

Patients Outside the Office

Value-Based Care and Proactive Patient Management – New Directions and Challenges for Oncology Practices

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Moving toward more aggressive patient management outside of the four practice walls for quality and value-based care Initiatives

- As practices seek to proactively position themselves under value-based care expectations, they face varying perspectives on value-based care, patient management, and the need for more aggressive patient management outside of the office visits. Today we will:
 - Explore how different entities perceive value-based care and patient management, and what that may mean for the practice's position in the health care delivery system
 - Learn about disrupters to healthcare delivery and value-based concepts and the potential impact on traditional care delivery
 - Review how patient management outside of the office can affect quality and total costs of care
 - Identify opportunities for patient management and practice positioning under different types of value-based care opportunities
 - Take away ideas for internal review and opportunities for integrating patient management and value-based care in your practice

Defining Value is a challenge, and there is no one right answer – but medical practices may not be the driver's seat

- Perspectives on what is value vary:
 - Physicians – clinically focused, improving patient care, safe, timely effective efficient, equitable and patient-centered^{12,13}
 - Patient – quality of care with lower out of pocket costs¹⁴
 - Payer – change payment models and reduce variation in treatment decisions to incentivize cost effective quality care^{15,16}
 - Pharma – focus on outcomes to lower costs puts pressure on traditional pharma business model¹⁷
 - Employer – benefit design can incentivize employees for health and care purchase decisions that improve outcomes and reduce costs^{18,19}
- **Moving toward Value can be defined as a process, a delivery model, or a contracting option²⁰**
- **All variants can affect treatment choices and care alternatives**
- **While we are defining value in our own way, be aware that disrupters are changing the conversation at levels far beyond our conventional reach**
- **Value is a matter of perspective, and monetary goals and targets from those who pay for care may de facto drive change and potentially conflict with those who deliver or receive care**

Variation in value models and perspectives raise hurdles and create inconsistency

- There is **no national consensus** on **quality** measures, or even if they focus on care delivery or choice of drug
 - Each program creates their own
 - The OCM program changed quality measures frequently across the performance periods, reflecting feedback from participating practices on the quality measures³¹
- There is **no national consensus** on oncology **outcomes** measures³²
 - In 2019, one paper reviewed 7 oncology quality assessment frameworks with 142 quality metrics, presenting 34 quality measures for consideration in 5 domains.
 - “Despite innovations in the payment landscape, limited consensus exists about what constitutes indispensable quality measures in oncology. The absence of such consensus may not only limit the development of better payment models, which increasingly link payment to quality of care, but also result in a lack of agreement on how value should be defined (and demonstrated) in an era of innovative, ever more expensive cancer therapies.”
- **Demands** for physicians to better manage costs of care are challenged by **lack of data on health care costs**, tools to analyze costs related to outcomes, and aligned financial incentives. ³³
- Oncology **drug and treatment choices** are likely to remain a part of value-based care.
 - CMMI has repeatedly been told that doctors do not control the price of drugs. True, but where choice is present, doctors do control the drugs they choose to prescribe, which may indirectly affect price as companies compete for market share. When properly incentivized, they make high-value choices. This has been demonstrated in multiple pathway programs from US Oncology, United Healthcare, and Anthem/WellPoint's Cancer Care Quality Program. Specifically, the WellPoint model demonstrated savings of \$9,204 in chemotherapy and \$8,564 in supportive care costs (mostly through decreased use of G-CSF) in a breast cancer pilot. Importantly, within OCM itself, practice participants have shown the ability to decrease drug costs when applying the principles of high-value care.³⁴
- **The transition to value-based care is a journey, not an event. Several challenges remain and many providers and payers still have mis-aligned incentives and perspectives, leading to tension and inconsistency in the care delivery system**

Quality Metrics are Important in a Value-Based Discussion, but which ones?

- OCM measures were collected from every participating practice, and changed during the program (<https://innovation.cms.gov/files/x/ocm-otherpayercoremeasure.pdf>)
- ASCO Qopi measures are self reported by practices, and change each year - https://practice.asco.org/sites/default/files/drupalfiles/QOPI_2021_Round_2_Reporting_Track_Public_Posting.pdf
- NCCN has created visual representations of 5 measures for therapy recommendations – NCCN Evidence Blocks™ <https://www.nccn.org/guidelines/guidelines-with-evidence-blocks>
- Key elements to any basic practice quality measurement program include:
 - Hospitalizations/ER visits
 - Drug Costs and choices
 - Symptom and Side Effect management
- ICER has created a Value Assessment Framework that focused on their calculated cost-effectiveness of treatments <https://icer.org/our-approach/methods-process/value-assessment-framework/>
- Others: Total costs of care, response, quality months lived, affordability, site of care, center of excellence, one stop shopping, clinical integration, primary care population management.....

Variation and dissonance open doors to disrupters

Disruption in the “Healthcare Food Chain” and Its Consequences

- Who Will Be the Shark(s) in the Community Pool in 2022? FAANG+M
- What Are the Mega Deals and/or Technology Inflection Point Areas to Watch?



FAANG + Microsoft

- Facebook → Data, Data, etc.
 - Apple → Medical Clinics, Wearables
 - ✓ – Amazon → Amazon Care, Prescriptions, Cloud, HCA Partnership
 - Netflix → Minimal Healthcare Entry
 - ✓ – Google/Alphabet → AI, Oscar, Fitbit, Deep Mind, Calico, Verily, AmWell, One Medical - \$100MM+ Bets
 - ✓ – Microsoft → Azure Blue Cloud, Nuance- \$19.7B Acquisition 4/21
- Market Capitalization \$ 2 Trillion+ - \$ 1.5 Trillion+

- Aetna/CVS → Whole Health/Minute Clinics
 - Blue Cross → Direct to CIN, Medicaid, IU
 - Cigna → Express Scripts / MD Groups
 - Humana → Kindred / MA / TriCare/ Iora
 - ✓ – Target/Walmart → PCPs in stores, Pharma, MeMD
 - ✓ – United Health/Optum → VA CCN, PCPs, ASCs, Change
 - Equality Health → Social Determinants/ Members
 - Kaiser → Customer Experience, SDOH
 - VA → VA Hospitals vs VA CCN
 - ✓ – Merck, Pfizer, J&J, Amgen → mRNA COVID, mRNA, Cancer
 - Leidos, IBM, etc. → Big Data - COVID, Cancer, member experience, AI, etc.
- Market Capitalization \$ 500 Billion+ - \$200 Billion+

✓ = Partial Inflection Point

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Disruption in the “Healthcare Food Chain” and Its Consequences

Types of Healthcare Transactions and Enablers

- 1. Vertical & Horizontal Integrators** – Summit/CityMD, CVS Health/Aetna, Optum/DaVita Medical Group, Cigna and Express Scripts(Civica Rx), etc. These hybrid organizations are trying to lower costs of the supply chain by owning more of it and extending those savings to consumers. The challenge? **Execution risk is very high and capital intense, but some hybrid models survived COVID in much better shape than others. COVID IMPACT – Variable/ Scale matters – Summit, United Health, etc. doing well but IPO market has significantly cooled from 2021.**
- 2. Employer Sponsored Initiatives** – HAVEN -JPMorgan/Berkshire Hathaway/Amazon Abandoned Due to Execution Failure. Combinations such as this are setting out to limit the growth of their own healthcare costs. The challenge? **Previous employer lead initiatives have had variable success and sustainability (e.g., SCE, Ford, Macy, Kaiser, etc.) and always require geographic concentration and scope of services scale. COVID IMPACT – Variable/HAVEN abandoned, Blackstone doing well.**
- 3. Technology Invaders** – FAANG+M, Lyft and Uber live in this class. These deals will command more space in the healthcare industry, and they have an advantage in their understanding of modern consumer expectations and new currently nonexistent healthcare relevant technologic advances. The challenge? **Technology invaders need technology that is applicable and actually provides real synergy in both the clinical and business facing applications. COVID IMPACT – Variable/Mostly Positive Because of Business/Valuation Shift to Big Tech. AmWell and Google start Collaboration**
✓✓ **Inflection Point – April 12, 2021: Microsoft pays \$19.7B for Nuance (Health Care AI Company- Voice and Text Recognition). First, \$ 20 Billion acquisition. Additionally, AI Imaging Companies (e.g., Artrya, Heart Flow, etc.) improve workflow, CAD predictability, road to transformational outcomes improvement begin to get traction in the market.**
- 4. Health Retailers** – Retailers including Walmart, Target, Walgreens, CVS Health, Amazon and Rite Aid want to gain market share by functioning as healthcare providers directly or as referral conduits. The challenge? **Scope of care, complexity of treatment, virtual medicine (tele health, tele monitoring, etc.) complicate the patient/provider/payer relationships.**
✓✓ **Inflection Point – Accelerated by COVID Product increase in healthcare consumables/ pharmaceuticals and vaccine distribution role.**

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Aggregator Strategies and Critical Mass Continue to Rule the Day

Optum Is The Largest MD Employer in the US – MD Care Acquisitions and Footprint

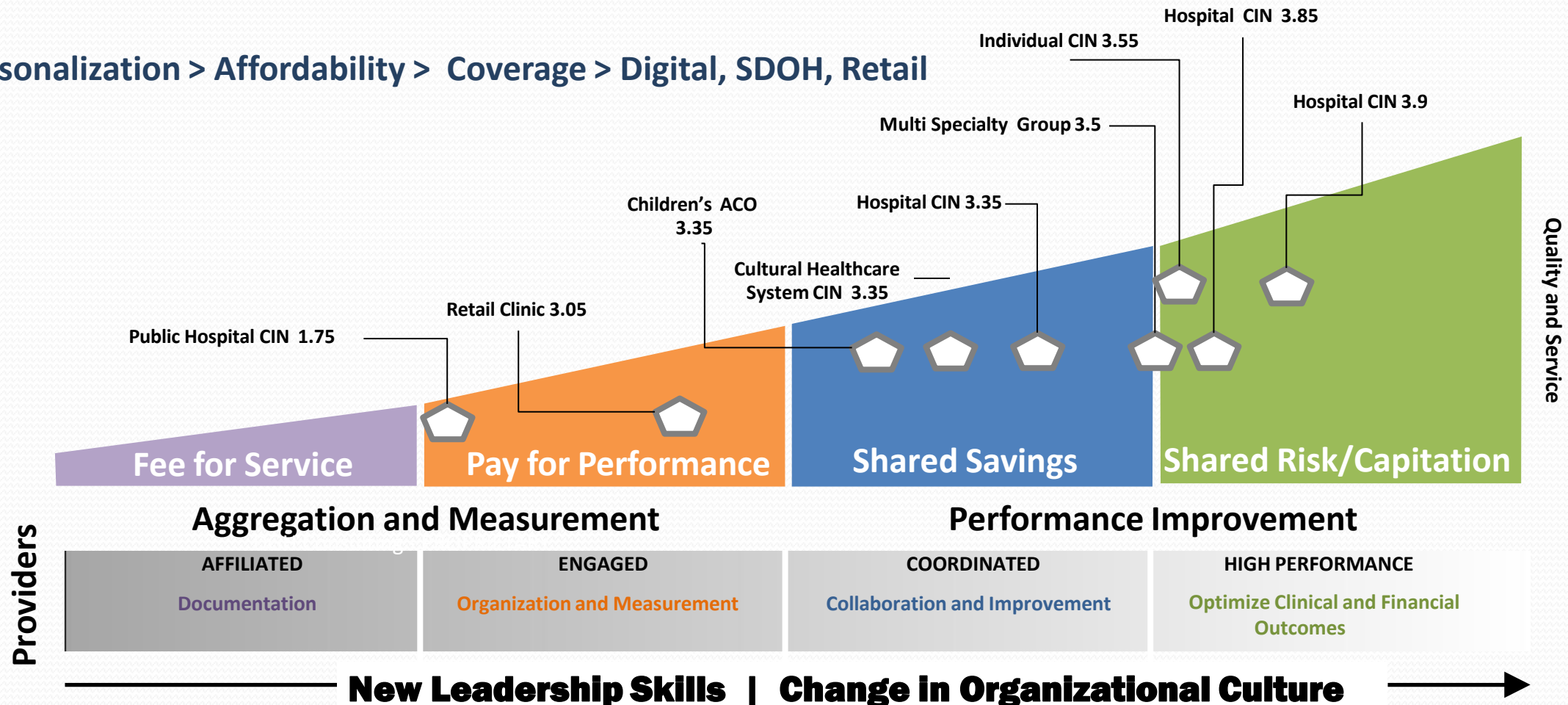


Source: <https://www.optumcare.com/about/about.html>

New Types/Sponsors of “Value Based” Products Drive Sophistication of CINs

– Examples of VBC Provider Organizations for a Geographic Area

Personalization > Affordability > Coverage > Digital, SDOH, Retail



New Types of “Value Based” Products

– AZ Is Ground Zero for Medicare in 2022

– (25 DCE Participants + MA) DCE in Arizona 2022 is MA in South Florida 1995

Payment Mechanism elected by the DCE DCE (Direct Contracting Entity) become ACO REACH (Realizing Equity Access and Community Health)	Risk Arrangement elected by the DCE	
	Global Option (Full Risk)	Professional Option (Partial Risk)
Total Care Capitation (TCC)		
... Scope of Capitation Payment	All Services	Not Available
... Capitation payment replaces FFS payment	Yes	
... Capitation payment reconciled against FFS payment	No	
Primary Care Capitation (PCC)		
... Scope of Capitation Payment	Primary Care	Primary Care
... Capitation payment replaces FFS payment	Yes	Yes
... Capitation payment reconciled against FFS payment	No	No
Advanced Payment Option (APO)		
... Scope of Advanced Payment	Non-primary care services	Non-primary care services
... FFS provider payment	Reduced	Reduced
... Advanced payment reconciled against FFS payment	Yes	Yes

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AZ Is Ground Zero for Medicare in 2022 – (25 DCE Participants + MA)

DCE in Arizona 2022 is MA in South Florida 1995 AZ Primary Care Capitation (PCC) + Advanced Payment Option (APO) Payment Category

Legal Business Name	Cohort	DCE Type	DCE Type	Capitation Payment Mechanism	States
24/7 Health Plan Inc	2022	High Needs Population	Professional	PCC + APO	AZ, CA
360 Health DCE Inc	2021	Standard	Professional	PCC + APO	AZ, CA
Advanced Illness Partners, LLC	2021	High Needs Population	Global	PCC + APO	AL, AR, AZ, CA, CO, DC, FL, IL, KY, LA MD, MI, MS, NV, NY, OH, OR, SC, TN, TX, VA
American Choice Healthcare, LLC	2021	Standard	Global	PCC + APO	AR, AZ, CA, CO, FL, IL, IN, MI, MS, NC, NJ, NM, NV, NY, SC, TN, TX
Arizona Care Network - Next, LLC	2022	Standard	Professional	PCC + APO	AZ
Arizona Health Advantage, Inc	2021	New Entrant	Professional	PCC + APO	AZ
Bluerock Care Community LLC (DBA: Penn Ave Health)	2022	New Entrant	Professional	PCC + APO	AZ, DC, GA, MA, MD, ME, NC, NH, NJ, NY, PA, TX, VA
CareConnectMD DCE LLC	2021	High Needs Population	Global	PCC + APO	AZ, CA, CO, GA, IN, NV, OH, TX
Clover Health Partners LLC	2021	Standard	Global	PCC + APO	AL, AR, AZ, CO, FL, GA, IL, IN, KS, MO, MS, MT, NJ, NM, NY, OH, OK, PA, RI, SC, TN, TX, VT
Florence CIN II LLC	2022	New Entrant	Global	PCC + APO	AZ, CA, IN
Nevada Care Connect	2021	High Needs Population	Professional	PCC + APO	AZ, NV, PA
Q Point Health, LLC (wholly-owned subsidiary of Equality Health)	2022	Standard	Professional	PCC + APO	AZ
Renovis Health LLC	2021	Standard	Global	PCC + APO	AZ, CA, IL, IN, MD, MI, NV, NY,
Steward Integrated Care Network, Inc.	2022	Standard	Professional	PCC + APO	AZ, FL



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AZ Is Ground Zero for Medicare in 2022 – (25 DCE Participants + MA)

DCE in Arizona 2022 is MA in South Florida 1995

AZ DCE Total Care Capitation (TCC) Payment Category

Legal Business Name	Cohort	DCE Type	DCE Type	Capitation Payment Mechanism	States
ADVANCED VALUE CARE II	2021	Standard	Global	TCC	AL, AR, AZ, CA, CO, CT, FL, GA, IA, IL, IN, KY, LA, MA, MD, ME, MI, MS, NC, NJ, NM, NV, NY, OK, PA, PR, SC, SD, TN, TX, VA, VT, WA, WV
AKOS MD IPA, LLC	2021	Standard	Global	TCC	AZ, FL, TX
APA ACO Inc.	2022	Standard	Global	TCC	AZ, CA, GA, HI, TX, WA
Asaar Medical, LLC	2022	Standard	Global	TCC	AL, AZ, CA, FL, IL, MI, NJ, NM, NV, NY, PA, TX,
VillageMD Arizona ACO, LLC	2021	Standard	Global	TCC	AZ, NV

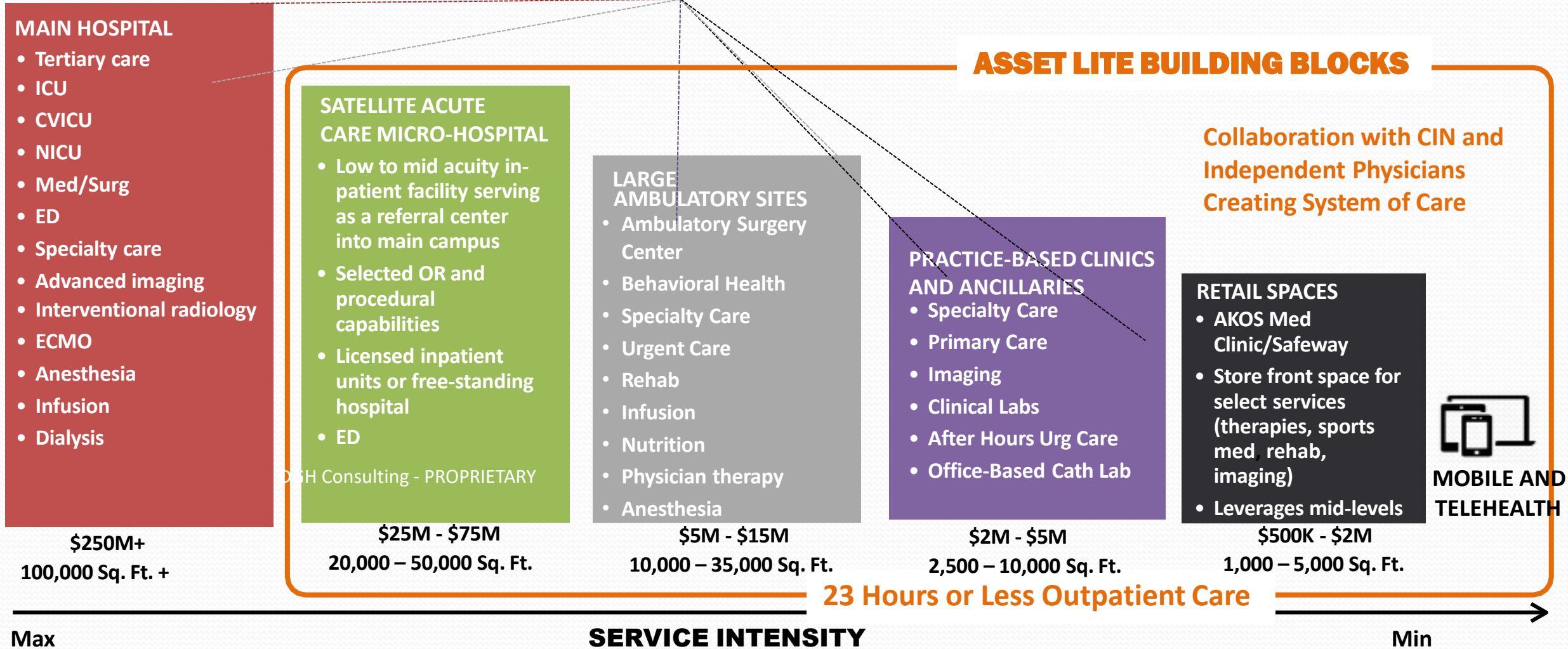
- In 2022, there are 10 new DCEs and 15 previously established DCEs operating in Arizona
- 14 DCEs are operating under the Primary Care Capitation (PCC) + Advanced Payment Option (APO) payment mechanism, 6 are operating under PCC, and 5 are operating under **Total Care Capitation (TCC)**

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Healthcare “Micro Footprint” is a combination of different target population enhanced outpatient centers

Right Care, Right Time, Right Cost, Right Facility

The Consumer/Member/Patient Experience – Care Outside of the Hospital – ED Evolves to Multiple Front Doors



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Super Consumer/Member/Patient Experience – Virtual/Non-Virtual Components

Healthcare “Micro Footprint” is also a combination of different population enhanced patient entry points

Type of Care	Telehealth	At Home Complex Care	Retail Clinic	Primary Care	Behavioral Health	Employer 1°Care/ Workers Comp On-site Clinics	Urgent Care	Hybrid/ED Urgent Care	ED
		Rash, HTN, Diabetes, nonspecific back pain, wellness visit	CHF, Diabetes, High ED Utilizers	Bronchitis, Ear Infections, Sore throat	Wellness & Screening Rash, Non-allergy HTN, Diabetes	1° Mental Health Issues, Addiction, Hybrid Health Problems	Employee Primary Care & Workers Comp On-site Care	Injury, Sprain, Bronchitis URI, Ear Infections, Sinus, UTI, Open wounds	Chest pain, Fever, Shortness of breath, bleeding
Expectation of Patient	Convenience	High	High	Med	High	High	High	High	Low
	Intensity Level	+ - +++	+++	+	+ - ++	+ - ++	++	++ - +++	+++
	Cost	\$ - \$\$	\$\$	\$	\$\$	\$\$	\$	\$\$ - \$\$\$	\$\$\$\$

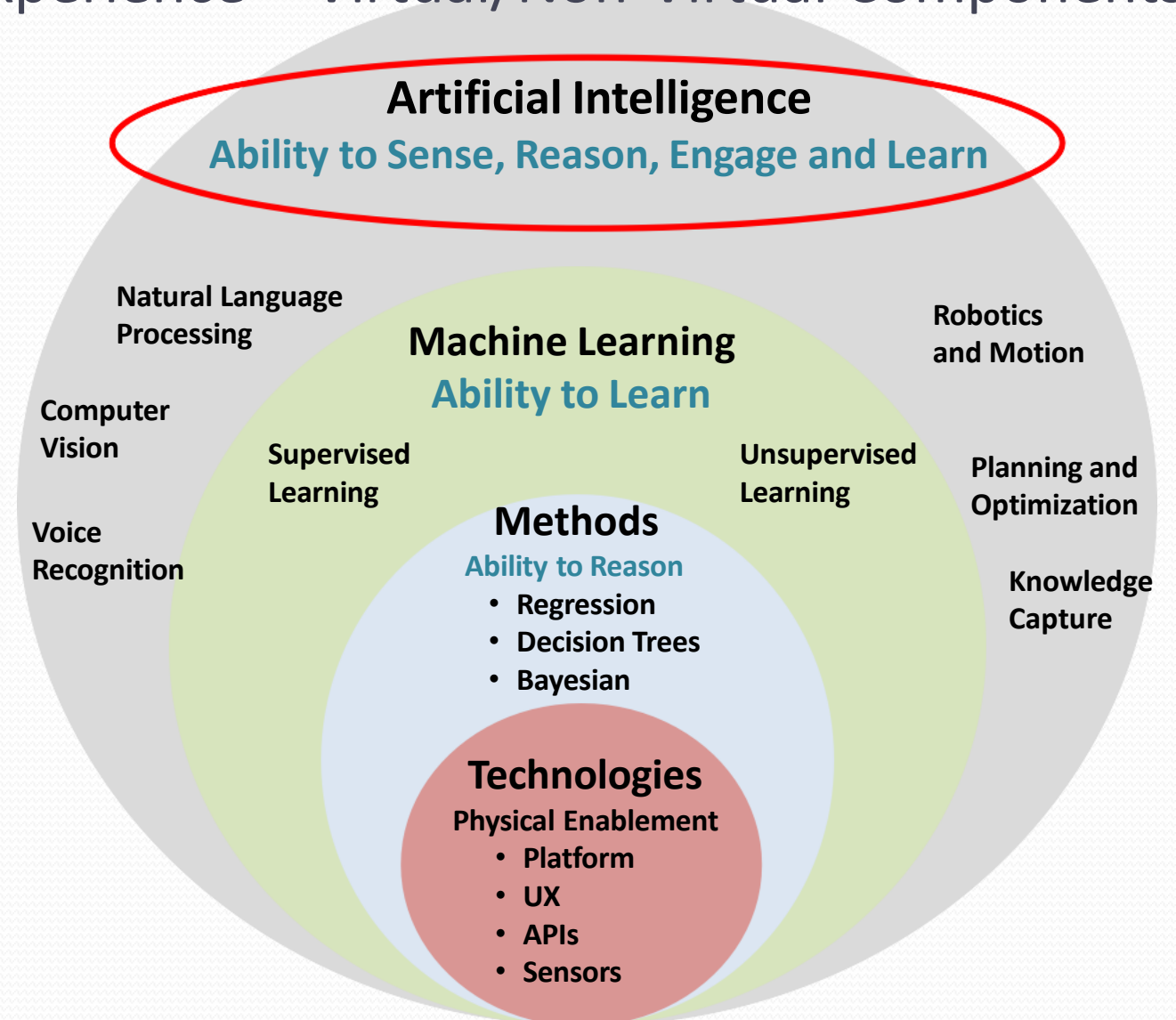
Grow: This is the Universal - Channel strategy matters in both the volume and value worlds. Channels drive growth and growth drives organizational investments and economies of scale. All organizations--- even those in predominately value-based payment environments--- need to grow – Home Health

Super Consumer/Member/Patient Experience – Virtual/Non-Virtual Components

– Advanced Artificial Intelligence and Expert Systems



What is Artificial Intelligence?



Source: James Bates, AdviNow

NAMCP Fall Conference

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Super Consumer/Member/Patient Experience – Virtual/Non-Virtual Components

– Digital Health / Telehealth / Telemedicine / Tele-Monitoring / RPA Extraction

AI Enabled Virtual Clinic



- Phone/ Medical Station
- ID/Insurance Card Scan, OCR
- Facial Recognition
- AI dynamic Q/A
- Care Coordination

2 Minutes

AI-Driven Exam



- Chief Complaint Collected
- AI Completes Q&A
- AR Guided Medical Measurement
- Otoscope, Stethoscope, Blood Pressure, Thermometer, Pulse Oximeter, Scale
- AI Engagement until Diagnosis

10 Minutes

Curated Working Diagnosis



- Diagnosis Probability & Justification
- Images, Sounds, Measurements
- AI Suggested Treatment Options
- AI Charts Patient

1 Minute

Optimized Provider Consult



- Provider Verifies AI Collected Data
- Diagnosis & Treatment Confirmation
- AI Scribes EHR SOAP Notes
- AI Scribes Discharge Notes
- AI Orders Script, Lab, Images Ordered
- AI Completes Chart for Billing

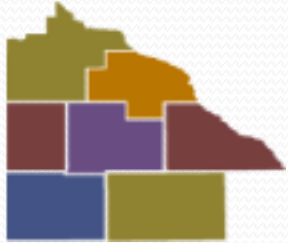
2 Minutes

Conclusions, Critical Takeaways and Relevance – 2022



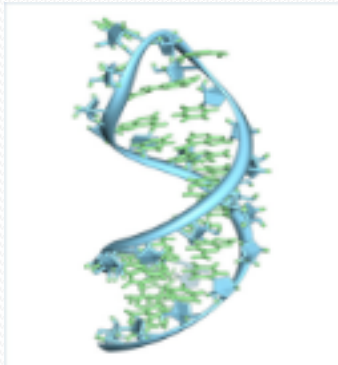
Evolution of “Value Based” Products – The “Next Generation” CINs, ACOs, DCEs Start of Come of Age

- Value Based Health Plans – Driven by increasingly sophisticated plan, delivery system and member facing technology will drive an increasingly technologically advanced Value Based Contracting requirements so that Providers will evolve on a continuum of reimbursement structures ranging from “Shared Savings, Upside/Downside Models” to “Percent of Premium/Capitation/DCE-ACO Reach Models” based on internal analytic capabilities.



Super Consumer/ Member/ Patient Experience with Multiple “Front door” and Medical Destination Enhancements

- The Super Consumer /Member/ Patient Experience will be altered by Facilities, Digital Technology Wraparounds, and Virtual Complex Care.
- Destination Medical Centers similar to Mayo – Rochester, Scottsdale and Florida development plans will become common with a Medical Center, Medical School and Surrounding Community Expenditures exceeding \$ 10+ Billion over the next 10 years at certain regional; geographic locations and institutions.



Transformational mRNA COVID19 Vaccines and DNA products have paved the way for “Next Generation” Cancer Diagnostics and Therapies

- Transformational mRNA technology has seen proof of concept with Human mRNA COVID19 Vaccines. “Next Generational” diagnostic and therapeutic mRNA and DNA advances especially in “mRNA frame shift array technology” will provide some of the earliest, diagnosis of cancer and drug effectiveness in cancer treatment ever seen. Ultimately, the First, prophylactic Canine Cancer Vaccine results may be in Dog Trials published in 2022. AI enabled CCTA will amplify CAD outcome predictability.

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Georgia Activities

Georgia's Drive to Value-Based Care

1. Major health systems have made substantial commitments and investments in value-based payments and population health.
CIN – Northeast Georgia Health System (NHS), Northeast Georgia Health Partners (ACO) Network (with HP2 physician-led CIN alignment)
Georgia Physicians for Accountable Care - ACO
2. Georgia Health information Network (Gahin) the state-designated entity for health information exchange. So far, primary care and health systems)
www.gahin.org
3. The largest commercial player, Blue Cross Blue Shield Georgia (BCBSGa) is playing an active role. Focus on data, communications, population health management
4. Atlanta Business Chronicle –
 - GA landscape moving toward wellness management rather than sickness management
 - Primary care based (IPAs and ACOs)
 - Considering patients who present in office as well as those who haven't
 - Early participants in Medicare ACO models (since 2012)
 - About 80% of business through BCBSGA is self insured
 - Will require different conversations and partnerships, in 2017 maybe on the 5 yard line, 95 yards to go
 - Can be hospital centric or patient centric, not both
 - Rural markets driving networked care solutions
 - Solo innovation won't work, requires collaboration
- Georgia Business & Industry Association dissolved December 2016

“Value-Based Health Care”, *Atlanta Business Chronicle Table of Experts*, Dec. 8, 2017, <https://www.bizjournals.com/atlanta/feature/table-of-experts/value-based-health-care.html>

Medicare is forging ahead, and
looking back later to see what
worked and what didn't

Medicare is Pushing Ahead as a Key Driver

- Medicare has begun (and ended) several Value Based Programs that were national in scope and crossed many specialties, including oncology^{21,22}
 - Goal set in 2015 was to achieve 90% of Medicare payments to hospitals and doctors to be tied to measures of quality by 2018. ²³
- In 2018, 56.9% of patients with Cancer were 65 years or older, making Medicare the payer with the highest Market Share of cancer patients²⁴
- Data sharing, collection and reporting – Medicare has provided over 260 reports on initiatives within the CMS Innovation Center on ongoing projects²⁵
- **Medicare, as the largest single payer for oncology specialists, and most other specialties, took an early lead in rolling out pilots and demonstration projects for value-based initiatives**

The OCM Model - Program Overview

- The CMS Oncology Care Model – 2016 – 2022 (Extended 1 year during pandemic)²⁶
 - A national network – Initially nearly 200 physician groups and 17 payers, by 2021 – 176 groups and fewer payers
 - Covering nearly all cancer types, all Medicare beneficiaries of the practice, for all Medicare Part A and Part B services received during twelve 6-month episodes of care
- All costs – Not just cancer costs but every dollar paid by Medicare for each beneficiary – encouraging attention to patient population management, and co-morbidities and downstream costs
- All beneficiaries – All patients of the participating cancer group were automatically enrolled and attributed by Medicare
- Payment – Participating practices received a regular Fee For Service payment for services, plus 1) a Monthly Enhanced Oncology Services (MEOS) \$160 PBPM and 2) a Performance-Based Payment for OCM Episodes
- Quality Metrics – Quality measurements did change over performance periods, Medicare tracked over patient- and practice-reported measures as well as claims-based measures.
- Reporting and Feedback was provided on quarterly and performance period periods, on practice and patient level details.

CMS OCM Goals

- The Innovation Center's Oncology Care Model (OCM) focuses on an episode of cancer care, specifically a chemotherapy episode of care
- The goals of OCM are to utilize appropriately aligned financial incentives to improve:
 - Care coordination
 - Appropriateness of care
 - Access for beneficiaries undergoing chemotherapy
- Financial incentives encourage participating practices to **work collaboratively** to **comprehensively** address the complex care needs of beneficiaries receiving chemotherapy treatment and **encourage the use of services that improve health outcomes.**
- But hindsight evaluation reports focus on lack of savings and little changes in quality

Implications of the CMS OCM Approach

- First time a major payer has made MDs accountable for total costs of care
- First time MDs have been given total claims for patients on a large scale
- Drugs are part of the cost structure
- The bottom line becomes a top line target
- Extensive quality measure reporting in effort to avoid shortcuts in care
- A True Game Changer

OCM Practice Transformation – Patient Access

- Provide the core functions of patient navigation;
- Document a care plan that contains the 13 components in the Institute of Medicine Care Management Plan outlined in the Institute of Medicine report, “Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis”;^[2]
- Provide 24 hours a day, 7 days a week patient access to an appropriate clinician who has real-time access to practice’s medical records;
- Treat patients with therapies consistent with nationally recognized clinical guidelines;
- Use data to drive continuous quality improvement; and
- Use an ONC-certified electronic health record and attest to Stage 2 of meaningful use by the end of the third model performance year.

Care Management – Patient Engagement (but mostly in office)

1. Patient information (e.g., name, date of birth, medication list, and allergies)
2. Diagnosis, including specific tissue information, relevant biomarkers, and stage
3. Prognosis
4. Treatment goals (curative, life-prolonging, symptom control, palliative care)
5. Initial plan for treatment and proposed duration, including specific chemotherapy drug names, doses, and schedule as well as surgery and radiation therapy (if applicable)
6. Expected response to treatment
7. Treatment benefits and harms, including common and rare toxicities and how to manage these toxicities, as well as short-term and late effects of treatment
8. Information on quality of life and a patient's likely experience with treatment
9. Who will take responsibility for specific aspects of a patient's care (e.g., the cancer care team, the primary care/geriatrics care team, or other care teams)
10. Advance care plans, including advanced directives and other legal documents
11. Estimated total and out-of-pocket costs of cancer treatment
12. A plan for addressing a patient's psychosocial health needs, including psychological, vocational, disability, legal, or financial concerns and their management
13. Survivorship plan, including a summary of treatment and information on recommended followup activities and surveillance, as well as risk reduction and health promotion activities

Patient Navigation - Proactive

1. Coordinating appointments with providers to ensure timely delivery of diagnostic and treatment services
2. Maintaining communication with patients, survivors, families, and the health care providers to monitor patient satisfaction with the cancer care experience
3. Ensuring that appropriate medical records are available at scheduled appointments
4. Arranging language translation or interpretation services
5. Facilitating financial support and helping with paperwork
6. Arranging transportation and/or child/elder care
7. Facilitating linkages to follow-up services
8. Community outreach
9. Providing access to clinical trials, and
10. Building partnerships with local agencies and groups (e.g., referrals to other services and/or cancer survivor support groups).

OCM Practice Challenges for Transformation

- Technology Infrastructure (access to own data)
 - Patient Identification and Billing
 - Patient Reconciliation
 - Coding – Billing and Comorbidities
 - Building Quality Measure Tracking and Reporting
 - Patient Care Plan, Navigation and Care Management Fulfillment, Work Flow and Reporting for Continuous Quality Improvement
 - Quality Measures tracking, and reporting to CMS and payers
 - CMS Data Analytics, Prediction, and Risk Assessment
- Resources and Work Flow
 - Patient Communication
 - Care Management
 - Team Integration Across Practice
 - Staffing, Training, Rapid Implementation
- Quality
 - Identification of Gaps
 - Reporting, Analytics, Integration into Teams and Daily Practice Life
 - Reviewing for Continuous Quality Improvement
- Costs
 - Recognizing and Tracking Costs external to practice: drivers, existence, barriers, opportunities
 - Patient severity and risk stratification
 - Eye on the goal: CMS savings of 2.75% or 4% for each performance period
- **The low hanging fruit ultimately were not enough, drug costs and choices became differentiating factor. The challenges remain high.**

Medicare OCM – Reports experience through the first half of the program not optimal

CMS Reported on the OCM for Performance Period 1 to 6, the first half of the program

- The majority of cancer episodes were classified as higher-risk
- Practices did shift toward Higher-Value supportive care drugs
 - More cost conscious choices of supportive care drugs (higher value)
 - No sign that OCM is driving value-oriented chemotherapy or radiation treatment
- Healthcare service utilization (ED visits, hospitalizations overall, chemotherapy-related side effects, office visits, or post-acute care or hospice use remained largely unchanged
- Payment reductions concentrated in four higher-risk cancer episodes: lung, Lymphoma, colorectal and high-risk breast
- *“OCM aims to achieve cost savings by improving care delivery processes such as patient navigation and adherence to national clinical guidelines. Many OCM practices focused on proactive outreach to patients and same-day care to avoid ED visits and hospitalizations. However, there was no OCM impact on patient-reported symptom management, or ED visits/hospitalizations due to chemotherapy side effects. Medicare payments for higher-risk episodes declined relative to comparisons but increased for lower-risk episodes. When model payments from PP1-4 were included (MEOS and PBP), OCM resulted in net losses for Medicare.”* CMS Findings At a Glance Oncology Care Model Evaluation of Performance Periods 1 to 5
- *“The cost of cancer treatment in the United States continues to rise, with a projected expenditure of \$246 billion by 2030. 17 TEP for OCM and comparison episodes also increased over time, from an average of \$28,500 during the baseline period, to an average of \$34,000 during the intervention period (from PP1 through PP6). This steep increase in TEP was primarily due to growth in spending for Part B chemotherapy drugs and for oral Part D drugs. “*
- **Is this Value-Based Care from Medicare’s perspective?**

Participating Oncology Centers/Practices report that the OCM Program has been effective

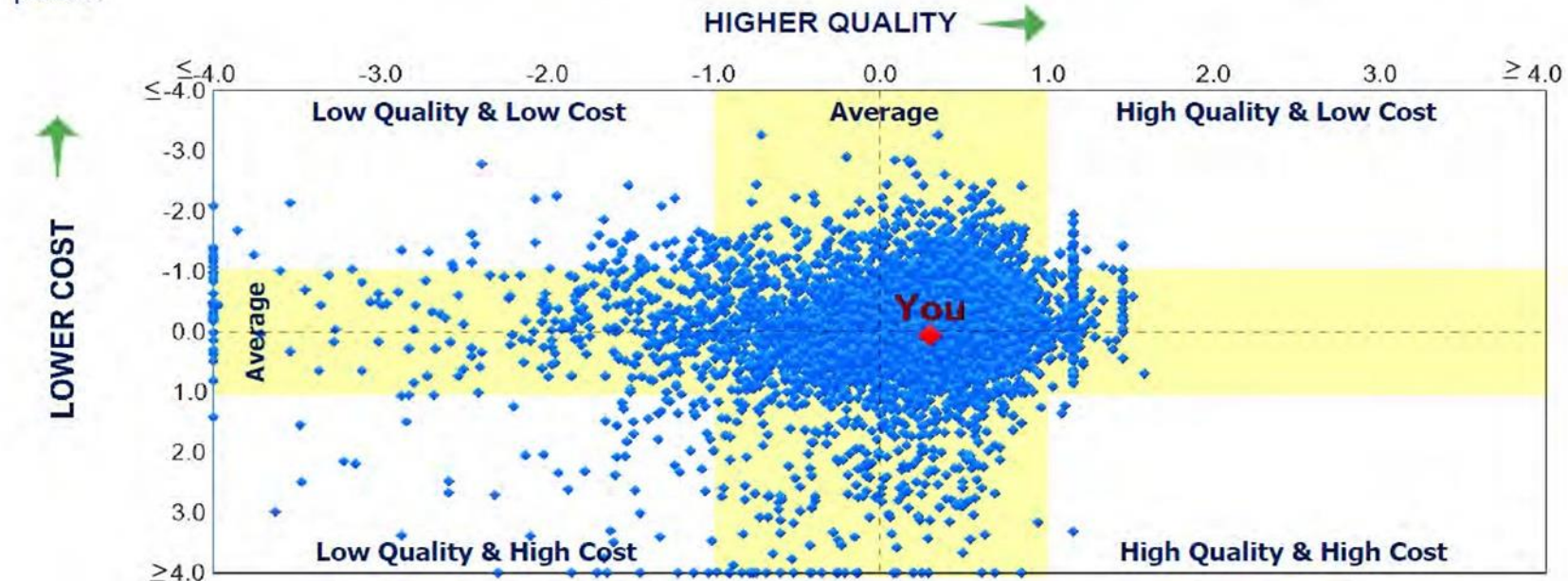
- Practice transformation^{28, 29} led to significant improvements in patient management, communication and support
 - Practices invested heavily in data analytics
 - Created care navigation touchpoints
 - Incorporated electronic patient reported outcome monitoring to improve patient care
 - Built palliative care programs
 - Nurse navigation
 - Enhanced triage
 - Telehealth Services
 - Urgent Care within the clinic/practice
- Physician perspective on results of the program^{29,30}
 - Since the launch of the OCM, Florida Cancer Specialists & Research Institute has saved Medicare more than \$140 million, \$31.7 million in the last performance period (probably PP8 but not stated)
 - Hospital admissions were 8% lower than other OCM practices
 - Emergency room visits not leading to admission was 21% lower than other practices
 - Results from the 8th performance period (PP8) revealed that all 14 US Oncology participating practices (about ¼ of all providers in the whole OCM program) saved Medicare about \$54 million, and \$197 million in total savings since the beginning of the program.
 - Tennessee Oncology saved Medicare over \$5 million between the 2nd half of 2019 and the first half of 2020 (PP8), while receiving a 100% quality score, a 20% reduction in hospitalizations and a 27% reduction in emergency visits
 - *“Transforming to value-based care is not easy and takes time....The recent OCM report suggests the model did not succeed; however, our experience shows that for practices that commit to high value care....For Tennessee Oncology, we are finally here and excited to be on the cutting edge of care delivery innovation to improve patient care,” said Natalie Dickson, MD, president and chief medical officer at Tennessee Oncology*²⁹ again
 - **The OCM program took time to develop, time to receive feedback from CMS, and time to transform practices. Major savings are being seen in Performance Periods later than current CMS evaluations. Is this Value-Based Care from the providers perspective?**

Value = Quality and Cost Medicare MIPS Program

- Value Based Modifier Scoring and Comparisons – CMS Quality Resource Utilization Report (QRUR) **but is this a Value Program?**

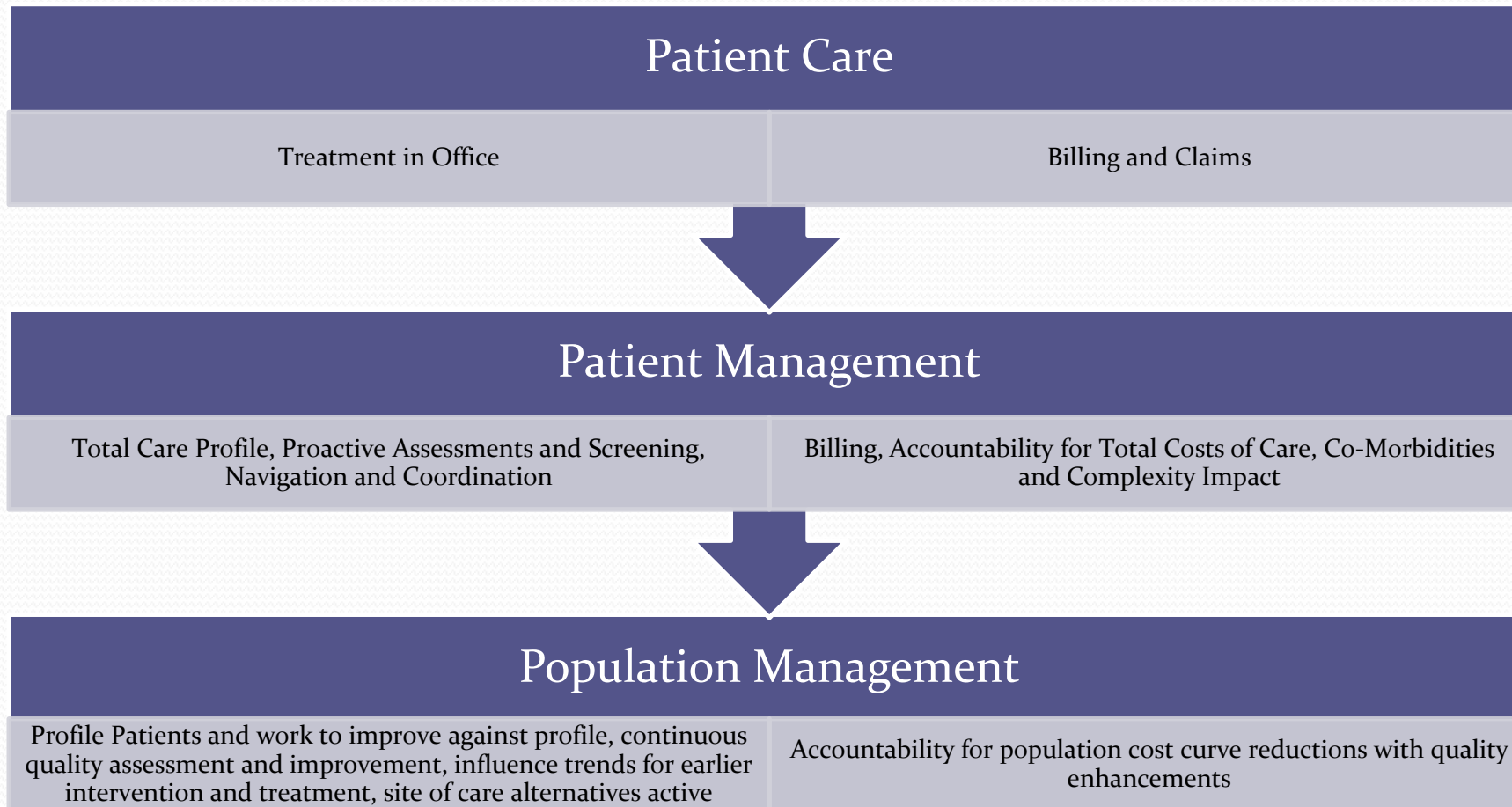
Your TIN's Performance: Average Quality, Average Cost

The scatter plot below displays your TIN's quality and cost performance ("You" diamond), relative to that of your peers.



Transformation

Paradigm Shift



New Reality

- 4 Walls no longer our window on patients
- New Mindsets
 - Patient management
 - External Costs Awareness and Management
 - Upstream and Downstream Accountability
 - Technology Expansion beyond HER
 - New Expectations Just to Stay in Game, let alone Maintain Role

**Patient Engagement is the key to
the future**

Patient Engagement outside the office walls is value-based care

- Telemedicine can extend the reach of care providers and support into rural areas or to home bound patients
- Alerts and reminders keep patients and their treatments on track for best effectiveness
- Wearables provide information about patients and the effectiveness of their treatments (heart rate, sleeping patterns, daily exercise, etc.)
- Information, libraries, groups, provide 24/7 access on patient's terms for education and guidance
- Regular check-ins, prompts, interactions can offer support, prevention, behavioral or actionable solutions/adaptions, that can help patients self manage, or escalate to appropriate clinical intervention before patient seeks emergency department or needs hospitalization
- **Challenge – The Best Cancer Outcome is to not get it, prevention, screening, early diagnosis, co-morbidities and adverse event management – much outside of oncology office**

Behaviors Drive Health Actions

Evidence-based behavioral and cognitive science using proven psychological techniques, leveraging emotional attributes and cognition to motivate in-the-moment actions.

- **Emotional attributes** such as trust, credibility, outlook, reciprocity.
- **Cognitive functions** such as brain encoding, storage, retrieval.
- Uses technology to get people to want to listen, learn, be “**resilient**” and stay on course.



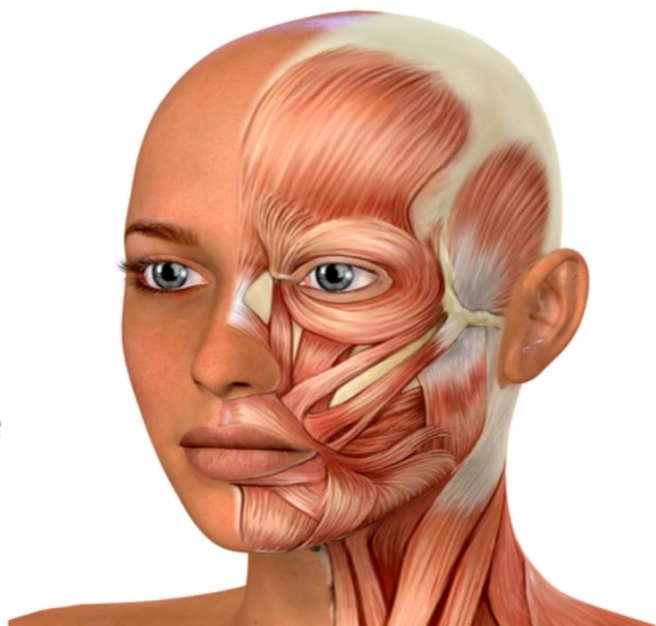
Behaviors Drive Health Actions

Engage The Person, Not The Disease

The Science

BehavioralRx®

- ✓ *Behaviors*
- ✓ *Emotions*
- ✓ *Cognition*
- ✓ *Human Factors*



Medical Science

- ✓ *Biology*
- ✓ *Chemistry*
- ✓ *Anatomy*
- ✓ *Physiology*

New Skillsets for Physicians and Administrators

- Population management accounting and leadership
- Integration of new digital therapeutics to augment staff resources
- Collaboration
 - Outside entities
 - Payers
 - Employers
- Analytics
 - Population (Practice and Global Claims, Screenings and Assessments)
 - Value
 - Risk
 - Bundling
- Regulatory Management/Advocacy
- Patient Support and Assessments Outside the Practice

Dashboard Measures – Practice, Physician

- Emergency Department Visits (Frequency, Cause)
- Outpatient Visits (Frequency, Cause)
- Inpatient Utilization (Frequency, Cause)
- Days of Treatment before Death
- Days in Hospice Care at End of Life
- Advanced Care Planning Discussions
- Lines of Therapy
- Medical CoMorbidity
- Orals Compliance
- Actionable Opportunities to intervene in care process to change costs and variation – Actual Care Planning and Navigation
- Avg PMPY
- Active Chemo Mbr Months
- Active chemo PMPM
- IP Avg LOS (with Cause)
- Annual pnt costs (by category – labs, drugs, etc)
- Clinical Care Plan Measures – Patient screening results and responses
- High Risk Patients – Daily, Weekly, Monthly Status
- **Many new questions that are not in our EMRs....Need new analytics and technology**

Proactive Patient Management in the field

Patient Engagement outside the MD Office

Outreach Comes from Many Sources

- Specialty Pharmacies
- Pharmacy Benefits Managers
- Wellness and Prevention Vendors
- Patient Engagement Contracted Vendors
- Employers
- Health Plans
- Accountable Care Organizations
- Health Systems
- Primary Care
- Pharma Industry
- Patients themselves
- **Oncology Providers?**

Patient Engagement Takes Many Forms

- Telehealth
- Patient Portals
- Apps
- Wearables
- Appointment Reminder and Scheduling
- Virtual Advice, Chat, Visits
- Monitors
- Lifestyle behavior modification
- Medication Support and Adherence
- Messaging on Condition Management and Quality of Life
- De-escalation assistance through bi-directional messaging
- Day-to-day psychosocial resources
- Enable patients to self manage for anxiety, stress, fatigue, distress and sleep challenges
- **How are Oncology Providers Engaging?**

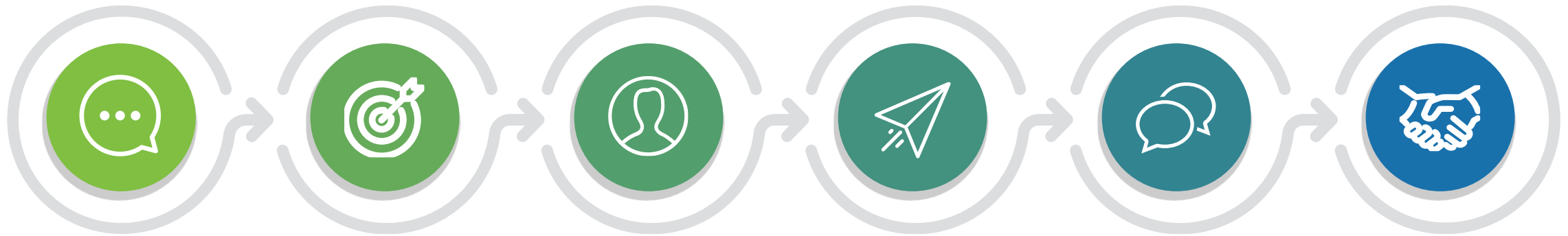
Patients are more than their doctor visits

- Alice – Cancer Patient
 - Sees MD x times over period for diagnosis, treatment and followup
- **The rest of the time, Alice:**
 - Works (or calls out sick from work)
 - Claims disability
 - Incurs medical costs
 - Gets second opinions
 - Searches the internet for advice, support, validation,
 - Changes the dosage or frequency of some at home medications for a variety of reasons
 - Uses alternative home therapies
 - Experiences worry, frustration, sickness, financial challenges, home and family stressors, transportation and psychosocial concerns
 - May have adverse events, symptoms and side effects that she may or may not report to her treating physician
 - May have co-morbidities that are managed or not during the cancer journey
 - Goes to the emergency room or hospital
 - Has questions
- Someone wants to monitor, track, collect data on Alice, and
 - Get paid for doing so
 - Monetize what they learn and the interactions they have with Alice
 - **This is/will usually happen with or without the involvement, knowledge/coordination with the treating physician**

View from One Active Oncology Digital Therapeutics Specialist – the Potential

- Connecting daily with patients in their own environments, encouraging them to participate in the development and activation of their care plans, and communicating in real time is what makes digital therapeutics unique and successful for patients and providers alike.
- Managing a cancer diagnosis affects the body and mind, substantiated by psychological or outlook-related issues representing more than 50% of the top escalations to clinical care teams.
- Through the use of digital therapeutics, we can learn how to support patients by tracking their stress and anxiety levels to keep them as healthy as possible while they are going through treatment.
- Patients and providers can build a deeper connection through consistent support and communication, focusing together on specific needs to deliver the highest quality of care.
- **The Best Cancer Outcome is the one that is prevented, caught early, managed to avoid progression – disruption, not chasing metastatic or end stage disease.**
- Bob Gold, “Digital Therapeutics in the Oncology Outpatient Setting”, Oncology Practice Management, March 21, last accessed 12/6/2021 at <https://www.oncpracticemanagement.com/issues/2021/march-2021-vol-11-no-3/2212-digital-therapeutics-in-the-oncology-outpatient-setting>

What "True" Engagement Looks Like



**Simple and
Highly
Directed**

**In the
Moment**

**It is and
Feels
Personal –
Creates
Intimacy**

**Concierge
Care Goes to
the Person**

**Enable
Patients to
Influence
Based on
Their Lives**

**Optimizes
Human
HCP Talent,
Minimizes
Adverse Events**

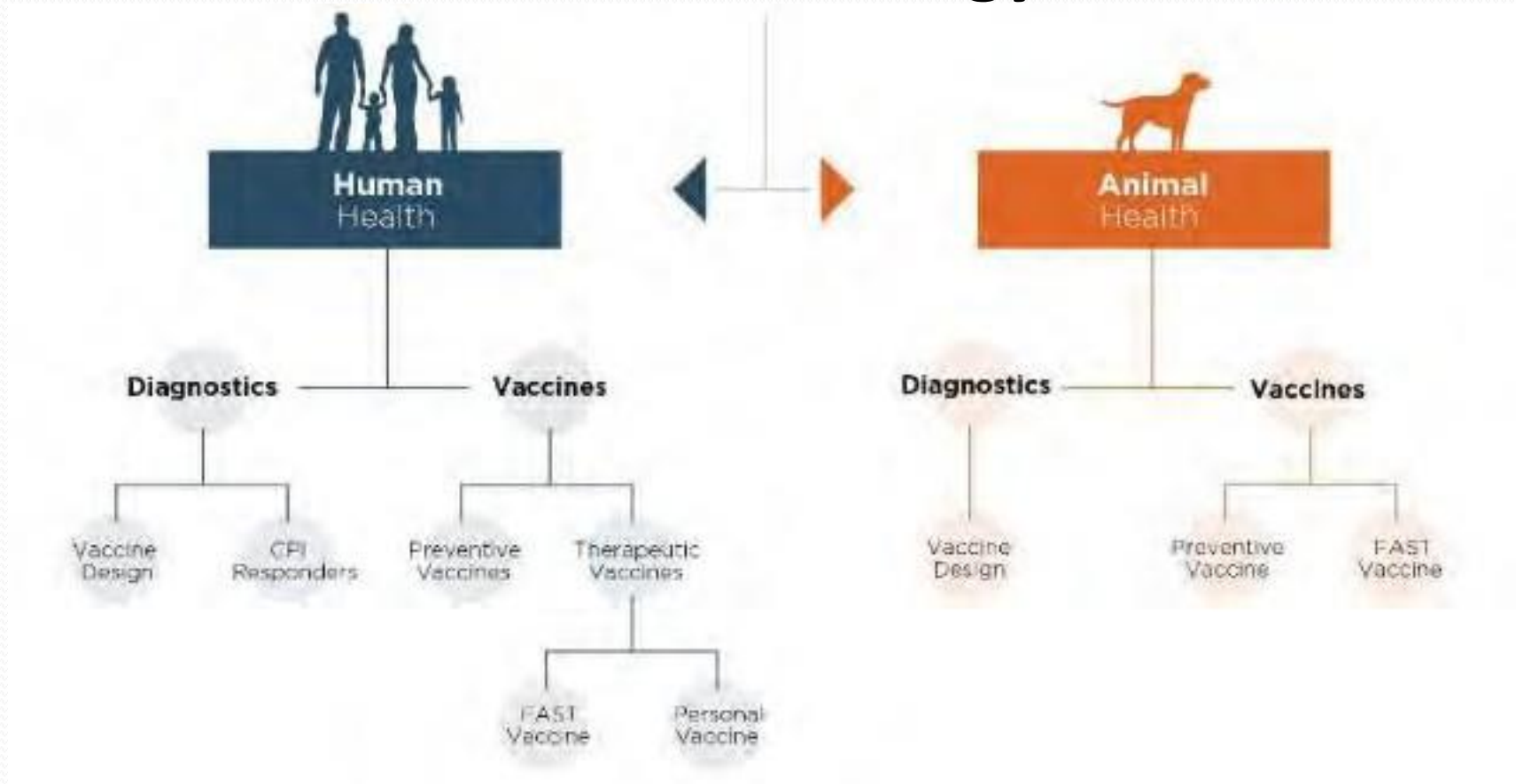
**“Value” and how it is delivered
may be very different in the not-
so-far-off future.**

What will Oncology Care look like in a few years?
Are there drivers we may not be considering?

Transformational mRNA Technology

– Discoveries and Technology Lead to a Broad Product Portfolio

mRNA Technology



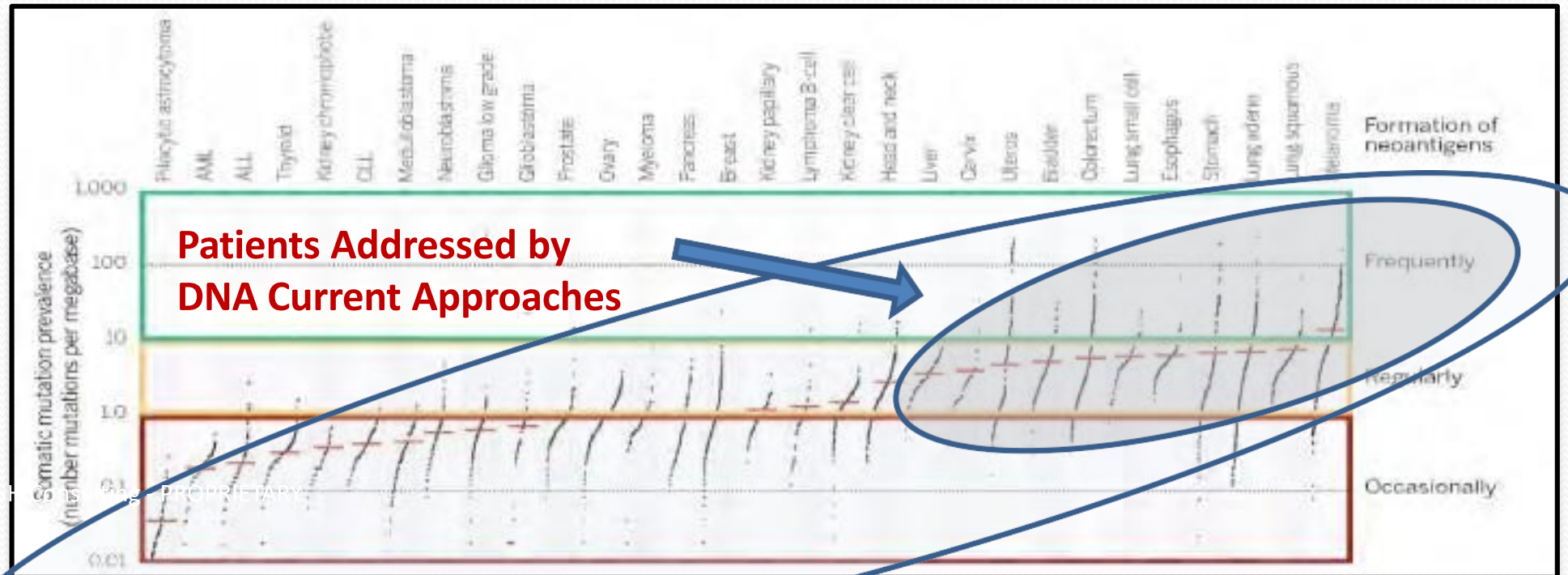
Source: Stephen Johnston PhD, CEO Calviri

Transformational mRNA Technology – Cancer Diagnosis & Treatment Impact

RNA Neo-epitopes Drive New Cancer Diagnosis and Treatment Models

Production of Personalized and Standardized Cancer Vaccines for “Hot and Cold Cancers”

RNA Neo-epitope Approach Could Address All Patients



Transformational mRNA Technology

– The World’s Largest Canine Interventional Clinical Trial: PREVENT Cancer



- mRNA Technology is conducting the world’s largest study, Vaccine Against Canine Cancer (VACCS) among 800 dogs
- Objective is to test the efficacy (over 5 years) of a preventative vaccine against all major cancers. Double Blind, Equal Arms.
- Study funded by a \$6.4M grant from Open Philanthropy Project and mRNA Technology
- 2 years, 600+ Dogs Enrolled 5/2021. No Vaccine Safety Issue.

Clinical Research Sites



Source: Stephen Johnston PhD, CEO Calviri

Transformational mRNA Technology – Progress on Select Studies

Treatment

Prevention

Diagnostics

Humans

- A study to build a test to predict Immune Checkpoint Inhibitors (ICI) has been completed and is nearing publication.
- A Pediatric Brain Cancer diagnostic study is being prepared for publication; a vaccine trial is readied.
- An early-stage Breast Cancer diagnostic study is underway; a vaccine study is designed.

Dogs

- The largest dog vaccine trial in the world is underway at three premier Veterinary Universities. The five-year trial will assess the performance of a preventative cancer vaccine.
- HSA, Hemangiosarcoma, is one of the most aggressive and common dog cancers. Both diagnostic and vaccine studies are ongoing

		Indication	Preclinical	Clinical/POC	Phase 1	Phase 2
Human Health	Diagnostics	Breast Cancer Stage 1	→			
		ICI Response/iAE	→			
	Vaccines	Renal Cancer Therapeutic	→			
		Pediatric Brain Cancer NF1	→			
Animal Health	Diagnostics	HSA Stage 1	→			
	Vaccines	HSA Therapeutic Vaccine	→			
		Preventative Vaccine	→			

Source: Stephen Johnston PhD, CEO Calviri

Conclusions, Critical Takeaways and Relevance – 2021/2022



FAANG+M Creating Multi-Layered Direct/ Indirect Effects in Healthcare

- FAANG + M – Facebook, Apple, Amazon, Netflix, Google + Microsoft with 25%+ of the S&P Value pushing aggressively into healthcare and healthcare adjacencies– delivery, insurance, distribution, pharma, device, platform development, etc. First individual \$ 19+ Billion FAANG+M acquisition occurred 4/21 – Signals key inflection point. Multiple Mega-Deals at \$ 100M+ will happen in the next 12 months.

TopCo. / HoldCo.

Aggregators of All Types Making Inroads

- Healthcare/Physician “Unicorns” – Summit Health, Envision, and DaVita Are the First Private/Then Sometimes Publicly held \$ 5-\$10 Billion+ non-Mayo Clinic, non-Cleveland Clinic, PPM entities with Regional/National Impact. Optum and Private Equity Organizations actively purchasing PCP practices, will hit 60,000 employed MDs this year driving up prices for large groups repeatedly over the billion-dollar mark.



Digital Health / Telehealth /Telemedicine/ Tele monitoring + Development of Adaptive Artificial Intelligence

- “Tele Everything” is re equilibrating to in-between Tele Everything to Targeted Digital Health. Adaptive artificial intelligence and expert systems will enhance and support high performing, population-specific clinically integrated health plans/delivery systems. Early adopters already in the market largely for administrative function simplification – registration, eligibility, payment, artificial language and clinical data extraction from the EMR, etc.

Conclusions, Critical Takeaways and Relevance – 2021/2022



Evolution of “Value Based” Products – The “Next Generation” CINs, ACOs, DCEs Start of Come of Age

- Value Based Health Plans – Driven by increasingly sophisticated plan, delivery system and member facing technology will drive an increasingly technologically advanced Value Based Contracting requirements so that Providers will evolve on a continuum of reimbursement structures ranging from “Shared Savings, Upside/Downside Models” to “Percent of Premium/Capitation/DCE Models” based on internal analytic capabilities



Super Consumer/ Member/ Patient Experience with Multiple “Front door” and Medical Destination Enhancements

- The Super Consumer /Member/ Patient Experience will be altered by Facilities, Digital Technology Wraparounds, and Virtual Complex Care.
- Destination Medical Centers similar to Mayo – Rochester, Scottsdale and Florida development plans will become common with a Medical Center, Medical School and Surrounding Community Expenditures exceeding \$ 10+ Billion over the next 10 years at certain regional; geographic locations and institutions.



Transformation mRNA COVID19 Vaccines have paved the way for “Next Generation” mRNA Cancer Diagnostics and Therapies

- Transformational mRNA technology has seen proof of concept with Human mRNA COVID19 Vaccines. “Next Generational” diagnostic and therapeutic mRNA advances especially in “mRNA frame shift array technology” will provide some of the earliest, diagnosis of cancer and drug effectiveness in cancer treatment ever seen. Ultimately, the First, prophylactic Canine Cancer Vaccine results may be in Dog Trials 2022.

Thoughts for GASCO

- Practices need a seat at the table, locally and potentially nationally
- Watch the bigger picture, and how your group/center will fit into a primary care patient management model, accountable care organizations, clinically integrated organizations, transformation and pay for performance market changes
- Don't forget to look behind you, and all around you. Others are constantly moving and moving in on your patients. Decide how to stake your position and differentiate yourself and your patient management from the growing noise.
- Value may ultimately be defined by the one paying for care, and require a repositioning of the groups position in a larger ecosystem (not necessarily acquired, but collaborating)
- Patient engagement is being transformed every day, provider groups need to be at the table and take the lead to control the chaos.
- **Quality is the goal, but may not be the measurement for some**



Thank You, and Good Luck

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