example—reminders to PCPs or directly to patients about testing for drug levels like warfarin, digoxin, etc.

- Value generation potential—studies show keeping patients with the target INR zone significantly decreases the rate of hemorrhages and thromboembolic adverse events. This may reduce ER visits and admissions.

\(^{24}\)Rasmussen, J. N. et al. JAMA 2007;297:177-186


\(^{26}\)G2 Intelligence interview with Philip Chen, M.D., Ph.D., director of informatics for the Department of Pathology at the University of Miami, June 15, 2011, in “Creating a Value-Driven Laboratory: Opportunities in the New Marketplace,” G2 Intelligence, 2011 Kennedy Information, LLC.
Offerings for Hospitalists and ER (Hosp and ER): Informatics-based risk prediction for Hosp and ER - Our practice pathway mines our lab testing data and clinical data to identify inpatients who are at particularly high risk for a complication or adverse event (beyond what would be evident to a clinician), and to alert clinicians to tests that might be indicated based on lab results that point to early signs of a particular problem. For hospitalists, the reports on patients at high risk for an adverse event, complication or mortality are needed on a frequent reporting period, for example daily. For patients in critical units, it may be necessary to access point of care test results, as well, if a particularly challenging clinical situation requires an intensive solution.

Example – EHR applications for fluid and electrolyte problems. Our application could first alert the clinician to a low sodium upon admission; next, if the sodium declined during hospitalization, further alerts with suggestions for testing such as serum and urine osmolality could be sent; finally, based on results of tests, decision support algorithms for etiology of the disorder could be offered (e.g., is this hypovolemic, hypertensive, normovolemic, etc.).

Fluid and electrolyte disturbances, hyponatremia being the most common, are a major hospital problem with significant quality and cost consequences. One study found that 11 percent of surgical ICU patients had hyponatremia at admission to the ICU and 31 percent acquired hyponatremia while in the ICU. The inpatient costs of patients with hyponatremia are more than twice those with normal sodium. When hyponatremia is corrected, the heightened mortality associated with it decreases to levels associated with normonatremia.

There are a number of studies that report that clinician management of fluid and electrolyte disorders is quite problematic, and thus is playing a causal role. Diagnosing the pathophysiology underlying the electrolyte disorder is complex and important to the treatment. Furthermore, laboratory testing plays a significant role in unraveling the etiology of the disorder. Importantly, one investigation found that “the adequacy of laboratory assessments during hospitalization directly relates to patient outcomes in hyponatremia.”

- Value generation potential – Based on the Prometheus data,

27Y Sakr “Fluctuations in serum sodium level are associated with an increased risk of death in surgical ICU patients.” Critical Care 2012, 16(Suppl 1):P145


Fluid and Electrolyte Disorders represent 1.5 percent of all PAC costs. When scaled to the national level and expanded beyond the commercial population based on our modeling, this represents potential avoidable costs of $1.14 billion nationally.

**Individualized medicine guidance for Hospital and ER** – Molecular testing to guide targeted antibiotic therapy for hospitalized patients presents a major opportunity to improve outcomes and generate cost savings. According to the Prometheus Payment Model, the leading infections (pneumonia, sepsis, meningitis, and urinary tract infections) comprise at least 10 percent of all avoidable costs, and most of these are inpatient costs.

One recent study estimated that the cost of an antimicrobial-resistant infection is $18,588 to $29,069 per patient, with an excess duration of hospital stay of 6.4 to 12.7 days and attributable mortality of 6.5 percent.30

Also, a growing evidence base supports the ability of antibiotic therapy based on molecular testing to improve outcomes and shorten lengths of stay – in other words, generate cost savings. In the next few years these tests will increasingly be available for routine, inpatient use for guiding antibiotic therapy, and we can bring the needed expertise of assessing which tests to use and interpreting results. Likely we will collaborate with pharmacy and infection control in these programs.

Example – an EMR application with guidelines specifying who is sufficiently high risk to warrant molecular infectious testing for antibiotic selection for UTIs and pneumonia.

**Quality and Coordination Programs for Hospital and ER** – One area for our pathology practice pathway to address in hospital and emergency room settings is glucose control – including diabetics with hypoglycemic episodes due to illness, operative procedures or iatrogenic insulin therapy, and other patients undergoing procedures and having their glucose managed. Diabetic episodes of hypo and hyperglycemia are identified by Prometheus to constitute 3 percent of all PAC costs, a substantial opportunity for savings. Further, hypoglycemia problems in hospitalized patients during attempts to manage their glucose are common, dangerous and costly.

The National Quality Forum prioritized inpatient glycemic control as one of the 34 Safe Practices it recommends to optimize hospital care of patients, admonishing hospitals to “Take actions to improve glycemic control by implementing evidence-based intervention practices that prevent hypoglycemia and optimize the care of patients with hyperglycemia and diabetes.”

Example – quality control and validation of bedside glucometers. Many studies have produced evidence that some of the hand-held glucometers used commonly in hospitals are not reliable in detecting clinically important hypoglycemia. When clinicians are trying to calibrate critically ill patients’ glucose levels using insulin, very precise glucose measurements are needed. Our practice can ensure this is the case through a quality program, with instrumentation replacements as needed.

**Offerings for Specialists – Medical Specialties, Surgeons, Proceduralists**

**Individualized medicine guidance for Specialists** – There are a number of areas where MDx and PGx will begin playing major roles in improving quality and generating cost savings across specialty areas. We’ve discussed infectious disease and how MDx can begin to move therapy from empiric to targeted. Oncology is another significant opportunity, but that is covered in another Practice Pathway, “High-Performance Pathology for High-Value Oncology.” PGx is a bit behind in the adoption curve, but as described above, the fact that the national PBMs are rolling out PGx testing for many tests and therapeutics indicates there is an economic rationale there. PGx tests are being developed rapidly and can have impact in selecting therapies that are most effective, driving dosing decisions, avoiding adverse events and bad outcomes in general, and saving pharmaceutical costs.

Example – Program for clopidogrel PGx testing – CYP2C19 for high risk patients. Evidence is accumulating rapidly that patients with loss of function CYP2C19 alleles do not get benefit from clopidogrel and thus have much higher rates (53 percent in one study) of mortality from cardiovascular events and a three-fold increase in stent thrombosis. A recent presentation by The Mayo Clinic commented about clopidogrel PGx testing, “Some would argue that there is sufficient evidence to provide this testing for certain groups of patients, such as those undergoing coronary stenting.”

- Our practice application could be programmed that enables clopidogrel PGx testing for stenting patients – guidelines, a testing solution, interpretation of results with recommendations on changing therapies, and a means of tracking results/registry. This would all be developed in conjunction with interventional cardiologists/radiologists.

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Pharmacogenomic guidelines, reference databases, and electronic platforms to integrate personal pharmacogenomic data into the clinical workflow would all be helpful in overcoming these barriers. Innovative strategies are needed to promote the widespread adoption of pharmacogenomic clinical applications by cardiovascular providers.

- A National Heart, Lung, and Blood Institute Working Group recently described how IT systems could integrate PGx into workflow. “One such strategy would be the use of information technology to integrate pharmacogenomics into the clinical workflow, which would follow a “learning by doing” model. For example, a provider using a computerized provider order entry system to prescribe clopidogrel for a patient would be asked whether the patient is known to have reduced-function CYP2C19 alleles and, if not, would be prompted to consider ordering a genotyping test. Extending this model, if the computerized provider order entry were linked to the patient’s medical record and found that the patient was known to have reduced-function CYP2C19 alleles, the system would prompt the provider to consider using an alternative antiplatelet medication. Thus, preemptive genotyping – placing data in computerized provider order entry – enabled electronic medical records – is another strategy that needs further evaluation.”

**Utilization Management for Specialists**

Blood product and transfusion management – There is a large body of evidence indicating that blood utilization is suboptimal and that managing utilization would result in substantial savings – in the hundreds of millions of dollars, according to Barry Portugal, President of Health Care Development Services, Inc. (HCDS).

- One study found that over 70 percent of transfusion orders were deemed inappropriate among medical staff at an academic hospital. Studies also show that utilization management programs can lower usage rates by 15-25 percent.


Portugal stated that most hospitals have no effective blood management program and that laboratories are in an excellent position to apply testing algorithms to reduce unnecessary transfusions and save hospitals significant money as well as reduce adverse events.\(^\text{35}\)

Example – our practice pathway blood transfusion utilization management program would have multiple components, perhaps including an assessment of suppliers, protocols for when to transfuse, coagulation consultative services to help evaluate complex operative cases with microvascular bleeding, etc.

**Quality and Coordination Programs for Specialists** – Lab testing protocols for referrals between providers – our practice can contribute to ACO care coordination by developing automated, protocol recommendations, based on lab and clinical data, for referring between specialists and PCPs. These protocols would be developed in conjunction with the specialists, and might also incorporate pharmacy data, which has the advantage of taking into account patient adherence to therapies. Philip Chen, MD, PhD, Director of Informatics for the Department of Pathology at the University of Miami, is developing protocols such as these and implementing them as EMR applications.\(^\text{36}\)

- The protocols could be developed as a hybrid between “standardization” to mitigate care variations and improve quality – this is critical for ACOs to achieve their quality measures – and individualized care, based on risk assessment from lab and clinical data.

- These protocols might also include indications for procedures, although obtaining physician buy-in for this will be more difficult. However, if the protocols are created and positioned as evidence-based, individualized medicine algorithms, rather than ACO rules, they may be adopted. These could be very powerful cost savings programs, as unnecessary procedures are a huge driver of spending.

Example – our practice pathway, in collaboration with cardiologists and PCPs, could develop an evidence-based, individualized algorithm and protocol for referrals to cardiologists based on risk for cardiovascular/thromboembolic events. The algorithm might take into account not only basic cardiovascular lab tests, and more esoteric biomarkers if the patient has...

\(^{35}\)G2 Intelligence interview with Barry Portugal, President of Health Care Development Services, Inc., June 2, 2011, in “Creating a Value-Driven Laboratory: Opportunities in the New Marketplace,” G2 Intelligence, 2011 Kennedy Information, LLC.

\(^{36}\)G2 Intelligence interview with Philip Chen, MD, PhD, on May 25, 2012
other risk factors, but also effectiveness of therapeutics and adherence data if known. A further protocol might make recommendations for stenting versus medical therapy based on patient risk factors, likely outcomes, etc.

### Offers for Population-wide Management/ACO Leadership

#### Informatics-based risk prediction for Population/Leadership

- Depending on the scope and depth of laboratory and clinical data we have available to us for informatics and data-mining, there may be many opportunities to produce very valuable applications for ACO population management.

- **Subpopulation reference ranges for more precise disease detection**
  
  With sufficient population data, we can use statistical techniques to derive more “individualized” reference ranges for lab tests. Applying these more personalized ranges equates to more clinically powerful testing, including earlier disease detection and more potent risk assessment.

- **Prediction of next year’s high cost patients.** A minority of patients comprise the majority of healthcare spending. A typical split is 20 percent of patients representing 80 percent of costs.

  In Chen’s research he observed that 3 percent of the population each year went from the low spending groups to the highest spending group. In other words, the 5 percent highest spending patients are not all chronically high spenders. This presents an opportunity for a laboratory to develop analytics to help identify these 3 percent, high-risk, “time bombs.” He commented that patients typically in this 3 percent were diabetics who are not well managed and are first time myocardial infarction patients.37

- **Identification of high adverse event areas**
  
  - Applying our expertise in statistical quality control to unusual laboratory test results may allow us to develop applications that alert ACO leadership to potential problems in particular provider areas.

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37G2 Intelligence interview with Philip Chen, MD, PhD, director of informatics for the Department of Pathology at the University of Miami, June 15, 2011, in “Creating a Value-Driven Laboratory: Opportunities in the New Marketplace,” G2 Intelligence, 2011 Kennedy Information, LLC
Example: An early warning surveillance application to identify care units experiencing/about to experience high rates of adverse events. Using laboratory QC process control charting techniques and critical value test reporting frequency “spikes,” a researcher at Ohio State University Medical Center developed an application that predicted units with 2.5 times higher rates of adverse events in the two weeks following the critical value spikes.

A patient adverse event was defined as cardiac injury, cerebrovascular adverse events, major bleeding episode, prolongation of hospital stay, or death. With the lead time provided by the early warning, the care unit can be assessed for operational, quality and resource problems. Also, additional care management services and interventions can be directed at particularly high-risk patients. Although this application likely needs validation, it appears quite promising and would have significant value from both a cost and quality perspective.

**Individualized Medicine Guidance for Population/Leadership** – Development of guidelines for PGx and MDx testing by risk status and cost-effectiveness modeling.

- A component of our practice pathway’s leadership for the ACO is developing a type of molecular testing “formulary,” with associated guidelines or decision trees. Again, the guidelines/protocols for when to test and which tests to use should be individualized based on a patient’s risk status, determined in part by lab results. A major driver will, of course, be the level of clinical evidence supporting a particular indication. Also, our analytic assessment of the various assay platforms will be important in selecting and validating testing systems.

- A new role in this regard for many of us involves an economic assessment of these tests, not from the perspective of the test cost versus its revenues, but from a population health care perspective. This essentially entails conducting value-based economic modeling whereby the test’s impact on subsequent spending and outcomes is compared to not performing the test in various population cohorts with different risk and clinical profiles.

- By working with economic specialists or the ACO, we can help develop these economic analyses and use them to inform decisions regarding when to introduce new MDx and PGx tests into ACO guidelines.

**Quality and Coordination Programs for Population/Leadership** – Pathogen surveillance and/or antibiotic stewardship programs – the opportunity for a tremendous value impact is simply too large to not take a leadership role in advancing whatever infection control/antibiotic stewardship might be in place at the ACO’s facilities at the start. There are a number of ways we might take these programs to a new
level of effectiveness.

As we’ve reiterated, resistant organisms are a major problem, both in community and hospital settings. Although MRSA rates seem to be declining nationally, gram-negative organisms are showing disturbingly accelerating rates of resistance. With the advent of molecular testing for pathogen identification we have a truly effective answer in hand, and we need to utilize our expertise to bring this into routine care in the next couple of years.

A recent study used rigorous analytic techniques and a robust database to estimate the differences in costs between resistant and susceptible pathogen infections in community and healthcare-acquired infections. They found, “Consistent with previous findings, our results from all models indicate that resistant infections lead to generally higher charges and length of stay for both healthcare- and community-acquired infections.” The differences in hospital charges were significantly higher, with an average of $15,626 higher for resistant healthcare-associated infections and $25,573 for community-associated infections. The infections studied included pneumonia, blood-stream and urinary tract.38

Antimicrobial stewardship programs reportedly generate form $200,000 to $900,000 in annual savings from drug costs alone.39

Example – components of a stewardship or surveillance program we could lead include:

- MDx testing protocols integrated into antibiotic pre-prescription guidelines.
- Using MDx testing to direct antibiotic de-escalation.
- Conducting, analyzing and disseminating frequent antibiograms throughout the inpatient and outpatient ACO network, and working with the pharmacy to continuously update and correlate drug usage data.
- Methicillin Resistant Staph Aureus (MRSA) and C difficile screening programs.
- Frederick L. Kiechle, MD, PhD, FCA, medical director of clinical pathology at Memorial Healthcare System, Hollywood, FL, estimates that his institution’s MRSA has generated $8.8 million in cost savings.40

PLANNING FOR THE PATHWAY

The plethora of potential applications, services and programs we might deliver to an ACO for population care management may seem onerous at the outset, but we need only select a subset for our initial practice. This focus should be determined by the priorities of our client ACO and our capabilities and resources.

By targeting the ACO leadership’s highest priorities and needs with a practice pathway program designed to specifically address them, we are significantly improving our negotiating power. For example, are they prioritizing inpatient adverse events, PCP chronic care management, or infections most highly? Perhaps between provider coordination is a concern, or clinician guideline adoption.

The pathway also allows for flexibility in terms of offering multiple axes along which to define our practice focus, as shown in Figure 10. For example, we can start by implementing a practice serving mainly ACO PCPs, or one focused on diabetes, or on infections, etc.

Finally, we need to consider the relative strengths and weaknesses of our group in molecular testing and informatics in determining which focus to pursue. We will eventually need to bring in expertise and resources to ensure both of these capabilities are strong, given they are key engines for this opportunity.
Figure 12: Possible Axes for Defining a Focused Coordinated Population Care Practice

Provider Setting
- PCP Focus
- Hospital Focus
- Specialty Focus
- Community Focus

Application
- Risk Prediction
- Utilization management
- Chronic care management
- Safety/adverse events

Disease Area
- Diabetes
- Cardiovascular
- Infectious
- Oncology
- Etc.

Technology
- Informatics
- Molecular Testing

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
Getting a Seat at the ACO Table

Our first hurdle is getting “a seat at the ACO table” by establishing to the executive leadership that our pathology laboratory group has a value proposition of significance. This requires some type of evidence showing that our pathway interventions can produce cost savings in whatever targeted areas we have chosen. This evidence can be a combination of peer-reviewed studies and pre- and postobservational data.

For some services and applications that require development resources, there is a chicken and egg problem here, in that we cannot generate the evidence until we have developed the pathway interventions. In this case, we need to create a business proposal focused on an investment case for resourcing these interventions, with the return investment projections based on the literature or pilot studies.

After convincing the ACO that we have significant economic value to add, we move to negotiations regarding compensation. As there are no market precedents yet to draw upon, we have the opportunity to determine our own financial destiny here. First, we need to clarify that ACOs continue to be paid by Medicare on a fee-for-service basis, so our testing revenues continue, although they may decline due to utilization management by the ACO.

If our pathway interventions allow for discrete measurement, we have the option of using the first year to prove our case and ask for an attractive share of bonus payments, contingent on hitting target savings metrics. Another possibility is that the ACO is cautious and wants to evaluate our performance the first year, in which case we might negotiate a service contract with a small, performance-based bonus.

In terms of what percentage of the ACO’s shared savings bonus we might negotiate, we can start by looking at what approaches are being used by ACOs currently. Each ACO determines its own payment allocation methodology, and these are not generally made public. In a recent report on ACO payment allocation by the actuarial firm Milliman, a variety of methodologies were described, including divisions based on volume of services, RVU counts, cost per episode targets, and responsibility by service line.

The complete report on all of the Practice Pathways to be published later this year will describe implementation plans for this Pathway, as well as further details on the Pathway itself.

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CONCLUSIONS

For ACOs, integrated delivery networks and Medical Homes to implement population health management, there is a clear need for both a population-based view of care delivery as well as individualized, patient-centric care. Pathologists alone have the dual approach that marries “top-down” population lab informatics applications that systematize care with “bottom-up” patient-specific, molecular testing tools that individualize treatment guidelines. We also have particular expertise in other areas critical to population health management, such as test analytics, instrumentation, and infectious disease.

The population health management model also demands novel approaches to risk management and prevention. Because pathologists deliver the most potent of predictive tools in health care – in the form of individualized diagnostics and biomarkers – and because lab testing is performed frequently, pathologists are uniquely able to provide a steady supply of temporal predictive data to keep risk assessments fresh. Pathologists also have the expertise to utilize this data in powerful predictive applications that can prevent adverse events.

In most circumstances, a pathology group that was already contractually tied to either an ACO hospital or ACO physician organization (one in which a physician organization rather than a hospital-led organization contracts with the payer) for diagnostic testing services will be the best candidate for this pathway. Because there are many different types of ACOs, there will be significant variability in how a pathology group approaches implementing this pathway.

The way forward will vary from practice to practice depending on the highest priorities of the ACO. Step one for any practice will involve working with its local ACOs or the groups with which they already have contracts to identify the highest priority needs and then responding with services based on core capabilities that deliver clear value. Most practices will need to start with targeted offerings and then expand over time to add new capabilities, such as molecular testing expertise, and to develop additional services.

Compensation for these services will likely be based on value payments, such as ACO shared savings bonuses. To demonstrate the value of the Coordinated Population Care Pathway to the ACO, we will need to develop a business case that documents oppor-
tunities for cost savings and increased quality and allows us to negotiate a share of the ACO’s net savings.

The number of ACOs is growing and the ACO model is maturing, so ACOs are rapidly developing the solutions they need to implement population health management. If pathologists want to play a larger role than data suppliers in this new business landscape, they must act now and apply their skills and expertise to design the valuable services ACOs need.
PROMISING PRACTICE PATHWAYS™:
PATIENT DIAGNOSTIC SERVICES CENTER

COLLEGE OF AMERICAN PATHOLOGISTS
As the health care system transitions to value-based purchasing and coordinated care, health care delivery is becoming more patient-centric. Not only are hospitals and providers using patient satisfaction measures as key quality indicators, but new approaches to health insurance are shifting costs to patients and turning them into health care consumers.

These shifting market dynamics are raising the bar for health care providers. In addition to providing quality clinical care, they must now cater to their patients as true consumers who shop around for affordable and convenient services with quick turnaround-times and low error rates.

At the same time, ACOs, hospitals and other providers are looking for ways to improve clinical quality and decrease costs. One way to improve quality is to reduce diagnostic errors both in the laboratory and in the clinic, where overburdened clinicians are often called upon to interpret fragmented and asynchronous results. Yet much of our health care system’s current model for performing diagnostic testing on patients—be it laboratory, pathology or imaging testing—is a poor fit with these new needs. Diagnostic testing offers few to no conveniences, in terms of co-location, coordination and scheduling, to patients who need to have multiple types of tests performed. Also radiology and laboratory medicine/pathology operate primarily as silos, which can negatively impact the accuracy of the final diagnosis.

Our “Patient Diagnostic Services Center” Pathway opportunity involves developing new models for diagnostic testing services. The keys to addressing these market needs are integrating across types of testing, centering services on the patient, and focusing on operational efficiency and quality. A patient testing facility with integrated, quality-focused and coordinated diagnostic services could meet this growing need for increased accuracy, efficiency and convenience.

To be successful in this emerging marketplace with such a model, pathology and imaging services must realign themselves. There are historic turf conflicts between radiologists and pathologists to be overcome, for example. However, given that the value-based market is realigning provider incentives, and given the strong business case for our collaboration, we see these obstacles as surmountable.

We’re offering this pathway guide because we believe that the market is ready for innovative ventures in diagnostic testing. Pathology groups that provide forward-looking Patient Diagnostic Services are likely to grow with this new consumer-oriented marketplace.
In its most enterprising forms, this pathway can be a risky endeavor. But by leveraging partnerships and existing provider relationships, this pathway can be accessible across several practice types, settings, resource levels and capability portfolios.

Because this pathway is truly novel in the U.S. market, this guide does not present a “how to” for every practice, but it does offer examples of possible approaches in multiple types of practices. Hopefully our guide gives you a sense of (1) the attractiveness of this practice model both professionally and financially, (2) the opportunities to improve health care quality and at the same time embrace what could otherwise be a daunting shift to health care consumerism, and (3) the attainability of this opportunity.

The guide is structured as follows:

- Market Need: A New Way to Perform Diagnostic Testing Services
- Market Opportunity
- Practice Pathway: Into the Patient Diagnostic Services Center
- Examples of Patient Diagnostic Services Centers
- Implementation Plans: The Way Forward
MARKET NEED: A NEW WAY TO PERFORM DIAGNOSTIC TESTING SERVICES

Hospitals and providers increasingly have their compensation tied to quality measures and their health care spending rates, and patients have now become true health care consumers. As a result, diagnostic testing services’ suboptimal performance in the areas of patient experience, costs and accuracy may begin to have negative impacts financially on any provider group being compensated under alternative payment programs – i.e., non-fee-for-service (NFFS).

Providers have four major types of needs that might be addressed by an improved system for patient diagnostic testing services:

- Providing a high quality patient experience,
- Attracting health care consumers,
- Lowering health care spending,
- Improving health care quality/avoiding errors and adverse events.

These needs present an opportunity for us to better engage these value-driven clients and consumers by designing next generation diagnostic service models. Indeed, in a health care market system transitioning to value-based purchasing, coordinated-care and consumerism, the current antiquated model for delivering pathology and laboratory diagnostics has deleterious consequences. To be successful, this new model must be patient-centered, efficient/LEAN, coordinated and integrated across testing services.

Patients Matter: A High Quality Experience

Providers need all aspects of patients’ health care experiences, including the diagnostic testing process, to be convenient, pleasant, understandable, streamlined, timely and error-free because they are now being measured on how well their patients judge the quality of their experience. These metrics are being used in both inpatient and ambulatory value-based payment programs, and in many cases are being published by payers to drive consumer comparative shopping.

For example, of Medicare’s ACO shared savings program’s 33 quality measures used to determine payment, seven are tied to patient experience.¹

¹http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_QualityMeasures.pdf
According to the “Clinician and Group Consumer Assessment of Health Care Providers and Systems” (CAHPS) patient satisfaction surveys, topics include:

- Getting Timely Care, Appointments, and Information.
- How Well Your Doctors Communicate.
- Patient Rating of Doctor.
- Access to Specialist.

Under Medicare’s “Value Based Purchasing (VBP)” program, patient experience scores have been proposed that represent up to 30 percent of hospital incentive payments. This puts patient experience at the top of hospital executives’ agendas in the near future. Beginning in FY13, the program will start to reward hospitals for improving and maintaining high levels of measurable quality:

“Although the differences in payment for the identified groups may not seem significant, facilities receiving a [total performance score] TPS of 0 will have a 1.0 percent reduction in revenue. Similarly, hospitals achieving a TPS grade of 100 will receive a 1.6 percent bonus. In future years, these extremes will double. Further, hospitals will need to be prepared to explain their quality measurements to all public interests, such as patients, physicians, and insurers. Hospitals that are most successful in achieving high levels of quality will also have the opportunity to promote their accomplishments to public interests. VBP is a program under which "average" hospitals do not fare well.”

This trend affects diagnostic testing centers directly. Those that do not provide patients with timely, convenient, high-quality services might hurt the patient experience and result in value destruction, so there is a need and opportunity to propose new patient-pleasing diagnostic testing centers to our hospitals, medical centers or ACOs. Diagnostic testing is of great interest to patients, so solutions designed to improve patient engagement are likely to have outsized positive impacts. For example, a recent survey by Mayo Clinic found that of 1,972 patients, 70 percent were very interested and 20 percent somewhat interested in using a Mayo Clinic website to view their laboratory test results.

Overall there are sufficient market

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2Presentation: “National Provider Call: Hospital Value-Based Purchasing,” Centers for Medicare & Medicaid Services, July 11, 2012

3Ed Klein and Paul Shoemaker, “Value-based purchasing: a preview of quality scoring and incentive payments: findings of a recent study suggest that some types of hospitals participating in CMS’s Value-Based Purchasing (VBP) program can expect to perform much better than other types,” Health Care Financial Management, January 1, 2012

4Patrice Wendling, “Patients want online access to test results Stat,” Skin and Allergy News, May 1, 2012
drivers to make a business case that positions us as value generators rather than as cost centers. Conveniences in scheduling, parking, childcare, payment, instructions, receiving reports and aftercare can create loyal patients. Similarly, a streamlined operational flow and coordinated approach to developing a diagnostic testing plan is likely to instill a sense of security and confidence in the patients regarding the medical care they are receiving.

Consumers Are the New Market
Not only must hospitals and provider groups please their patients, they must also compete for their patients’ business. Patients have become savvy consumers of health care services out of necessity, because they are bearing more of the burden of health costs.

“According to our modeling of the 2010 flow of health care funds, consumers now pay more in health care costs than do employers. This cost is split among direct payment of non-covered services, out-of-pocket expenses after insurance, and the consumers’ share of premium expenses,” writes McKinsey.

A trend towards high-deductible insurance is driving this shift:

- One survey found that 70 percent of large companies indicated they will offer high-deductible insurance by 2013. Nearly a fifth of the firms that responded indicated that this high-deductible coverage would be the only option by 2013.
- In the Kaiser Family Foundation’s 2011 employer survey, 17 percent of the covered workers were enrolled in a high-deductible plan, up from 4 percent in 2006.
- A RAND researcher believes these “consumer-directed plans” could reach the 50 percent enrollment level over the coming decade.

High deductibles are forcing patients to shop around to reduce their out-of-pocket costs and to be more selective about the health care they pursue. According to a RAND study, “Families in consumer-directed plans used fewer brand-name drugs, had fewer visits to specialists and had fewer elective hospital admissions than families in traditional plans.”

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This new dynamic, where patients don’t just follow doctor’s orders and let their insurance take care of the costs, is putting the onus on health care providers to meet – on top of demands for their expert medical services – the demands of consumers who want convenience, quality and affordability.

For example, for diagnostic services, patients are shopping around for “retail” level customer services. “We are seeing that patients are willing to go to other locations if they can be seen sooner,” says Jennifer Nichols, director of patient access at Spectrum Health in Grand Rapids, MI, where same-day scheduling is now offered to radiology patients. “They will often call multiple hospital or service providers.”

Since hospitals and doctors are also vying for their patients’ business, they are also attracted to same-day diagnostic service. “Provider offices prefer this option,” she says. “They are eager to have the diagnostic results back in order to proceed with patient care.”

Patients also want to know up-front what their tests and procedures are going to cost them so that they can make informed choices. But the costs of diagnostic tests and procedures vary widely. A hernia repair might cost between $4,026 and $7,498, and a colonoscopy could cost from $1,450 to $2,973. Consumers are realizing that higher prices don’t always mean better service or higher quality. So they are shopping around and sharing information with one another on the Web.

Some providers are offering “bundled,” flat-rate pricing to address this consumer market, while others are developing alternative solutions. Cancer Treatment Centers of America (CTCA) recently launched an example of a flat-rate diagnostic testing bundle for consumers, as described in the “High-Performance Pathology for High Value Oncology” Practice Pathway chapter. Their offerings include a comprehensive set of pathology and radiology testing with a guaranteed five-day turn-around time, set package price and personalized care plan with suggested next steps, and are priced at $12,200 for a breast cancer patient, $11,400 for colorectal cancer, $14,500 for lung cancer, and $10,000 for prostate cancer.

Meanwhile, insurers are giving patients cash incentives to select lower-cost care: “Some Anthem Blue Cross and Blue Shield members in New Hampshire, Connecticut and Indiana can receive $50 to $200 if they get a diagnostic test or elective procedure at a less expensive facility than the one their doctor recommended. The offer covers nearly 40 services, from standard radiology tests such as mammograms and MRIs to such surgical procedures as hip and knee replacements, hernia repair, bariatric surgery and tonsillectomies.”

9“Patients will expect same-day scheduling,” Hospital Access Management, July 1, 2012.
The need to satisfy patients as consumers making choices about care based on quality, comfort and price represents a completely new dynamic in diagnostic testing. Patients need “retail” level customer services, clearly labeled price tags, one-stop shopping, and timely results.

**Lowering Health Care Spending**

The denominator in the value equation is spending, or rather lowering spending through cost savings. Value-based payments are all about the bottom line. So most providers are very focused on lowering their costs these days using means that go beyond the typical chase to stay ahead of reimbursement cuts.

“According to [the November 2011 HealthLeaders Intelligence Report], 55 percent of leaders said that even with annual cost savings from initiatives over the past three years, they need to pull an additional 4 percent-10 percent out of their operating budgets, and 23 percent said they need to pull an additional 11 percent or more. To achieve this magnitude of savings and maintain it requires organizations to shed reactive, tactical approaches in favor of deliberate, well-planned approaches. Several health care systems have achieved financial and clinical rewards through different approaches—using a value management methodology, sharing costs with partners, redesigning inpatient care, and leaning on Lean process techniques.”

In this context, the estimated 8 percent of costs that laboratory, pathology and radiology testing services together comprise can be financially material to a provider organization. If the diagnostic testing service processes or facilities are wasteful, inefficient or otherwise driving avoidable costs, leadership will be interested in pursuing remedies. We can respond by reducing inefficiencies by implementing Lean programs and integrating services.

Another approach provider organizations are taking to lower their costs and simultaneously respond to the consumer health care market is to transition services to outpatient care:

“In the early 1990s, outpatient care accounted for only 10 percent to 15 percent of hospital revenue, says Guy David, an associate professor of health care management at the Wharton School of Business at the University of Pennsylvania. Today, that figure...

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12 Shaping sustainable cost control: HealthLeaders magazine, Health Care Leadership Review, September 1, 2012

13 This estimate is based on IMS Institute for Health Care Informatics’ commercially insured database for outpatient claims, and is discussed in the context of all of spending because outpatient expenditures are almost three times as much as inpatient—56 percent vs. 20 percent of total costs. Reference—“Health Care Spending Among Privately Insured Individuals Under Age 65,” IMS Institute for Health Care Informatics, February 2012
Outpatient care takes the inside track; Ambulatory services continue to account for growing share of systems' revenue, as they work to bring care closer to the customer, Modern Health Care August 6, 2012

Outpatient care takes the inside track; Ambulatory services continue to account for growing share of systems' revenue, as they work to bring care closer to the customer, Modern Health Care August 6, 2012

S Snyder and D Stampfli, “Ambulatory care offers significant opportunities for lenders: the rise of outpatient services and other health care trends will strengthen this sector,” The RMA Journal, June 1, 2011

Outpatient care takes the inside track; Ambulatory services continue to account for growing share of systems' revenue, as they work to bring care closer to the customer, Modern Health Care August 6, 2012

A number of factors are driving this trend. For example, less invasive technologies allow procedures to be performed with less need for long-term observation. An estimated 60-70 percent of all surgeries are done on an outpatient basis.15

The primary forces moving care to the ambulatory settings are financial, though. Estimates suggest that outpatient services provide nearly two-thirds of a hospital’s margin.

“Significant growth in outpatient volumes for imaging, rehabilitation, endoscopy, and other services has created a wave of ambulatory care development by hospitals and other providers (primarily single-service centers such as ambulatory surgery centers, diagnostic imaging centers, and physical therapy satellites).”16

Hospitals and health systems are even developing new health care “malls” that provide patients with the ambulatory services they need. These malls deliver a retail-quality customer experience and, at the same time, they are reducing the costs of care by focusing specifically on outpatient services.

As an example: “WellStar Health System envisions a health care mall, of sorts, where mom can get a mammogram, dad can refill his cholesterol medication and junior can get his sports physical, all in the same place.”17

There are a multitude of initiatives providers are pursuing to lower their spending base. What we can take away pertaining to our diagnostic patient testing services is potential opportunities for adding value through reducing costs. These might include moving services from inpatient to ambulatory settings and removing inefficiencies and wastes from our services through integration and Lean programs.
Improving Quality

The numerator in value is quality. Providers in value-based payment programs must manage and improve a range of quality metrics. We have already discussed their need for excellence in patient quality measures, so we now turn to the remaining clinical quality issues.

Providers in reform settings get a high return on investing in clinical quality improvement, whether those investments target particular metrics or reduce avoidable and costly complications. Simply put, relentlessly pursuing high quality is a new priority for value-compensated providers.

This need for improved clinical quality also relates to diagnostic testing services. Radiology, pathology, laboratory medicine and other diagnostic testing modalities are typically ordered separately, performed in different areas, interpreted without the benefit of other patient test results, and reported independently of each other. In short, the legacy model for diagnostic testing services is a siloed system. This system’s lack of integration can contribute to diagnostic errors that lower quality.

Fragmented Testing and Clinical Errors

There are two primary sources of inaccuracies that reduce clinical quality. The first derives from diagnostic errors when the clinician receives, aggregates and interprets patient results. The second comes from diagnostic errors made by the pathologists or radiologists during evaluation and reporting of the test results.

The clinicians’ diagnostic errors are a more frequent and significant problem. As discussed in the “High-Performance Diagnostic Services Practice Pathway,” clinical diagnostic errors include cases in which the clinician misdiagnoses, misses making a diagnosis or experiences a clinically significant delay in making a diagnosis.

These errors are common, serious and financially significant. Diagnostic error experts Paul Epner, MBA, MEd, and Michael Astion, MD, PhD write, “A variety of studies, including comparison of autopsy results with physician diagnoses, suggest that such errors occur in an astounding 10–15 percent of diagnostic encounters.”

Clinical diagnostic errors can have a significant impact on clinical quality:

- They “make up a large fraction of all medical errors and cause substantial suffering and injury,”
- They “probably cause 40,000-80,000 preventable deaths an-

18Paul Epner, MBA, MEd, and Michael Astion, MD, PhD, “Focusing on Test Ordering Practices to Cut Diagnostic Errors.” Clinical Laboratory News: Reducing Diagnostic Errors, July 2012
nually in U.S. hospitals alone, and these estimates fail to account for mortality from ambulatory misdiagnosis and non-lethal morbidity due to diagnostic error.”

- They hit the bottom line, sitting in the top three most expensive of all medically adverse events, according to one investigation.

- Failure to order appropriate diagnostic or laboratory tests was a contributing factor in 55 percent of cases.

- Incorrect interpretation [by clinicians] of diagnostic or laboratory tests contributed to 37 percent of cases.

- Failure to retrieve diagnostic or laboratory test results was a factor in 13 percent of cases.

Furthermore, in a study of diagnostic errors by internists:

- Cognitive errors were identified as the cause in 92 percent of the wrong diagnosis errors.

- The most common cognitive error was faulty synthesis or processing of data, comprising 83 percent of identified mistakes.

- A common “faulty data gathering” error was clinicians having problems with test coordination.

At the same time, testing is becoming more complex, multimodal and voluminous as medical science advances our molecular understanding of pathology. In turn, diagnosis is becoming more challenging. The task of synthesizing test results is needlessly made more complex when data arrives asynchronously and without an integrated interpretation.

One example supporting the idea that integrating diagnostic information can lower clinician errors comes from Michael Laposata, MD, PhD. Laposata ran a coagulation interpretive service while at Massachusetts General Hospital that operated as follows: “Information regarding the patient’s past clinical conditions and other related test results are integrated into the interpretation to provide a clinically relevant, patient specific interpretation of the patient’s laboratory test results.” He reported that 72 percent of the physician users

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22 Paul Epner, MBA, MEd, and Michael Astion, MD, PhD, “Focusing on Test Ordering Practices to Cut Diagnostic Errors,” Clinical Laboratory News: Reducing Diagnostic Errors, July 2012

he surveyed “felt that the interpretation helped avoid a misdiagnosis.”

Cancer diagnostics are also moving towards test integration. As multiple test modalities beyond histopathology began driving the diagnosis and treatment decisions of hematologic cancers, the need for a new approach to integrating findings grew stronger. Diagnostic reporting quickly moved to patient-centered, integrative, interpretive summaries that incorporated lymph node and bone marrow evaluations, flow cytometry, cytogenetics, molecular testing, FISH, etc. Once hem-oncs were aware of this alternative service, they responded with a tremendous demand for these integrated reports.

### Fragmented Testing and Diagnostic Errors

Hematologic malignancies also provide an illustration of the second source of errors deriving from testing services fragmentation: errors made by either pathologists or radiologists in evaluating test results. Given the diversity of tests involved in diagnosing hematologic malignancies, an integrated approach to analyzing and interpreting the findings and preparing a comprehensive report is critical.

A report by a Health and Human Services department panel asserted that, “Improvements to the collaborative workflow processes between radiologists and pathologists are critical in cancer diagnoses. Implementing a system or process that allows optimal communication exchange between radiology and pathology will provide immediate benefits for practitioners and patients.”

The United Kingdom has linked its diagnostic error problems in hematologic malignancies to fragmented diagnostic testing and launched an initiative to create integrated hematopathology testing centers about ten years ago.

This theme of diagnostic integration will only accelerate as digital pathology and information technology/cloud computing disseminate widely. Not only will we have digital imaging, but informatics will merge and integrate sequencing data, laboratory data, and clinical data.

Further, image-guided biopsies are driving radiology and pathology together. These biopsies have become increasingly popular, usurping surgical biopsies in recent years. According

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25The ASPE (Assistant Secretary for Planning and Evaluation) Technical Expert Panel on Improving Cancer Policy Research through Information Technology

26“Improvements to the Collaborative Workflow Processes between Radiologists and Pathologists are Critical in Cancer Diagnoses. Implementing a System or Process that Allows Optimal Communication Exchange between Radiology and Pathology Will Provide Immediate Benefits for Practitioners and Patients.”

27Robin Ireland, “Haematological malignancies: the rationale for integrated haematopathology services, key elements of organization and wider contribution to patient care,” Histopathology 2011, 58, 145-154
to the Radiological Society of North America, even in 2008 radiologists were performing about 55 percent of all biopsies.\textsuperscript{28}

The International Society for Strategic Studies in Radiology puts the need succinctly: “What is required is a new concept of “integrated diagnostics”: the convergence of imaging, pathology, and laboratory tests with advanced information technology (IT).”\textsuperscript{29}

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\textsuperscript{29}GP Krestin et al. “Integrated diagnostics: proceedings from the 9th biennial symposium of the International Society for Strategic Studies in Radiology,” Eur Radiol, published online June 2012
\end{flushright}
MARKET OPPORTUNITY

We have the opportunity to launch a new model of diagnostic testing center, in collaboration with our radiologist colleagues. This patient-centered, integrated diagnostics service center is a powerful business opportunity because it answers multiple market needs, such as improving quality, decreasing costs and increasing consumer business, for multiple stakeholder groups.

Although traditionally pathology and radiology have had challenges collaborating professionally, given the move away from fee-for-service and toward a value-based market many turf battles between specialties may be minimized as incentives realign. Particularly in ACO settings, the incentives are no longer to perform as many tests as possible or increase patient referrals, as the top line is not what drives compensation.

We believe that as the business incentives drive both specialties toward collaboration, legacy competitive issues can be overcome.

The value-based purchasing market is not well served by a fragmented, inconvenient, inefficient diagnostic testing patient services model. The market needs a testing service model that:

1) Provides a high quality patient experience, given the importance of these measures in the value marketplace.

2) Can attract health care consumers with “retail-like” services at relatively lower price points and high quality.

3) Can help lower health care spending, perhaps with efficiencies or by moving services to ambulatory settings.

4) Can help improve diagnostic accuracy and overall clinical quality.

Meanwhile, as science and technology push diagnostic testing modalities together, we are on the brink of integrating diagnostic interpretation through information technology. Also, we appear interested in collaborations with radiologists. According to a 2009 CAP survey, 88 percent of responding pathologists indicated that they would like to review radiologic images.30

This is evidenced through a collaborative effort between radiology and pathology at the University of Kan-

30College of American Pathologists, Diagnostic Intelligence and Health Information Technology (DIHIT), June 2009 survey
sas, described in a later section in this document. In this example radiologists and pathologists have crossed their respective borders and recognized that they are not competing practices but rather complements of one another with congruent goals.

So the pieces seem to be coming together for us to take action and develop a new, integrated patient testing model that addresses these market needs and takes advantage of the technology winds that are blowing.

Synthesizing all of these market dynamics, one clear picture for our market opportunity emerges – an ambulatory, integrated patient diagnostic services center (IPDSC, or “The Center”). In this model, pathologists and radiologists would collaboratively operate free-standing centers that offer convenient, high quality, efficient, “one-stop” diagnostic testing for a particular disease area or diagnostic question.

Our “Patient Diagnostic Services Center” Practice Pathway provides the rationale and, ultimately, a guide for developing these IPDSCs.

In this section we’ll look at:

- The Center as a disruptive idea whose time has come.
- Design elements for The Center.
- Market segments and types of Centers.
- Business considerations and market estimates.

The Center - A Disruptive Innovation for a Ready Market

To our knowledge, there are not yet any examples in the United States of integrated (e.g., pathology and imaging) patient testing centers that address the market needs we’ve described. This likely reflects the timing of market demand.

It is only recently that 1) a critical mass of consumers with high-deductible health plans paying first dollar for imaging tests (except preventive screening) has emerged, and 2) a critical mass of provider organizations such as ACOs paid based on value and looking to move to patient-friendly, ambulatory services has become a reality. Without the economic demand for higher quality, lower costs, and/or retail services, sufficient financial impetus for re-engineering patient testing services probably would not be available.

But given the market dynamics, there is financial impetus. Further, there is a need for a disruptive innovation in the diagnostic services arena that will help shape and strengthen this new value-based market by acknowledging that there is a new set of consumers to cater to. In fact, there is a need for disruption across the entire health care services arena:

“With a rapidly aging population increasing demand for services and highlighting system inadequacies, traditional approaches to cost containment, such as provider discounts and cost shifting, will not suffice,” writes David
Gruber, MD, director of the health care industry group of global professional services firm Alvarez & Marsal, and author of the report, “Getting Much Closer to the Cost Precipice,” which provides a detailed look at why the options on the table will not accomplish what they are supposed to.

“While the Affordable Care Act is often held up as the solution to the country’s health care costs problem, Gruber said, the real solutions will come from business leaders in local communities finding business models that will disrupt the system.

“The question is, given where we are today and given where the marketplace is going, who will be best positioned to take advantage of those changes that are inevitably going to come,” he said. “What you need is the innovator.”

An Innovative Center Example: Before Its Time
A case-in-point was made back in 2008 by the then founder and chair of a rapid diagnostic testing center for breast and prostate cancer: Ronald S. Weinstein, MD, Chairman of UltraClinics Inc. Using digital pathology, based on an award-winning technology from the University of Arizona for digitizing slides called “DMetrix,” and microwave-based rapid tissue processing, these clinics provide answers on biopsies within 24 hours of the biopsies being taken, alleviating the agony of waiting and anxiety for the majority of patients. The model incorporates integration of imaging and pathology, as well as a laser focus on what the founder had identified as the most important patient issue in mammography biopsies: waiting for results.

Three years post the 2005 launch, although UltraClinics’ model was operating well from the patient, technical and clinical standpoints, it was not yet generating the volume they anticipated. A journalist who explored the UltraClinics story concluded, “UltraClinics, for now, is an example of the inertia that can strike medical advances— not because the core ideas don’t work, but because the health care delivery apparatus isn’t designed or prepared to support them. The irony is that while UltraClinics sits more or less motionless, its founder is almost certainly correct when he says that what the company offers is a model for how medicine will be practiced, perhaps in the near future.”

In fact, Weinstein was quite prescient in his identification that consumer demand was the missing ingredient

for the business model: “UltraClinics is dependent on patient-driven health care and patients having a health care account. That is the carrot for us, and we’re trying to design a business model that will thrive in that environment. … The people behind UltraClinics like to believe – and probably pray for – the day when consumer-driven health care is available on a wide basis. That’s necessary if we’re going to bundle these services.”  

Currently, UltraClinics does not appear to be in commercial operations, at least as can be determined by public websites. While other, isolated, same-day, integrated imaging and biopsy services may exist in the United States, commercial centers are not prominent or widespread.

However, rapid assessment breast clinics, relying mostly on a triple assessment of clinical examination, mammography and fine needle aspiration, are relatively common in parts of Europe, for example. In fact, developed regions outside of the United States commonly employ comprehensive patient testing centers that include imaging, pathology and laboratory testing, according to experts in the area, such as Karim E. Sirgi, MD, President, UniPath P.C.  

**Design for a New Model**

As depicted in Figure 1, our integrated patient diagnostic services center would address the four market needs as follows:

1. **High quality patient experience:**
   - Rapid results – some centers might focus on being same-day or “rapid” clinics, such as rapid breast clinics in Europe, where patients can get mammograms and preliminary biopsy results if indicated within one-two days. Regardless, generating test results as soon as possible will be a top priority.
   - High quality – the clinical quality of the testing center’s services will be important to patients and consumers and evident in the sophistication of technology and testing used, staff credentials, ubiquity of Lean and Six Sigma throughout operations (and transparent in patient service flow), and use of digital pathology and radiology for quality control consultations.

2. **Attracting health care consumers:**
   - Conveniences – e.g., community and ambulatory setting, same-day scheduling, coordination of all types of testing, onsite daycare, free and ample parking, extensive patient edu-

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34G2 Intelligence interview with Karim E. Sirgi, M.D., President, UniPath P.C., May 24, 2012
cation pre- and post-procedures, etc.

- Pricing – for consumers, prices would be relatively low, and payments would be convenient, with credit card billing and financing programs offered.

3. Lower spending/cost savings:

   The center’s ambulatory/community setting instantly lowers costs compared to inpatient services.

   Designing the center from the start based on Lean and Six Sigma will drive waste and inefficiencies out on a continuous basis - i.e., has been shown to lower costs.

   The center will be designed to grow to realize economies of scale, through, for instance, either contracts with ACOs, or organic consumer market growth by being sited to draw from a large catchment area.

   With experience and accumulation of evidence the center can develop diagnostic algorithms that guide decision making regarding which tests to order. Modeling has shown that these algorithms can save money by avoiding unnecessary testing and downstream services.

4. Improve clinical quality/diagnostic accuracy:

   Leveraging individualized planning, technological integration and evidence-based test interpretation - e.g., a diagnostic specialist, likely pathologist, orchestrates (in collaboration with multi-specialty team) the testing plan. As findings are produced, team reviews and adjusts plan accordingly, as indicated. Diagnostic specialist creates integrated, interpretive report at conclusion, with treatment recommendations as indicated. This integrative, interpretive approach has been shown by Laposata, in the area of coagulation, to avert errors in the area of coagulation, according to his clinicians.35

   Lean and Six Sigma – the very high quality operational processes that result from an organization dedicated to Lean and Six Sigma will carry over to reduction in errors in diagnostic testing clinical quality.

   Volume-based advantages – designed to reach high volumes in targeted testing areas, and to leverage this experience for continuous quality improvement clinically via a volume-advantaged learning curve.

Figure 1: New Patient Diagnostic Services Center Model – Designed to Address Value-Based Market Needs

- Integrated Dx service modalities
- Interpretive reporting
- Six Sigma

- Ambulatory setting
- LEAN operations
- Algorithmic optimization
- Economies of scale

Clinical Quality

Cost Savings

Patient Experience

Health Care Consumers

- Co-location and scheduling conveniences
- Patient-centered
- Rapid results

- Community setting
- Retail-level services
- Low prices and financing
- High quality

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
We can distill these strategies into six “design elements” for The center’s model, as follows:

1) A community and ambulatory setting.
2) Integration of testing modalities (including imaging).
3) Operations based on Lean and Six Sigma.
4) Use of “high touch” customer services.
5) Reliance on advanced IT and automation systems through operations.
6) Catchment and facility economies.

As shown in Figure 2, with one exception, each of these design components drives value improvement targeted at more than one market need area, so the overall impact can be thought of as additive or synergistic. In business model economics, this cross reinforcement between design elements and value propositions suggests a robust foundation.

**Figure 2: How the Design Elements of The Center Align with Key Market Value Propositions**

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
Market Analysis: Market Segments and Types of Testing Centers

Given the multiple value propositions offered by our vision for a patient diagnostics center, there are several stakeholder groups who might be clients, partners or investors. Our potential markets include ACOs, hospitals and health care systems, academic medical centers, health plans, physician organizations, consumers, private investors, and radiology imaging companies.

We can also analyze our patient diagnostics services center market in terms of the types of centers, as there can be a spectrum of “flavors” along two dimensions (see Figure 3):

- The “conditions or therapeutic areas” dimension – the center might be a breast clinic with mammography and biopsies and rapid results, or a broader therapeutic specialty area such as gastroenterology or hematologic malignancies, or a “one-stop shop” evaluation for newly discovered masses.

- The “value proposition” dimension – the testing center might focus more toward the clinical accuracy, cost savings and streamlined testing operations or toward consumer services and low pricing for test bundles.

As the purpose of the pathways is to ensure our participation in the value marketplace, we want to advance our patient testing services model toward delivering and documenting improvements in quality and decreases in costs.
Assessing Potential Target Clients

The best target client – e.g., ACO, hospital or direct to consumer – will depend on which of these various patient testing center designs is used. Three examples illustrate potential clients:

- A **hospital** based on only fee-for-service revenues might be most interested in a patient testing center that focuses on attracting consumers, but also on lowering its cost base and (as a potential side benefit) helping to avert readmissions.

  For example, there are a few reports recently of hospitals acquiring U.S. community imaging centers and relaunching them as broader testing centers. One such case occurred in July 2012, when an Ohio medical center acquired an imaging facility located next to an ambulatory surgery center for about $800,000. The ambulatory imaging center includes a laboratory and radiology services, and the new owner is now calling the facility “Fairfield Medical Diagnostic Services at River View.”

  [36]Sabrina Rodak, “Fairfield Medical Center in Ohio Buys Imaging Center for $800k,” Becker’s Hospital Review, July 11, 2012
• An ACO might be most interested in a patient testing center that offers value in the form of cost savings and improved outcomes through better diagnostic accuracy.

• The new health care consumers with high-deductible plans, numbering about 13.5 million as of May 2012, will be interested in value, too, in the form of low testing prices and high quality, along with conveniences and good service.

The ACO and hospital market segments are likely the most interesting in the near term, with consumers being a close third. Let’s briefly review the ACO sector, although we have covered this topic in other pathway chapters, particularly in the “Coordination Population Care Services” practice pathway chapter.

The ACO market is substantial, growing quickly, and dominated by the private sector. Many analysts estimate there are now more than 300 operating ACOs in the country. Susan Dentzer, editor of Health Affairs, remarked at the Third National Accountable Care Organization Summit in June 2012, “300 ACOs are now up and running, they are no longer unicorns.”

Furthermore, given that “ACO news releases show increased activity by payers in the expansion of their ACO partnering with providers and providers showing growth in the number of physicians joining an established ACO,” and that “more than 400 organizations have submitted notices to apply for the CMS 2013 ACO program,” some analysts expect there to be up to 600 ACOs in 2013.

According to Leavitt Partners’ tracking of 221 ACOs as of May 2012, these ACOs were sponsored by hospitals (53 percent), physician groups (31 percent), payers (13 percent) and community-based organizations (2 percent).

ACOs sponsored by physician groups may be particularly interested in our patient testing centers, because they are particularly focused on providing as many services as possible in an ambulatory setting, and do not have legacy inpatient imaging units to navigate in this regard.

As we discussed earlier in the chapter, the hospital market is also an attrac-

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38Patricia Salber, “I Think I Saw a Unicorn – An Update on ACOs,” The Doctor Weighs In, June 10, 2012
40David Muhlestein et al. “Growth and Dispersion of Accountable Care Organizations: June 2012 Update,” Leavitt Partners, June 2012
tive opportunity, because hospitals are pursuing new sources of ambulatory service revenues, especially those that might attract consumers. This may be an ideal opportunity for those of us in community pathology groups contracted with hospitals, as we could propose the development of a community patient testing facility designed to best meet the needs of our hospital.

**Business Considerations and Market Estimates**

This practice pathway is different from the others in that it is based primarily on testing services, although integrated with imaging and in some cases endoscopic procedures. In fact, in its “complete form,” it comprises a patient testing services facility. As such, its revenues will be based on some mix of “fee for service” and value-based or global payment structures, depending on the clientele.

The revenue model for a particular testing center will depend entirely on the type of center and client. There are many, many permutations that might be negotiated given the many potential configurations, market segments and payment models. For example:

- For an ACO, the model may be a mix of fee for service testing revenues, as well as shared savings if performance targets are met.

- Or, an ACO agreement might involve a capitated contract for diagnostic testing services for some range of conditions, or for all image-guided diagnostic testing, for example, with a bonus component of shared savings.

- For a hospital-owned patient testing center, the revenue model might be performance-based. For example, employees of the center might receive bonuses based on the center’s revenue or value performance targets.

As a result, estimating the size of this market opportunity is not easy. As with all market estimates, we need to caveat that these rely on multiple assumptions, by necessity, and this should be taken as only high-level indicators of the potential revenues available.

We analyzed the market using both a “top down” and “bottom up” methodology, as a means to increase the estimates’ accuracy. Given that the estimates employ very different approaches, the fact that their market revenue totals are close to each other, $17B vs. $19B, supports the analysis.

We focused both analyses on the market for cancer diagnostics based on the following assumptions, which suggest lower cost diagnostic testing centers will be a growth market over the next 10 years:

- The demographics of aging Baby Boomers is driving increases in cancer.

- The trend towards high-deductible insurance is shifting consumers towards paying more of their own health bills.
The patient integrated diagnostic testing center market estimates that we provide here are restricted to centers offering services for diagnosing major cancers, such as breast, lung, colon, hematologic cancers, and other solid tumors diagnosed by fine needle biopsies. Note, however, that these markets do not include all cancers (such as prostate), nor do they include complete work-ups of cancers, gastroenterology, or other complex diagnostic conditions, such as coagulation disorders, stroke, neurologic diseases, or developmental disorders.

**Top Down Market Analysis**

Our “top down” method estimates diagnostic testing services using a series of assumptions to estimate the share of outpatient, per capita expenditures in ACOs for radiology, pathology and laboratory that might comprise these services. As this method does not account for colonoscopies, it is lower than it should be.

The benefit of starting with the ACO market is we also have a size estimate for this target market segment. In 2013, we estimate that patient diagnostic testing services for these cancers might represent about $820,000. We then scale up for the entire country, to get an estimate of $17 billion for adults (See Figure 4).
## Figure 4: Patient Testing Center Market Estimate #1: Top Down ACO Methodology

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<tbody>
<tr>
<td><strong>Medicare ACOs</strong></td>
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<tr>
<td>Estimated number of CMS ACOs</td>
<td>154</td>
<td>350</td>
<td>450</td>
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<tr>
<td>Estimated number of covered lives per ACO</td>
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<tr>
<td>Estimated per capita medical expenditures for Medicare beneficiaries in 2013</td>
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<td>$11,400</td>
<td>$12,012</td>
<td>$12,613</td>
<td>$13,243</td>
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<tr>
<td>Radiology – 4 percent of spend (IMS outpatient date)</td>
<td>$440</td>
<td>$458</td>
<td>$480</td>
<td>$505</td>
<td>$530</td>
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<td>Assume ~40 percent is relevant to cancers (about 50 percent of radiology costs are for chronic conditions in outpatient)</td>
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<td>$183</td>
<td>$192</td>
<td>$202</td>
<td>$212</td>
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<tr>
<td>Imaging for major cancers per person per yr</td>
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<td>$458</td>
<td>$480</td>
<td>$505</td>
<td>$530</td>
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<tr>
<td>Path – 4 percent of spend (IMS outpatient data)</td>
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<td>$183</td>
<td>$192</td>
<td>$202</td>
<td>$212</td>
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<tr>
<td>Assume 50 percent is relevant to major cancers</td>
<td>$88</td>
<td>$92</td>
<td>$96</td>
<td>$101</td>
<td>$106</td>
</tr>
<tr>
<td>Lab and path for major cancers per person per yr</td>
<td>$88</td>
<td>$92</td>
<td>$96</td>
<td>$101</td>
<td>$106</td>
</tr>
<tr>
<td>Imaging + lab and path for major cancers pppy</td>
<td>$264</td>
<td>$275</td>
<td>$288</td>
<td>$303</td>
<td>$318</td>
</tr>
<tr>
<td>Assume ~50 percent of path/lab + imaging for new work-ups/diagnostic questions</td>
<td>$132</td>
<td>$137</td>
<td>$144</td>
<td>$151</td>
<td>$159</td>
</tr>
<tr>
<td>CMS ACOs revenue opportunity</td>
<td>$304,920,000</td>
<td>$720,720,000</td>
<td>$972,972,000</td>
<td>$1,135,134,000</td>
<td>$1,311,079,770</td>
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</table>

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
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<tr>
<td><strong>Private Market ACOs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated number of</td>
<td>300</td>
<td>400</td>
<td>500</td>
<td>550</td>
<td>600</td>
</tr>
<tr>
<td>private market ACOs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated number of</td>
<td>30,000</td>
<td>30,000</td>
<td>30,000</td>
<td>30,000</td>
<td>30,000</td>
</tr>
<tr>
<td>covered lives per ACO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated per capita</td>
<td>$4,800</td>
<td>$5,040</td>
<td>$5,292</td>
<td>$5,557</td>
<td>$5,834</td>
</tr>
<tr>
<td>medical expenditures for</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>commercial beneficiaries</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiology – 4 percent of</td>
<td>$192</td>
<td>$202</td>
<td>$212</td>
<td>$222</td>
<td>$233</td>
</tr>
<tr>
<td>spend (IMS outpatient data)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assume ~40 percent is</td>
<td>$77</td>
<td>$81</td>
<td>$85</td>
<td>$89</td>
<td>$93</td>
</tr>
<tr>
<td>relevant to cancers (about</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50 percent of radiology costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imaging for major cancers</td>
<td>$192</td>
<td>$202</td>
<td>$212</td>
<td>$222</td>
<td>$233</td>
</tr>
<tr>
<td>per person per yr</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab and Path – 4 percent of</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>spend (IMS outpatient data)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40 percent is esoteric, AP</td>
<td>$77</td>
<td>$81</td>
<td>$85</td>
<td>$89</td>
<td>$93</td>
</tr>
<tr>
<td>Assume 50 percent is</td>
<td>$38</td>
<td>$40</td>
<td>$42</td>
<td>$44</td>
<td>$47</td>
</tr>
<tr>
<td>relevant to major cancers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab and path for major</td>
<td>$38</td>
<td>$40</td>
<td>$42</td>
<td>$44</td>
<td>$47</td>
</tr>
<tr>
<td>cancers per person per yr</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imaging + lab and path for</td>
<td>$115</td>
<td>$121</td>
<td>$127</td>
<td>$133</td>
<td>$140</td>
</tr>
<tr>
<td>major cancers pppy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assume ~50 percent of path/lab</td>
<td>$58</td>
<td>$60</td>
<td>$64</td>
<td>$67</td>
<td>$70</td>
</tr>
<tr>
<td>+ imaging for new work-ups/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>diagnostic questions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>**Private ACOs revenue</td>
<td>$518,400,000</td>
<td>$725,760,000</td>
<td>$952,560,000</td>
<td>$1,100,260,800</td>
<td>$1,260,236,880</td>
</tr>
<tr>
<td>opportunity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>**Total ACOs revenue</td>
<td>$823,320,000</td>
<td>$1,446,480,000</td>
<td>$1,925,532,000</td>
<td>$2,235,340,800</td>
<td>$2,571,316,650</td>
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<tr>
<td>opportunity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total ACO patients</strong></td>
<td>11,310,000</td>
<td>17,250,000</td>
<td>21,750,000</td>
<td>24,000,000</td>
<td>26,250,000</td>
</tr>
<tr>
<td>Population over 18 yrs old</td>
<td>234,000,000</td>
<td>234,000,000</td>
<td>234,000,000</td>
<td>234,000,000</td>
<td>234,000,000</td>
</tr>
<tr>
<td>(US Census 2010)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient testing center</td>
<td>$17,034,206,897</td>
<td>$19,621,815,652</td>
<td>$20,716,068,414</td>
<td>$21,794,572,800</td>
<td>$22,921,451,280</td>
</tr>
<tr>
<td>revenues (major cancers) for</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>entire U.S. population</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
**Bottom Up Market Analysis**

Our “bottom up” method uses statistics regarding the number of procedures, biopsies and other tests regarding these cancers, along with average reimbursement fees, to sum a total revenue opportunity by volume of patients.

Using this methodology, see Figure 5, we obtain a total revenue estimate for 2013 of $19 billion for potential patient integrated diagnostic testing centers, about 6 percent different from our first estimate.

**Figure 5: Patient Testing Center Market Estimate #6: Bottom Up Methodology**

<table>
<thead>
<tr>
<th>Patient Testing Center Bottom Up Market Estimate 2013</th>
<th>Imaging or Procedures</th>
<th>Est. Price of Test/Procedure</th>
<th>Diagnostic Biopsies</th>
<th>Est. Price of Test</th>
<th>Est. Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>22,000,000</td>
<td>$400</td>
<td>1,000,000</td>
<td>$150</td>
<td>$8,950,000,000</td>
</tr>
<tr>
<td>Chest</td>
<td>30,000,000</td>
<td>$35</td>
<td>530,901</td>
<td>$150</td>
<td>$1,129,635,216</td>
</tr>
<tr>
<td>Colon</td>
<td>3,700,000</td>
<td>$2,000</td>
<td>6,000,000</td>
<td>$150</td>
<td>$8,060,000,000</td>
</tr>
<tr>
<td>RNA</td>
<td>1,021,985</td>
<td>$150</td>
<td>153,297,791</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Hematologic Cancers**

| Bone marrow evals - path                              | 1,400,000             | $150                         | $211,000,000         |
| Bone marrows - outpatient procedures 2010            | 950,000               | $150                         | $145,500,000         |
| Lymph node evals - path                              | 1,200,000             | $150                         | $180,000,000         |
| Lymph node biopsies - outpatient procedures 2010     | 96,373                | $300                         | $28,911,900          |
| Leukemias and lymphomas (new work-ups except nodes and marrows; assumes 149,230 at ~1,000 each) | | $1,000 | $149,230,000 |

**Patient testing center revenues (select and major cancers) for entire U.S. population**

$19,004,574,907

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
Applying the Estimates
As challenging as it is to develop market estimates for a diverse and emerging marketplace, so it is for applying them to the business considerations of our innovative practice pathway. But disruptive and innovative ideas have succeeded before and, over time, patterns have emerged as to how to size their market share before they come to fruition.

One rule of thumb from venture business investing is that targeting a 1 percent share of a market with a disruptive idea such as this, if well marketed, is not unreasonable. Taking an average of our two market estimates, that would be 1 percent of $18 billion, or $180 million in annual revenues that might be generated through a substantially resourced patient integrated diagnostic testing center business.
PRACTICE PATHWAY: INTO THE PATIENT DIAGNOSTIC SERVICES CENTER

Our “Patient Diagnostic Services Center” Practice Pathway offers us an entry into the future of diagnostic services both clinically and commercially. All indicators point to imaging, pathology, and molecular diagnostics converging through computing in some way, perhaps to start with cross-communications between pathologists and radiologists. Given that image-guided biopsies are becoming the standard approach, having close collaborations between pathologists and radiologists is essential. While there is little justification for keeping pathology and radiology patient testing services so disconnected, there are many reasons for integrating them.

This is a sentinel opportunity for us to take the initiative in identifying a market need, a technology trend, and an evidence-based, pathology-led solution that can generate value for our employers, institutional leaders, or owners.

Pathway Operations: How the Patient Diagnostic Service Pathway Works

The operational aspects of the diagnostic center are not complex from a business standpoint. They involve assembling an experienced management team with expertise in functions that are well established, such as delivering excellence in customer services and Lean and Six Sigma operations. Alternatively, consultants and training courses can be employed to transfer these skills to the staff involved in launching the facility.

The more challenging components of the center involve optimizing the planning, integration and reporting of the various types of testing. Figure 6 shows a simple schematic of the patient service center workflow:
Figure 6: Schematic of Patient Diagnostic Testing Center Operational Flow

Scheduling and Reception – “Retail” Level Services

Phase 1: Apply Diagnostic Testing Algorithm and Develop Testing Plan

Phase 2: Patient Testing Flow Integration

Phase 3: Evaluation, Cross Review, Interpretation and Integration of Results

Phase 4: Report Integration

Source: Eleanor Herriman, MD, MBA, G2 Intelligence
This workflow follows four key phases.

**Phase 1: Apply Diagnostic Testing Algorithm and Develop Testing Plan**

The first phase in the process marks an important area of advancement in terms of employing evidence-based medicine and informatics to generating value. This step is led by the assigned “Senior” diagnostic specialist, presumably a specialist pathologist, depending on the case, and entails reviewing the patient’s history and prior clinical testing, then applying developed diagnostic algorithms that guide test plans based on a number of case variables.

The sophistication of such algorithms can vary widely, but one can envision that these computerized algorithms can become the codified, intellectual property representation of the experience the patient services center generates in diagnosing cases over time. As the center learns which tests are more or less helpful, for which patients, and in which order, based on which risk factors, these algorithms become one of the foundations for improved quality and cost avoidance.

The International Society for Strategic Studies in Radiology proceedings advocate for these algorithms:

“To date, there is too little coordination between the medical specialties responsible for ordering and performing these tests, nor is there enough consideration as to the optimal order of tests. This will change in a world of integrated diagnostics, where, instead of relying on individual provider bias in the selection of tests, data from diverse sources will be used to determine the most efficient diagnostic algorithms. ... Algorithms should start with the least expensive tests that will narrow down the possibilities and effectively increase the positive predictive value of subsequent tests. Each test in a diagnostic algorithm should break the tested population into smaller subpopulations with specific phenotypes, or sets of observable traits, for which the associated risks of disease are better defined. ... Determining the optimal use of diagnostic tests will require heavy use of IT to calculate the probabilities and discern linkages between data and disease, because the complexity of the data precludes depending solely on intuition and experience.”

Bruce Friedman, MD, Emeritus Professor of Pathology at University of Michigan Medical School, and longtime proponent of integrated diagnostic centers, which he terms “IDCs,” wrote in a recent presentation describing an IDC: “Assume that sequencing of tests/procedures will be managed by IDC

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computer algorithms based on protocols and positive results.”

**Phase 2: Patient Testing Flow Integration**

Phase 2 follows the test plan developed in the first phase by the diagnostic specialist and computer algorithm. The key value points here are to have operations be as efficient and error-free as possible (Lean) and as pleasant as possible from a patient experience perspective. In terms of efficiency, it can be built in and it can evolve through continuous improvement as the group applies the lessons it learns from experience to make small, positive changes that add up to a large value.

**Phase 3: Evaluation, Cross Review, Interpretation and Integration of Results**

Phase 3 is the heart of the pathologist and radiologist integration phase, so this phase involves close communication and coordination between the two as they evaluate what may be multiple tests from the same patient. There are a number of ways this integration might occur, especially given the flexibility offered by digital communications. Indeed the integration and communication can be virtual, as digital pathology can now be easily implemented.

As we’ll describe in the next section, there are groups such as University of California Los Angeles (UCLA) working on technology platforms and workflows that explicitly map the back and forth of imaging and pathology evaluations, cross reviews of the other’s reports, and reinterpretations as needed due to discordances.

This integrative evaluation phase involves three key functions for an individual patient case:

- The pathologist and radiologist review each other’s interpretations before they are completed to check for discordance and ensure accurate specimen sampling in the case of image-guided biopsies.
- Based on test results, and the center’s algorithm, the team makes decisions regarding what other tests to order.
- Upon completion of all testing, the diagnostic team reviews all test results and the clinical data and generates a diagnostic interpretation.

**Phase 4: Report Integration**

Phase 4 is comprehensive, integrated reporting, which we have also discussed. One issue to emphasize here is the importance to patients in cancer settings of getting results back as soon as possible. As an example, in Friedman’s description of his model IDC, he

42Bruce Friedman, MD, Presentation, “Integrated Diagnostics and Its Relationship to Digital Pathology: A Strategic Analysis,” April 27, 2012
states that the “goal is to establish a final tissue diagnosis in 48-72 hours.”

Some clinics in Europe use microwave tissue processing to facilitate same-day reporting of tissue biopsies.

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43 Bruce Friedman, MD, Presentation, “Integrated Diagnostics and Its Relationship to Digital Pathology: A Strategic Analysis.” April 27, 2012
There are no “full featured” patient diagnostic service centers in the U.S. market today, to our knowledge, especially in commercial markets. However, there are examples in the academic medical center arena that are instructive.

The two leaders in this regard are UCLA and Kansas University Medical Center. Each has demonstrated the feasibility and value of integrating pathology and radiology workflow for cancer diagnostics.

**Example: UCLA’s Rad-Path Department**

UCLA’s integrated diagnostic services model focuses primarily on one of our four market needs: improving clinical quality. Although they do not explicitly address cost savings as an objective, they would also likely result from the workflow integration and decrease in diagnostic errors.

The model is not designed to be an ambulatory facility that caters to the patient’s diagnostic testing experience, so those aspects of our market needs are not addressed.

The academic medical center at UCLA’s initiative for integrating imaging and pathology is described in the pathology department’s 2012 annual report as follows:

“The development of the UCLA Radiology Pathology Center (Rad-Path) is a joint venture between the UCLA Departments of Radiology and Pathology that is bringing together industry-leading experts in radiologic imaging and tissue diagnosis for enhanced diagnostic reporting and research development. In this new era of personalized medicine, the center seeks to develop a single, integrated report encompassing both radiological and pathological diagnostic modalities for better evaluation of a disease process.”

**An Integrated Workflow**

The primary focus of Rad-Path is developing both the human and computer workflow integration of “diagnostic pathology,” “diagnostic radiology,” “molecular pathology,” and “interventional radiology” in the field of cancer diagnosis. The UCLA Rad-Path team, including Michael D. Kuo, MD, Asso-
ate Professor of Radiological and Diagnostic Sciences, W. Dean Wallace, MD, Chief of Pulmonary Pathology, and Fareidoun Abtin, MD, Assistant Professor of Radiology, proposes an “integrative diagnostic model,” which they term “Rad-Path 2.0.”

Figure 7 shows one idealized workflow model developed by the ASPE Technical Expert Panel, including Wallace from UCLA, which exemplifies this integrated cancer diagnostic process. This model programmatically integrates the four pathology and radiology units so that (1) each radiologist and pathologist has the opportunity to review and revise his/her findings based on comparison with the other tests and discussions with the other physicians before reports are issued, and (2) the oncologist receives an integrated electronic report with Web links that track the status of each test component.

Figure 7: Integrated Diagnostic Workflow Model for Cancer Diagnostics

Source: Eleanor Herriman, MD, MBA, G2 Intelligence


46MD Kuo et al, “Next Generation Radiologic-Pathologic Correlation in Oncology: Rad-Path 2.0,” AJ R 2011; 197:990-997
Integrated Reviews and Reports

The group reported on its clinical Rad-Path experience with lung cancer in March of 2012.47 The group implemented a “single access report through creation of a system that integrates the radiographic, pathologic, and molecular characterization of cancer.” It found two parts of the process to be most important clinically: the review of diagnostic and procedural imaging to ensure the tissue was representative; and the reassessment of discordant cases. In addition, the system’s capacity for creating a database of well-characterized lung cancer patients is allowing for development of important decision support and quality control tools.

One of the challenges group members noted in their initial experience was lack of automated reminders for communication between radiologists and pathologists. They solved this “through email, paging and powerpath reminders.”

A Glimpse at the Future of Integration

On the cutting-edge research side, UCLA envisions as part of its Rad-Path 2.0 model a major role for “radiogenomics.” Radiogenomics involves identifying imaging phenotypes that are statistical surrogates for unique molecular tumor expression profiles. Radiologists would be able to “continue to provide structural and anatomic information at an organ, tissue, or cellular level for both disease detection and cell type diagnosis but could also add high-level molecular detail that could potentially be used for molecular characterization and targeted therapy selection. Thus, imaging could be leveraged across multiple scales of biology.”

The scientific thesis for radiogenomics is that there is sufficiently dense, structured and extractable information in conventional imaging to enable identification of these molecular-imaging associations.

Sound like science fiction? This work is undoubtedly far from clinical implementation, at least in the community. Nonetheless, early evidence has been generated. Kuo and colleagues conclude, “Thus, although early and still requiring additional validation, the initial data suggest that a radiogenomic approach appears both robust and scalable, capable of integrating data from the molecular to the microscopic and macroscopic levels, and supports the overall feasibility of the Rad-Path 2.0 concept.”48

How might this relate to our integrated patient testing center model? The UCLA team proposes radiogenomics as a Rad-Path 2.0 diagnostic platform,

47Fereidoun Abtin, MD, Assistant Professor of Radiology, David Geffen School of Medicine at UCLA. “Rad Path Report: Initial Experience with Combined Radiology and Pathology Reporting for Lung Cancer.” Presentation at STR, March 13 2012

48MD Kuo et al. “Next Generation Radiologic-Pathologic Correlation in Oncology: Rad-Path 2.0.” AJR 2011; 197:990-997
in the spirit of integrating radiology and pathology. Radiogenomics is proposed as a bridge across the multiple tumor biology levels, from molecules to organ systems, all contributing important information in the diagnosis of cancer. However, the UCLA team also posits that a multi-specialty, integrated pathology and radiology team, working collaboratively in a Rad-Path 2.0 type model, can bridge these biologic levels and bring the same value as this technology platform.49

If the UCLA Rad-Path improvements in clinical quality are substantiated, they provide a strong endorsement for this new, integrated cancer diagnostics testing.

A Second Example: The Kansas University Medical Center

Another academic medical center that has pioneered an integrating pathology and imaging service is The University of Kansas School of Medicine/Kansas University Medical Center (KUMC), led by Ossama Tawfik, MD, PhD, Professor and Director of Anatomic and Surgical Pathology, and Mark Redick, MD, PhD, Assistant Professor of Radiology.

The KUMC integrated diagnostic services model targets two of our market needs: improving clinical quality and generating cost savings. Like the UCLA program, it does not address the patient experience or consumer market needs.

The work at KUMC has centered on correlating breast cancer core needle biopsies with imaging to ensure diagnostic accuracy. The problem they have been addressing is the high rates of radiologic-pathologic discordance of core needle biopsy analysis, ranging from 1 percent to 6 percent. Further, many of these discordant cases are malignant when microcalcifications are present.50

The team has, over the past three or so years, utilized two types of innovations to improve the diagnostic breast core biopsy process.

First, team members implemented an integrated cross-review and collaboration process between the pathologists and radiologists using Aperio telepathology and teleradiology. Each case’s images and findings were reviewed via weekly teleconference by both specialists, and any discordances were resolved before issuing final reports.

A KUMC study51 of the impact of this

49MD Kuo et al. “Next Generation Radiologic-Pathologic Correlation in Oncology: Rad-Path 2.0,” AJR 2011; 197:990–997


process found that treatment decisions were altered in more than one-third of the 106 patient cases included in the investigation. Details of their integrated diagnostic model and the study were profiled by Agency for Health Care Research and Quality (AHRQ) on their website as a “Service Delivery Innovation” entitled “Joint Radiologist–Pathologist Review of Diagnostic Findings Improves Care of Patients Being Screened for Breast Cancer,” at http://www.innovations.ahrq.gov/content.aspx?id=2714.

Second, they developed a “Path/Rad Tissue Tray” to address residual discordances they were experiencing relating to locating difficult microcalcifications. These trays contain slots that allow for the core needle biopsy specimens to be separated, and for their integrity and orientation to be maintained throughout processing. The tray is placed in a slide cassette such that the gross specimens and microscopic slides have identical orientation, allowing for alignment and localization of microcalcifications on the original images, on imaging of the tissue trays and finally on the slides.

In a study of 440 core breast biopsy cases, the KUMC group found a significantly higher concordance between pathology and radiology using the Path/Rad Trays compared with not using them: 95.8 percent concordance with the tray versus 79.1 percent concordance without. The group wrote, “It improved diagnostic reliability, encouraged communication between pathologists and radiologists, and minimized false diagnoses and/or delays in cancer diagnosis.”

Furthermore, the KUMC team argued that its integrative approach can generate cost savings: “Reducing the number of false and delayed diagnoses will effectively lower health care costs by increasing the number of prompt, accurate breast cancer diagnoses by CNB.”

Collectively, these AMC initiatives provide evidence, guidance and innovative technologies to support our integrated patient testing center model.

An Example: Grupo Fleury – “The Lexus of Laboratories”
The best example model for our “Patient Diagnostic Services Center”


Practice Pathway is a large, national, publicly traded, commercial Brazilian laboratory company called “Grupo Fleury.” Fleury’s patient testing centers combine all the design elements we described and address all four market needs: improved clinical quality, cost savings (in their case through Lean operations), excellent patient experience, and services for the health care consumer market.

Although a company with an 86-year-old history, Fleury is growing quickly. Its 2011 gross revenues were ~$600M, a 31 percent increase over 2010. Its operating statistics for 2011, according to the company it performed: “3500 tests in 37 different diagnostic areas, roughly covering 40 million tests per year and 7 million clients serviced. To this end the company has more than 8000 employees and 1300 physicians.” Fleury’s tests include a broad range of assays and procedures from clinical lab, anatomic pathology, molecular pathology, diagnostic radiology, interventional radiology and clinical specialty areas such as gastroenterology.

Fleury’s lines of business include 200 patient service centers (83 percent of sales), diagnostic operations in hospitals, and a reference laboratory and preventive medicine. The company reports a 2011 gross margin of 35 percent.

Fleury’s business model is very innovative and successful and serves as a proof of concept for our pathway, with the caveat that Brazil is not the United States. However, the majority of Fleury’s revenues come from health plans, and another 14 percent directly from patients. Thus, from a client market perspective, Fleury may be more representative than we’d have thought, especially given the United States’s growing consumer market.

Fleury’s model combines “Lexus” like patient services, academic-level physician services, economies of scale and efficiency and a focus on clinical quality.

In short, Fleury’s service model formula appears to answer the core market needs we’ve been describing. Critically, the company’s strategic positioning statement communicates a conceptual leap we need to make: “From clinical laboratory to health services provider, solutions provider.”

Fleury’s strategy also entails delivering value to all key stakeholder groups, including patients, health plans, physicians and employers, as shown in Figure 8. The Brazilian diagnostic mar-

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55 Grupo Fleury “Management Report 2011”
56 Grupo Fleury “Management Report 2011”
ket’s interconnecting stakeholder recommendations regarding diagnostic service providers, as well as substantial consumer segment, may foreshadow that of the United States.

**Figure 8: Fleury’s Multi-Stakeholder Strategy**

Competitive Advantages for all Stakeholders

**Health Plan Providers**
- Offer several coverage options
- 72 percent of Fleury revenues
- Our brand portfolio covers the entire health plan coverage segmentation

**Employers**
- Choose health plan and service provider: for them Fleury is a must-have

**Patients**
- Choose service provider based on health plan coverage, personal preference and physician's indication
- Client satisfaction index above 90 percent

- Offers preventive medicine solutions to improve employee wellness

**Physicians**
- Recommend health service provider

**Integrated Solutions**
- Knowledge Generation
- Consultancy
- Innovation

- Best and most trusted center for diagnostic medicine for 85 percent of physicians


Rogerio Rabelo, MD, PhD, MBA, Executive Director, Operations, Fleury Group, presentation: “How Quality, Continuous Improvement, and Customer Service Built the ‘Lexus’ of Laboratories.”
Examples of Fleury’s accomplishments in 2011 include publication of 54 scientific papers with Grupo Fleury listed as a research institute, and the delivery of more than 10,000 integrated diagnostic reports for complex cases. It also launched a “Center of Imaging-Guided Procedures” with multi-disciplinary services.

The company describes the extension of its model’s value to the patients as providing “the benefit of a more precise and safe diagnosis, in one place, and out of the hospital environment, reinforcing the strategic positioning of intimacy with the client, with focus on his/her needs and the solving of his/her problems.”

Fleury sees the following elements as key to the success of its innovative service formula:

- **Focus on the primary client: the patient** - excellence in customer service, “one-stop shop experience,” and obtaining recommendations of physicians and health plans.
  - Designing services to meet patient needs along every step of process.
  - Measure, track, continuously improve performance; track and manage average wait times, complaint indices, time to delivery of results; also track social networking communications and try to intervene to correct problems.
  - Offer special services – kids’ activities, cafes, valets, etc.
  - Use of CRM technology.
  - Focus on interior space design.
  - Allow patients to choose service provider, e.g., lab, based on health plan coverage, personal preference and physician’s indication.
  - Maintain Fleury’s client satisfaction index above 90 percent.

- **Knowledge and innovation** - the company sees this as a key competitive advantage and fuels it by encouraging idea generation from all levels; new innovations (and academic papers) are generated on two sides:
  - Integrated reports, for example, artificial intelligence and informatics tools to analyze and integrate test results.
  - New diagnostic product innovations.

- **Lean and Six Sigma** - this is core to the company’s operations strategy, enabling high quality, and efficient, rapid results.

- **Comprehensive, integrated reports** - solution for physician and patient.

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50Grupo Fleury “Management Report 2011”
“Core information at a glance; Each report represents the result of the medical expertise accumulated at Fleury; Diagnostic conclusion and eventually treatment recommendation.”60

- Not just integrated reports, but integrated centers -
  - Tests performed in a rapid, sequential and prioritized way.
  - New centers: 2010/2011:
    - Integrated Neurology Center & Center for Sleep Disorders.
    - Advanced Gastroenterology & Endoscopy Center.
    - Lymphoma Center.
    - Center for Investigation & Rehabilitation of Urology Disorders.
    - Fetal Medicine Center.
    - Center of Complex Diagnostics Procedures.

The success of the Fleury service model serves as a partial proof of principle for our practice pathway. We say partial only because of the difference in geographic markets. Nonetheless, the company’s decided commercial and clinical success using a combination of excellent customer service, integrated and comprehensive diagnostic services, Lean operations, and academic-style innovation is a strong endorsement and blueprint for one version of our practice pathway.

60Rogerio Rabelo, MD, PhD, MBA, Executive Director, Operations, Fleury Group, presentation: “How Quality, Continuous Improvement, and Customer Service Built the “Lexus” of Laboratories.”
IMPLEMENTATION PLANS: THE WAY FORWARD

Whether we are at a community practice working with a hospital, at a hospital or medical center working as an employee, at an independent practice group, or at a reference lab, there are opportunities for pursuing the establishment of a patient diagnostic services center of some type.

Although there are certainly daunting aspects to developing a new service center, we are not suggesting that practices should all be launching start-up patient diagnostic service facilities. We are not in this alone. This is not a solo venture.

This pathway envisions these centers being developed through a variety of means, primarily in conjunction with health care institutions, investors and other types of partners.

At a minimum, our pathway involves collaborating with our colleague radiologists. Many of them can be helpful by leveraging their experience operating patient imaging centers. At a maximum, our pathway may involve securing venture capital and other partners to support building a new facility to house a new kind of business.

One sign of potential investment interest in this type of diagnostic testing center is the robust acquisition activity in imaging centers by both national and regional health systems over the past two years. For example: “Dallas-based Tenet Health Care Corp., in particular, has cited outpatient services as an integral part of its strategy for boosting its operating margins to match or exceed its peers' margins. Tenet told investors in January that it spent $65 million acquiring 24 outpatient centers in 2010 and expected to spend up to $100 million acquiring 15 to 25 centers this year [2011].”

These outpatient centers included urgent care, ambulatory surgery centers, and imaging centers. Vice President of outpatient services for Tenet Kyle Burtnett commented, “I think the payers really like the idea of an expanded footprint: urgent care, ambulatory surgery centers, imaging centers—good quality care at a quality price.”

In all cases, the patient testing center pathway represents a business venture that requires a strategic planning process and investment plan. Considerations about which potential pathway

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61 Vince Galloro, “Growth strategies; Chains look beyond inpatient side,” Modern Health Care, August 29, 2011
“flavor” best suits you will include:

- Identifying the appropriate target client in your local market,
- Identifying your core strengths and technical expertise.

- Balancing your desire to be an innovator with your comfort with risk.

In the upcoming, final report this pathway chapter will include a more detailed implementation section.
CONCLUSIONS

While a new patient-centric and consumer-oriented health care marketplace has not yet fully established itself, the market dynamics and trends towards value-based purchasing, coordinated care, and outpatient services, as well as the rise in high-deductible insurance plans, point to its inevitability. At the same time, ACOs compensated based on value are becoming prevalent and require high quality and efficiencies across all provider services.

In such a market, the shortcomings of a business-as-usual approach to diagnostic services and testing – with services that cater to providers rather than patients, with capabilities that are fragmented rather than integrated, and with reporting that is uncoordinated rather than synchronized and interpreted as a whole – may become liabilities.

To be a part of this emerging market and to have the chance to participate in shaping it and growing with it requires an innovative new vision that embraces this new market. We propose the Patient Diagnostic Services Center, a bold new approach to pathology and diagnostic medicine in which services and practices are aligned with the needs of this emerging consumer-based marketplace.

In this new model, we:

- Acknowledge that the patient is our customer and that our customers will demand high quality customer service.
- Acknowledge that patients and providers alike need affordable, accurate and coordinated results.
- Recognize that aligning with these new goals provides an opportunity to add value not only by improving the patient experience and lowering costs but also by providing more comprehensive and accurate diagnoses.

Our Patient Diagnostic Services Center can take on many different forms based on implementation decisions along two dimensions:

- Conditions and therapeutic areas.
- Central focus of value propositions.

The workflow in the Patient Diagnostic Services Center has four key phases, each built on principles that improve the patient experience, lower costs and increase accuracy. The phases include:

- Planning: applying expertise in pathology and IT-based algo-
- Algorithms to create an integrated and individualized testing plan for a patient.

- Integrated testing: applying evidence and experience to provide a streamlined, efficient and effective testing experience for patients.

- Integrated evaluation: employing IT-based platforms to interpret, collaborate with other diagnostic specialists, reconcile differences, and interpret integrated findings.

- Reporting: delivering a timely, comprehensive, integrated and patient-friendly report.

The Patient Diagnostic Services Center is accessible across several practice types, settings, resource levels and capability portfolios. In almost every case, launching a Patient Diagnostic Services Center will not be a solo venture. It will involve collaboration and partnerships with other institutions, investors and colleagues in pathology and imaging. The options range widely, but perhaps most importantly, the Patient Diagnostic Center is an opportunity to be a part of shaping the future of health care.
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She is the leader of G2 Intelligence’s advisory services, which provides strategic consulting and custom market research and assessments for a range of clients, including pathology groups, clinical labs, health systems, hospitals, medical centers, diagnostic technology companies, and investors.

She is the author of three G2 reports: Health Care Market Reforms: Implications and Prescriptions for Laboratories; How to Build a Molecular Testing Laboratory: Key Strategic & Operational Considerations; and Creating a Value-Driven Laboratory: Opportunities in the New Marketplace.

She earned her MD at Baylor College of Medicine, completed pathology residency at University of California San Francisco, and received an MBA from Harvard Business School with highest honors (Baker Scholar).