Molecular biomarker testing and targeted therapy patterns in patients with acute myelogenous leukemia (AML): a real-world data analysis

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Jeanna Wallenta Law[1], Zartash Gul[2], Anna B. Berry[1], Michael A. Thompson[2], Christopher Willner[3], Sowjanya Vuyyala[3], Haley McCracken[1], Kate Geverd[1], Frank Wolf[1], Thomas Brown[1], Philip Kuriakose[3]

[1]Syapse, San Francisco, CA; [2]Aurora Cancer Care, Advocate Aurora Health, Milwaukee, WI; [3]Henry Ford Health System, Detroit, MI

BACKGROUND

- Acute myelogenous leukemia (AML), characterized by the clonal expansion of myeloid blasts in the blood, bone marrow, and/or other tissues, accounts for only 1% of all cancers, but is both the most common and most deadly acute leukemia in adults in the United States (US).[1,2]
- For 2022, over 20,000 new cases are expected with 11,500 AML-related deaths.[2]
- Cytogenetics or molecular mutations are important prognostic factors and increasingly guide treatment choice as targeted therapies are being more commonly used for AML.[1,3,4]
- Broadly speaking, genetic and molecular testing includes karyotyping, fluorescence *in situ* hybridization (FISH), polymerase chain reaction (PCR)-associated testing, traditional sequencing, and next-generation sequencing (NGS).[3]
- Although National Comprehensive Cancer Network (NCCN) guidelines recommend molecular testing for both younger (< 60 years) and older patients, its use in the routine care setting is not well-understood.
- This study describes real-world testing patterns, including use of NGS, and targeted therapy use in patients with AML in two large US community health systems.

METHODS

- Patients ≥18 years old, diagnosed with AML between January 1, 2015 and December 31, 2020, were identified in a database containing clinical and genomic data from two integrated community delivery networks.
- Data through March 31, 2021 were included in the analytic database to allow for adequate follow up for each study patient.
- Actionable biomarkers were defined by the NCCN AML guideline, version 3, 2021.[4]

RESULTS

- The median age of the 541 patients (79%) who received NGS or single gene/small panel tests was 69 years, compared with 78 years for the 144 (21%) patients with no testing.
- Patients with de novo AML were more likely to be tested compared to patients with secondary AML (84% vs. 67%, p<0.001).
- No significant difference was found in testing receipt between Non-Hispanic White and Non-Hispanic Black patients (82% vs. 76%, p=0.3).
- Approximately 80% of patients underwent NGS testing within 30 days of initial AML diagnosis and 15% >30 days after initial AML diagnosis; timing of NGS testing was unknown in 5% of patients. NGS testing increased between 2015 and 2018, with 72% to 78% of patients receiving NGS annually from 2018–2020.
- Testing for actionable biomarkers varied by biomarker and year (**Figure 2**).
- 52/100 (52%) of patients with FLT3 (ITD or TKD) mutation, 5/27 (19%) with IDH1 mutation and 11/44 (25%) with IDH2 mutation received targeted therapy.

TABLE 1 Patient population

Characteristics	Overall (N=685)
Median age	70 years
Median follow-up	5.4 months
Sex	55% male 45% female
Race/ethnicity	73% NHW 10% NHB
AML	69% de novo
Cytogenic prognostic class	4% favorable 33% intermediate 30% adverse 33% unknown

NHB: non-Hispanic Black; NHW: non-Hispanic White

CONCLUSION

- Molecular biomarker testing has increased over time with NGS becoming the dominant modality. Testing uptake did not differ by race.
- Half of patients with FLT3 mutation, one quarter with IDH2 mutations, and one fifth with IDH1 received targeted therapy.
- Future research should explore ongoing testing and targeted therapy administration over time and address real world applicability of this in the community setting, to include an analysis of older patients.

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FIGURE 1 Molecular testing use by year

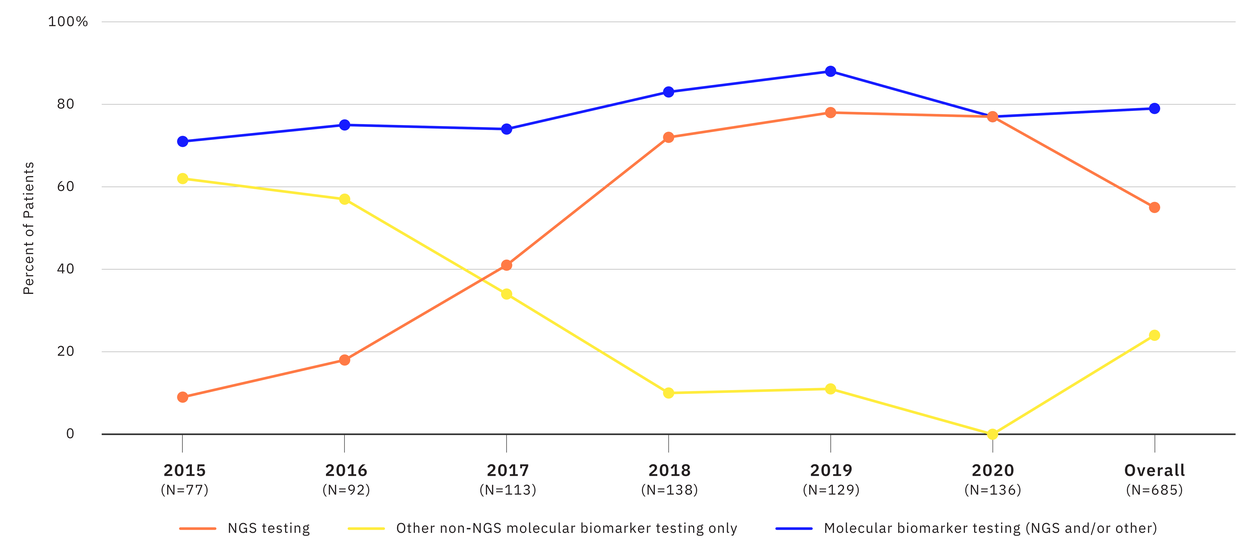
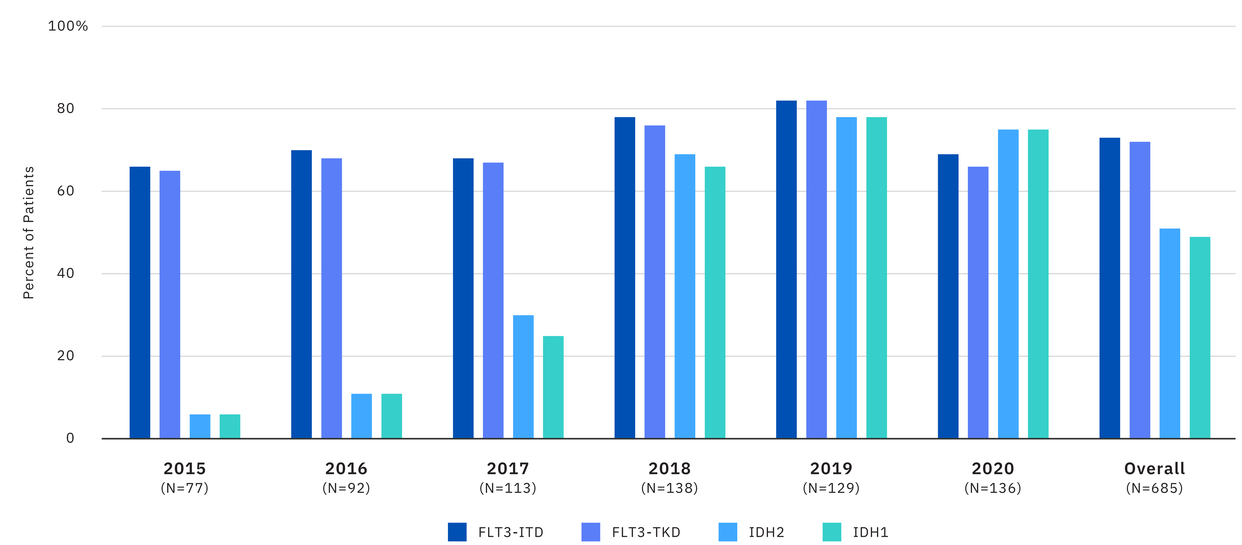


FIGURE 2 Testing for specific biomarkers by diagnosis year



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