

Are The New Changes in Congress an Answer for Inequity in Terms of Access to Molecular Testing and New Cancer Agents

- Kashyap Patel, MD, AboiM, BCMAS
- **Recognized by the US congress as an outstanding citizen who set the Gold Standard for decades**
- CEO, Carolina Blood and Cancer Care
- Imm past President, Community Oncology Alliance
- Imm. past Chairman, Clinical Affairs, Association of Community Cancer Centers
- Medical Director, International Oncology Network
- Medical Director, Blue Cross Blue Shields (consultant), SC
- Associate Editor in Chief, AJMC (EBO)
- Member task force, NCCN DEI initiative

Can congress or Govt solve problem?

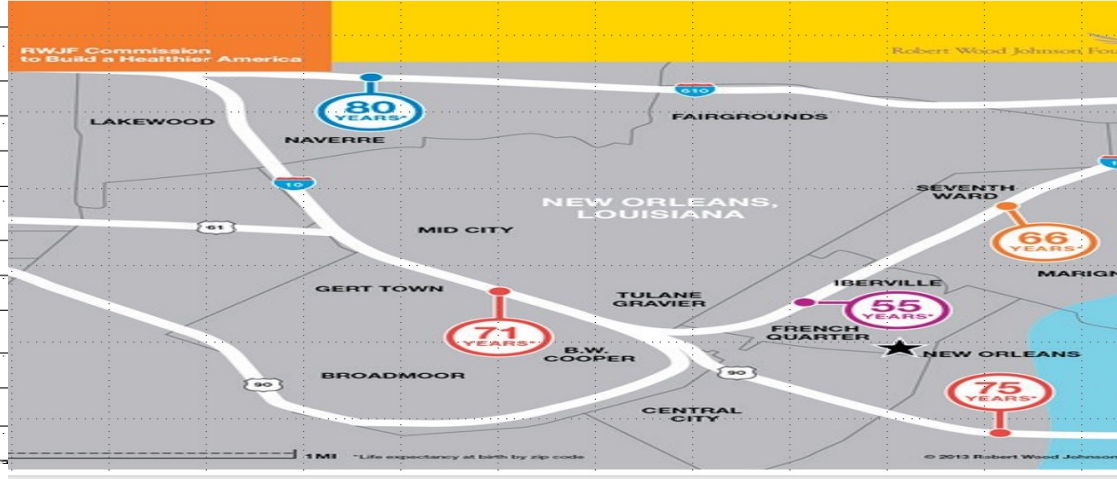
- Cancer Moonshot since 2015: Still we know that 34% of cancer deaths are preventable
- Personalized Medicine Initiatives - SOTU and still GWAS data suggested that only 2% Black patients 1% patients in genome wide studies
- VBC models concept of Value – equals to cost rather than true value to patients
- Too many fragmented, siloed and compartmentalized policies (like ACA and Medicaid Expansion)

34% Of all cancer deaths could be prevented if socioeconomic disparities are eliminated

Eliminating healthcare disparities for racial and ethnic minorities would have saved \$230 billion in direct healthcare costs and over \$1trillion in premature deaths and illnesses between 2003-6

DEATH RATES with cancer types	African Americans	White	Rate Ratio
Prostate, males	38.4	18.2	2.11
Stomach	5.3	2.6	2.04
Multiple myeloma	6.0	3.0	2.00
Cervix uteri, females	3.1	2.2	1.41
Breast, females	27.3	19.6	1.39
Colorectal	18.3	13.4	1.37
Liver/Cholangio	8.5	6.3	1.35
Pancreas	13.3	11.0	1.21
Lung and bronchus	40.2	39.3	1.02
Kidney/renal pelvis	3.4	3.7	0.92

Source: American Cancer Society, Cancer Facts and Figures, 2015. Data from SEER Cancer Statistics Review, 1975-2012. Notation: *Rate ratio is based on the white rate.

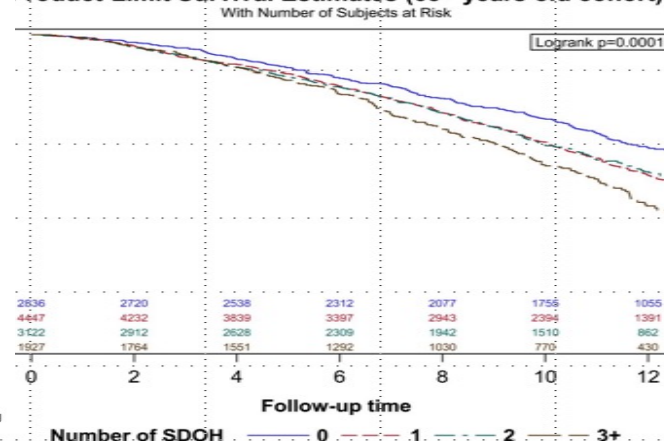


Lack of Screening and impact on individual and population health

- Cancer screening saves lives and reduces total cost of care during lifetime of beneficiaries
- 87% of Eligible Seniors Do Not Receive Lung Cancer Screenings; Lung cancer screenings were higher among Medicaid beneficiaries in states that covered the preventive service.
- Over 7,600 Medicaid beneficiaries—or 15.7 percent—received a screening, leaving approximately 84 percent that did not. Nearly 41,500—or 12.5 percent—of the Medicare beneficiaries received the screening. Over 292,400 Medicare beneficiaries who were eligible for a lung cancer screening—or 87.1 percent of eligible patients—did not get screened.
- Breast cancer is the most common cancer worldwide and the most common cancer diagnosed in American women. It is second leading cause of cancer death in American women.
- Even though curable when caught earlier (close to 99%), close to 30% women did not get mammography for breast cancer between 2017-2019



Product-Limit Survival Estimates (65+ years old cohort)



Social Determinants of Health (SDOH)

Economic Stability	Neighborhood and Physical Environment	Education	Food	Community and Social Context	Health Care System
Employment	Housing	Literacy	Hunger	Social integration	Health coverage
Income	Transportation	Language	Access to healthy options	Support systems	Provider availability
Expenses	Safety	Early childhood education		Community engagement	Provider linguistic and cultural competency
Debt	Parks	Vocational training		Discrimination	Quality of care
Medical bills	Walkability	Higher education			
Support	Zip code / geography				

Health Outcomes

Mortality, Morbidity, Life Expectancy, Health Care Expenditures, Health Status, Functional Limitations

Requirement	EOM/CMMI	Benefit to patients	Benefit to payers	Benefit to providers	Comments
24/7 patient access to appropriate clinician with access to EHR	Better care	<u>Yes</u> ; true PCOC	<u>Yes</u> ; reduce ER	Yes	
Use of ONC-certified EHR	Better care	Yes	<u>Yes</u> ; Data	better care coordination	
Utilize data for continuous quality improvement for healthcare Equity	Better care	Yes	yes	yes	
Provide core functions of patient navigation	Better care	Yes	Yes	Yes	
Document and share care plan with IOM plan	Better care	Yes	yes	Yes	
Guidelines concordant treatment	Better care	yes	Yes	Yes	
Socio demographic factors assessment and plans; place Z codes; Will help identify correctable factors,	Will get data without aligning goals of addressing SDoH/HrSN	Not likely; it would place moral and resource burden to provider (food insecurity, and other HRSN without addressing)	<u>Yes</u> ; data	Not at all as they will carry moral burden of seeing issues and not address it	Solution recommended on next page
Care Coordination	Better care				
Limited cancer types	Cost savings	Bias towards certain cancers based on cost and type of treatment	Yes	No	Keep all cancers inclusive as patients with cancer have all common challenges

- **Z55 series** – Problems related to literacy; **Z56 series** – Problems related to employment; **Z57 series** – Occupational exposure to risk factors; **Z59 series** – Problems related to housing and economic circumstances; **Z60 series** – Problems related to social environment; **Z62 series** – Problems related to upbringing; **Z63 series** – Other problems related to primary support group, including family circumstances; **Z64 series** – Problems related to certain psychosocial circumstances; **Z65 series** – Problems related to other psychosocial circumstances

Other measure that I learnt from our NOLA project recommend considering based on our experience of savings throughout five years

		Beneficiary	Cost	DEI
Extended Hours: weekend clinics to minimize risk of ER and/or hospital visits	This single step will likely reduce cost from 10-24% for cancer patients in total cost of care model	Patients, providers, and payers will all benefit	Will be better	Will address
Prevent Rehospitalization (HRRP) Implement Transitional Care Management and measure performance (99495/99496)-claims code	Yes	Yes	Better	Better
Biosimilars, generics (capture from claims codes)	Reduce costs for all		Better	Better
Guidelines concordant biomarker testing	Reduce cost, improve		Better	Better
Guidelines concordant germline test	Reduce cost by proactive steps		Better	Better
Expand access for walk in patients	Reduce ER visits; hospitalization and downstream costs	All stake holders	better	Better
Cancer screening based on USPSTF	Reduce total cost and improves Life expectancy	All stake holders	better	Better
ER visits in last 6 months; ICU stay in last 2 weeks Palliative care; Hospice care and place of death; LOS in hospice	42% of Americans die without hospice help that impacts quality of life for patients and care giver both; appropriate EOL care should be offered as a SOC	All stakeholders	Better	Better

TODAYS DATE		Chart No.	
FIRST NAME		LAST NAME	
DOB:			
1. What is your country of birth: USA, including Puerto Rico / Other			
2. How many years have you lived in the United States			
3. WHAT IS YOUR RACE?			
4. What is your Gender/sexual orientation: Male / Female/ Transgender /Prefer not to identify			
5. Sexual orientation: heterosexual/bisexual/LGBT/prefer not to identify			
6. EDUCATION status		Less than High school/high school/Undergraduate/Graduate/Doctorate	
7. WHAT IS YOUR MARITAL STATUS?		Married/living as married/Widowed/ Divorced/ Separated/ Never married/ Other	
8. ANNUAL INCOME? (household)		< than \$25,000/ \$25,000-\$49,999/ \$50,000-\$74,999/ \$75,000-\$100,000/\$100,000-149,999/\$150k-\$199,999/ \$200,000 or more How many members live on this income	
9. HOW OFTEN DO YOU FEEL THIS		I DON'T HAVE ENOUGH MONEY TO PAY MY BILLS NEVER / RARELY/ SOMETIMES/OFTEN/ALWAYS	
10. EMPLOYMENT		FULL TIME/PARTIME/ UN EMPLOYED/RETIRED/SELF EMPLOYED/STUDENT	
11. IF SELF- EMPLOYED (OR EMPLOYED-FIELDS		Sales/ IT/Hardware Software/Transportation/Homemaker/education/ clergy/ healthcare /hospitality	
Access to healthcare/Transportation			
Do you have a doctor or clinic for your regular care? <i>If no where do you get your care</i>		Yes	No
In the past year, was there a time when you needed health care but could not get		Yes	No
Do you have any problems with transportation to your health care visits?		Yes	No
Language/literacy/Mental Health			
Are you able to communicate with your doctor in your language?		Yes	No
Do you have cell phone/ access to the internet, if yes, do you use for visit		Yes	No
Do you often feel anxious, depressed, or worried? Are you experiencing any memory lapses or forgetfulness? Do you ever feel confused?		Yes	No
Are you under care from a psychologist and/or mental health counselor		Yes	No
Food insecurity			
In the past 12 months has there been a point where the food you bought just didn't last and you didn't have money to get more?			If yes, is it often or sometimes
Within the past 12 months, have you worried that your food would run out before you got money to buy more			If yes, is it <u>often</u> or sometimes
Family responsibilities for family members/friends/social support/community activity			
Are you responsible for child/elder care in your family? Do problems getting childcare make it difficult for you to work/study		Yes	No
Do problems getting childcare make it difficult for you to get healthcare?			
Do you have friends or neighbors support		Yes	No
Housing: access, utility services, household density			
Do you have any of these problems with your housing? Pest infestation/Mold/ <u>Lead</u> paint or pipes/ Inadequate heat/ Oven or Stove not working/ Water Leaks/ No or non-function smoke detector/ None of the above		Yes	No
How many people live in your house/apartment?			
Do you exercise		Yes	No
Do you drink alcohol		yes	No
Do you smoke		yes	No
Do you take any recreational drugs		yes	No
PERSONAL AND FAMILY HISTORY OF CANCER			
12. FAMILY H/O		CANCER (WRITE IN) TYPE OF CANCER?	
AGE/YEAR AT DIAGNOSIS			
a. SELF		Yes/ No	
b. Sibling		Yes/ No	
c. Birth mother		Yes/ No	
d. Her Parents		Yes/No	
e. Her Siblings		Yes/No	
f. Father		Yes/No	
g. His Parents		Yes/No	
h. His Siblings		Yes /No	

Colon Cancer Screening Assessment			
Does any of your family members had colon cancer		Yes (at what age)	No
Do you have ulcerative colitis/ Crohn's disease or IBD			
Have you been screened or provider discussed colon cancer screening			
Lung Cancer Screening Assessment			
Do/Did you smoke		Yes	No
How many packs and years			
Have you been screened for lung cancer		No insurance/did not know/never heard about it (is eligible)	
BREAST Cancer Screening			
Have you ever had a discussion with your doctor about the risk/benefits of breast cancer screening with mammogram?		Yes	No
Have you ever had a mammogram? If yes,		If Yes; when	No
Have you ever had a breast biopsy?		Yes	No
If "Yes", result of biopsy		Right/left	. Result: Breast cancer/pre-cancerous
Have you or anyone in your family been tested for breast cancer gene mutation?		Yes	No
CERVICAL CANCER ASSESSMENT			
Have you ever had a Pap smear?		Yes	No/ Don't know
27b. If "No", is there a reason why you have not had a Pap smear yet/in the past 2 years?			
Prostate Cancer Screening/:			
Have you ever had your PSA checked		Yes	No/ Don't know
Bone density:			
Have you ever had Bone density checked for osteoporosis		Yes	No/ Don't know
Advanced Care Planning			
Do you have a living will or have you completed advance care planning? Do you want us to help you? (will not cost you)		Yes	No/ Don't know
Research: Our cancer center participates in multiple national research studies to develop understanding about cancer, how it occurs, what tests help us, how best to develop new treatments and how to bring equity, equality and better access to all socioeconomic class of individuals (all of these studies are in full compliance of regulatory agencies like Office of Human Research Protection ACT)			
Would you be willing to participate in research to better understand disease process by certain tests (blood or tissue)		yes	no
Would you be willing to participate in a research that helps <u>develop</u> <u>newer drugs for cancer patients (including for you or future)</u>		yes	No
TASK List			
1 Reviewed by and action plan			
CANCER SCREENING SERVICES Needed		Yes/No	Scheduled
BREAST			
CERVICAL			
COLORECTAL			
LUNG			
PROSTATE			
Bone density			
SMOKING CESSATION			
Alcohol counselling			
Depression/Mental health counselling/cognitive screening			
Research participation			
Advance Care Planning			
Other			
Other SERVICES; DSS/Financial counsellor		YES/No	Referral/assistance
Medicaid/Dual Eligibility? LISS/DSS			Catawba agency on ageing/Norrell/Congressional office
Health Insurance/ACA/Other			
Foundation support			CBCCA financial counsellor/Pharmacy team
Free drugs			CBCCA financial counsellor/Pharmacy team
Mental Health Services			
Transportation			
Housing/Free clinics/FQHC/Food/Utility/Other			

No One Left Alone (NOLA)

Solving cancer health disparities through new value-based care models



Improve SDOH data collection

Mandate the collection and reporting of key data elements to better understand the sub-populations and their health outcomes



Improve access to cancer care

Increase access to cancer screening
Extend clinic availability, including after hours and weekends
Reduce financial toxicities



Improve access to testing and therapies

Include appropriate biomarker testing
Leverage biomarker findings to select most appropriate treatment options
Lower costs through the use of generics and biosimilars



Increase in clinical trial participation

Identify community clinic serving these patient populations
Provide customized patient materials to increase participation
Leverage real world evidence studies to better understand the impact of disparities on patient outcomes

SDOH: Social Determinants of Health



TRANSPORTATION



CLOTHING



BENEFITS (HEALTH INSURANCE, SNAP, WIC, ETC.)



IDENTIFICATION (STATE ID, BIRTH CERTIFICATE, SOCIAL SECURITY CARD)



FINANCIAL AND UTILITY ASSISTANCE



FOOD (PANTRY AND MEALS)



SHELTER (DAY SHELTER, EMERGENCY SHELTER, TRANSITIONAL HOMES)



HELP TO FIND AFFORDABLE HOUSING



EMPLOYMENT (JOB TRAINING, INTERVIEW COACHING, PLACEMENT)



EDUCATION (LITERACY, GED, ETC.)



MEDICAL HEALTH (ASSESSMENTS)



CRIMINAL RECORD (EXPUNGEMENT AND PARDON)



MENTAL HEALTH AND SUBSTANCE USE SUPPORT (COUNSELING)

Summary of Challenges and Pitfalls of Implementing Precision Medicine

1. Lack of appropriate representation of minorities in the genome-wide association studies, leading to cancer health disparities
2. Lack of uptake of next-generation sequencing testing in advanced cancers
3. Payer-related factors: limited coverage / health policy;
4. Payer policies are frequently a hindrance for access to testing
5. Physician and healthcare team education
6. Social determinants of health
7. Confusion between multiple diagnostic technologies
8. Pharmacogenomics
9. Germline testing

FIGURE 2. EDUCATION LEVEL

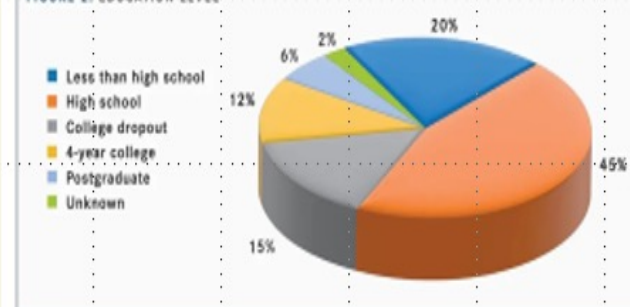
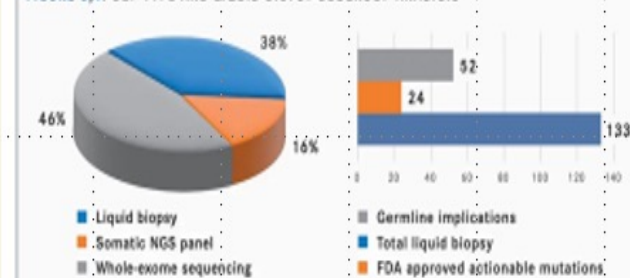
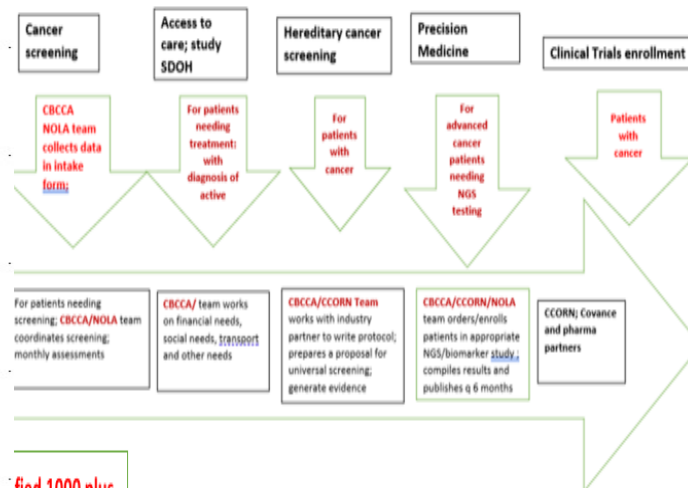
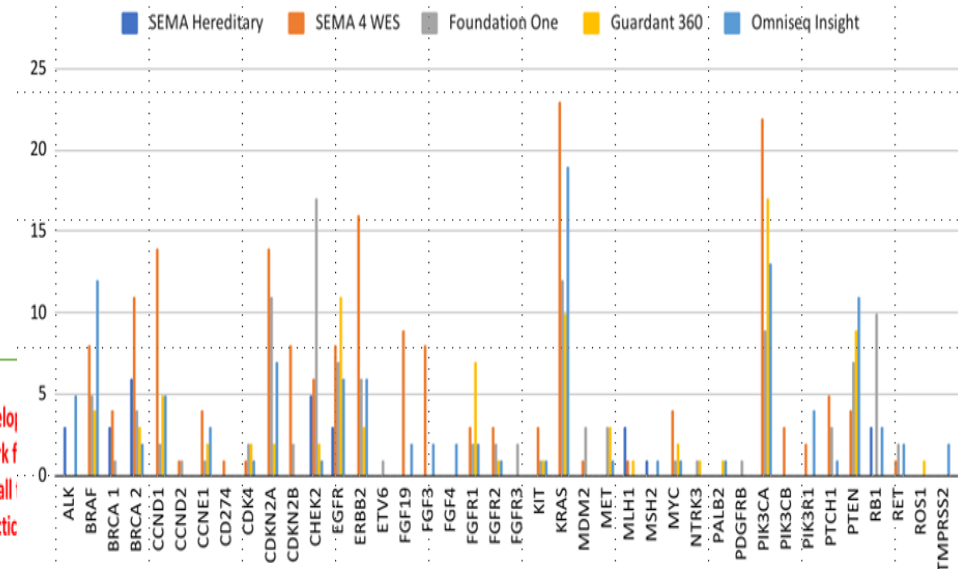


FIGURE 3.4. CGP TYPE AND LIQUID BIOPSY SUBGROUP ANALYSIS



CGP, comprehensive genomic profiling; NGS, next-generation sequencing

Mutations Identified Through NGS Testing



Identified 1000 plus patients who did not have cancer screening and assessments being made for same

Raised close to \$2.3 million last year for OOP cost or free drugs; Created insurance fund and already supported 20 plus patients

Pilot already in place with a large lab with purpose to identify gaps in germline tests; paper expected soon

Three large studies; reached NGS testing rate to 80% plus

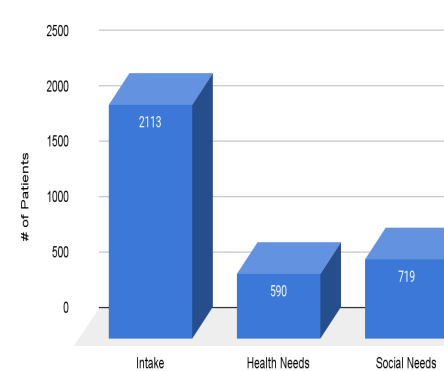
CCORN is developing trials network for multiple small to mid size practices

Private and confidential

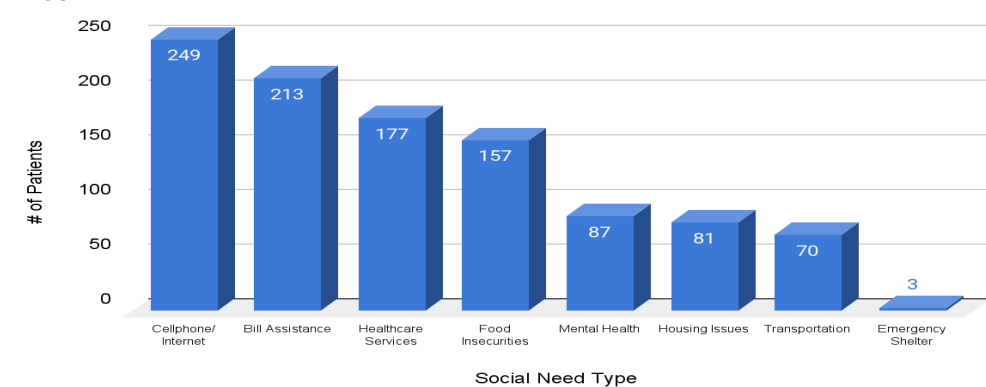
Health Need	Type of Need	Next App	Provider	Type of Need
Yes	Colon cancer screen		Naidu	not enough money for bills
Yes	Colon cancer screen		Rabara	Not enough money for bills, access to primary doctor
Yes	Colon cancer screen		Nathwani	Utilities, child/elder care difficulties
Yes	Colon cancer screen		Gor	Access to primary doctor, food insecurities
Yes	Lung screen (current)		Rabara	
Yes	Colon cancer screen		Rabara	Smoke detectors, water leaks
Yes	Colon cancer screen		Naidu	
Yes	Colon cancer screen		Nathwani	Utilities, difficulty with getting into doctor appts. n
No			Gor	Food insecurities, housing problems
Yes	Colon cancer screen		Patel	Not enough money for bills, food insecurities, hou
Yes	Colon cancer screen		Gor	
Yes	Colon cancer screen		Gor	
Yes	Colon cancer screen		Patel	
Yes	Colon cancer screen		Patel	Housing, not enough money for bills
Yes	Lung		Rabara	Not enough money for bills
Yes	Colon cancer screen		Patel	Not enough money, phone assistance; food inse
Yes	Colon cancer screen		Naidu	Utilities, phone/internet access
Yes	Lung		Naidu	Utilities, food insecurities
Yes	Lung		Gor	
Yes	Colon cancer screen		Patel	Not enough money, primary caregiver resources
Yes	Colon cancer screen		Rabara	Not enough money for bills, food insecurities
Yes	Lung		Rabara	
Yes	Colon cancer screen		Naidu	Not enough money for bills, housing problems
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Yes	Osteoporosis		Gor	Not enough money for bills. + mental health scree

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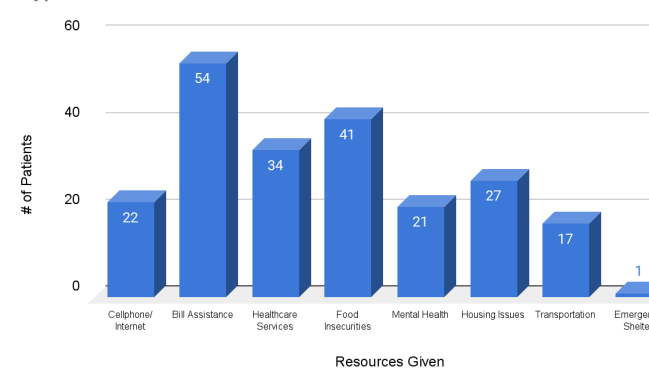
NOLA Intake



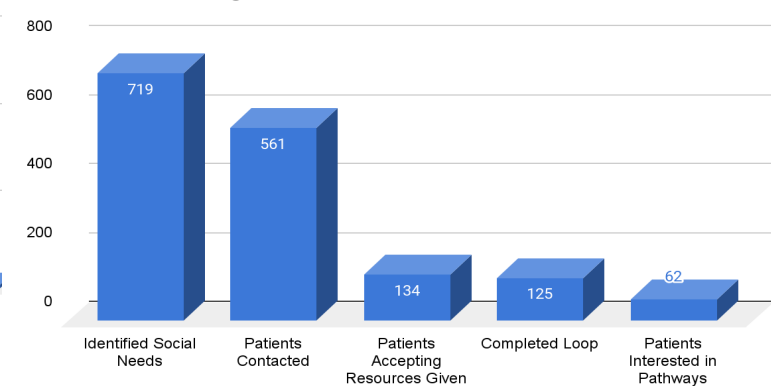
Type of Social Need



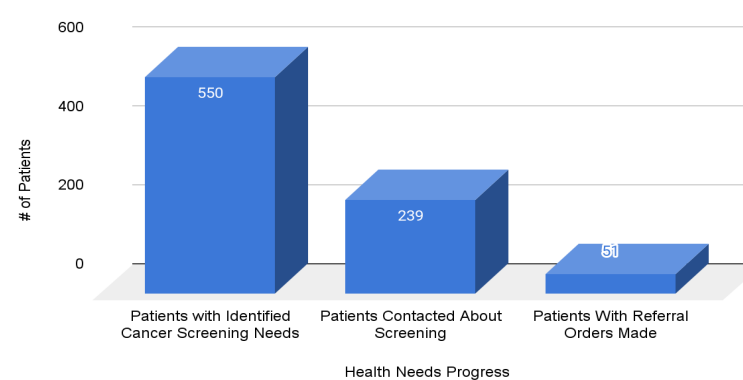
Types of Resources Given



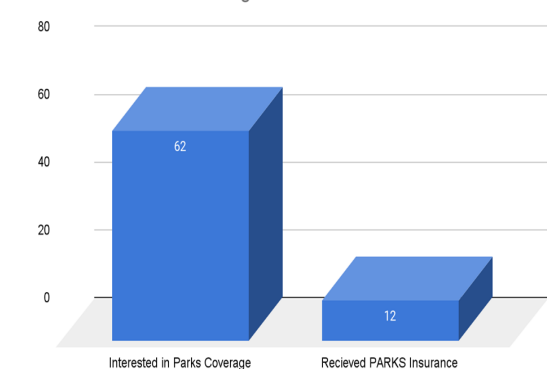
Social Needs Progress



Health Needs



PARKS Insurance Coverage



Incorporating Biomarker Testing in Community Cancer Clinics: A Real-World Pilot Study

Patel K et al Targeted Therapies in Oncology, May 2022, Volume 11, Issue 7

Summary of Challenges and Pitfalls of Implementing Precision Medicine

1. Lack of appropriate representation of minorities in the genome-wide association studies, leading to cancer health disparities
2. Lack of uptake of next-generation sequencing testing in advanced cancers
3. Payer-related factors: limited coverage / health policy:
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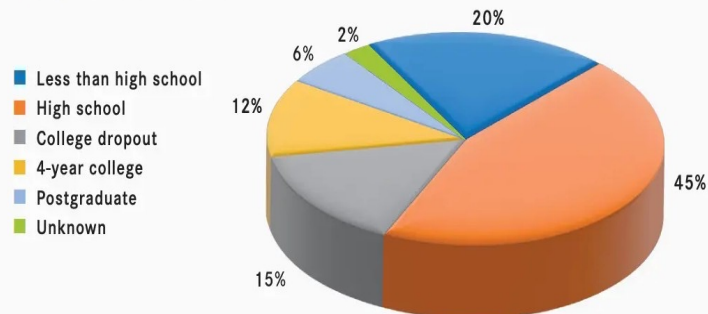
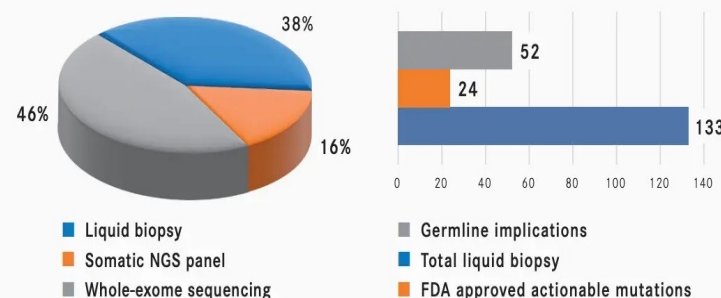
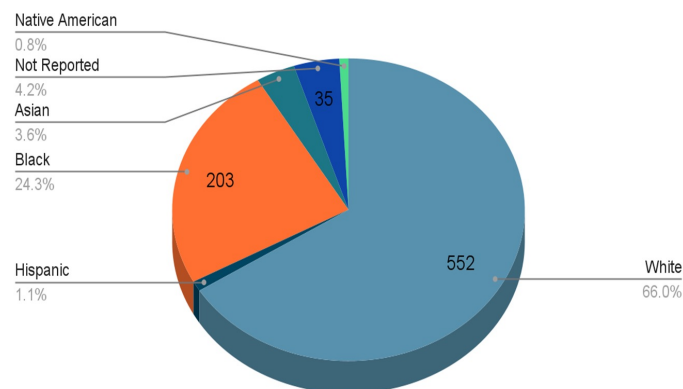


FIGURE 3,4. CGP TYPE AND LIQUID BIOPSY SUBGROUP ANALYSIS



CGP, comprehensive genomic profiling; NGS, next-generation sequencing

Patients Receiving NGS Testing by Race



FDA-Approved Therapies Available For This Mutation	173
Clinical Trials Available For This Mutation	1538
Potential Germline Implications	758
NCCN Guidelines Caution That This Mutation Is a Resistance Mechanism to a Certain Treatments	56
FDA-Approved Therapies Available For This Mutation After Progression/Resistance on Treatment	145
FDA-Approved Therapies Available For This Mutation In Breast Cancers with Different Hormonal Expression	6
FDA-Approved Therapies Available For Other Cancers with Mutations in This Gene	130
FDA-Approved Therapies Available for This Mutation in Subtype of Cancer Different Than Patient's Own	2
FDA-Approved Therapies Approved for This Mutation in Cancers with a Lower Stage than the Subject's Own	1
FDA-Approved Therapies Available for this Mutation in Cancers with Different Gene Expression (E.g EGFR expression)	54
NCCN-Guidelines-Approved Treatments Available for Other Cancers with Mutations in This Gene	2
NCCN-Recommended Treatments Available for This Mutation	77
NCCN-Recommended Treatments Available For This Mutation After Progression on Therapy	26
NCCN-Recommended Treatments Available For This Mutation in Breast Cancers with Different Hormonal Expressions	8
Potential Clonal Hematopoiesis Implications	66

22. Regulators crack down on Medicare Advantage charges

<https://thehill.com/newsletters/health-care/3934589-regulators-crack-down-on-medicare-advantage-charges/>

23. Regulators to crack down on deceptive Medicare Advantage advertisings

https://finance.yahoo.com/news/biden-admin-finalizes-rule-crack-142731035.html?guccounter=1&guce_referrer=aHR0cHM6Ly93d3cuZ29vZ2xlLmNvbS8&guce_referrer_sig=AQAAAFAX3MEbSj4FikR8OA_BJZPP7AMhBE5ieh0meCPFfi8jQnCNlOlckAVHJXvcf0-U4jZUyRWghiuKeqm6wcz4fNGt_mIThdp77Z3vfBdHyovjRLOUTq038QoTjS-BXTUiHTt3eZiMofdS18aeqGQlml9h_L4uXj8Vqt4nUH8JAuo

24. Medicare Advantage final rule addresses prior auths, health equity

<https://healthpayerintelligence.com/news/medicare-advantage-final-rule-addresses-prior-authorization-health-equity>

25. Social Security, Medicare insolvency looming; these changes may help

<https://www.cnbc.com/2023/04/05/insolvency-on-horizon-for-social-security-medicare-soon-expert-says.html>

26. Centrist Democrats hatch secret plan to head off debt ceiling calamity

<https://www.politico.com/news/2023/04/03/centrist-dems-debt-limit-backchannel-00089997>

27. House Republicans struggle to reach consensus on budget, delaying debt ceiling negotiations

<https://nlihc.org/resource/house-republicans-struggle-reach-consensus-budget-delaying-debt-ceiling-negotiations>

28. House GOP ratchets up focus on work requirements for government assistance programs

<https://thehill.com/business/budget/3932289-house-gop-ratchets-up-focus-on-tougher-work-requirements/>