Controlling Molecular Pathology Result Release Using Epic Rule Logic to Manage Impacts of the 21st Century Cures Act

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BACKGROUND

In October of 2022, implementation of rules related to the 21st Century Cures Act (21CC) changed regulatory requirements for patient access to health care data to prevent information blocking. This impacted the flow of genetic test results for surgical pathology specimens. Prior to implementation of the 21CC rule changes, molecular and surgical pathology reports were available to patients only after manual release by a clinician, and integrated data was reviewed by providers at clinic visits. Following the 21CC rule change, patients received immediate push notifications of molecular test results prior to the release of an integrated surgical pathology report. Receiving partial information caused patient confusion, with phone calls to providers and the lab seeking complete diagnostic information. To address this, we developed a report release system to coordinate molecular and surgical pathology data in a patient-focused reporting process.

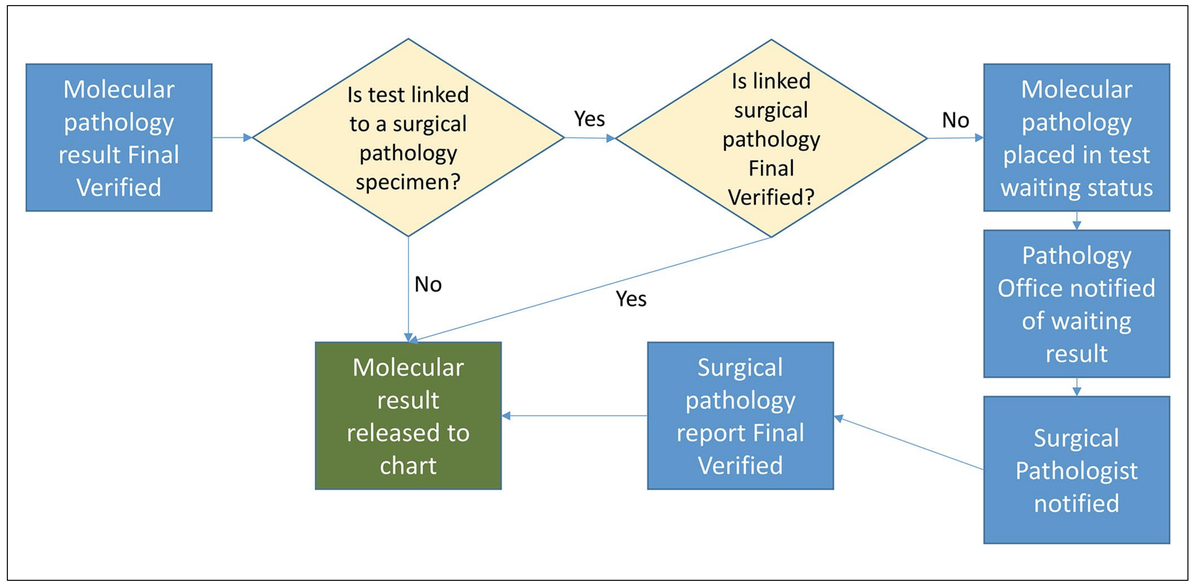
Table 1 2021 WHO Classification of Tumors of the Central Nervous System. Provisional Entities are in Italics

World Health Organization Classification of Tumors of the Central Nervous System, fifth edition
Gliomas, glioneuronal tumors, and neuronal tumors
Adult-type diffuse gliomas
Astrocytoma, IDH-mutant
Oligodendroglioma, IDH-mutant, and 1p/19q-codeleted
Glioblastoma, IDH-wildtype
Pediatric-type diffuse low-grade gliomas
Diffuse astrocytoma, *MYB*- or *MYBL1*-altered
Angiocentric glioma
Polymorphous low-grade neuroepithelial tumor of the young
Diffuse low-grade glioma, MAPK pathway-altered

Neuropathology diagnoses in the 2021 WHO Classification of Tumors of the Central Nervous System require molecular genetic data to assign specific diagnoses. (From Louis DN, et al., The 2021 WHO Classification of Tumors of the Central Nervous System: a summary. Neuro Oncol. 2021 Aug 2;23(8):1231-1251. PMID: 34185076).

METHODS

Utilizing tools within our Electronic Health Record (Epic), we implemented rules-based logic that allowed for concurrent release of integrated surgical pathology reports with linked molecular test results when surgical pathology reports are finalized. This provides a complete picture to patients and providers when results are released. This process did not require any workflow changes for completing molecular pathology reports.



RESULTS

Molecular testing is linked to a corresponding surgical pathology specimen. When a molecular test result is finalized, Epic rule logic determines if there is a linked surgical pathology test that has not been final verified. If so, the molecular test result is put in a test waiting status, and a notification is sent to a pathology administrative team that a molecular result is waiting. An appropriate surgical pathologist is notified, allowing the generation of an integrated report. When the surgical pathology report is finalized, Epic concurrently releases the surgical and molecular pathology results. The patient and provider are simultaneously notified with a complete diagnosis.

CONCLUSIONS

Our rules-based logic was particularly impactful for neurooncology patients because the current WHO classification requires molecular test data to assign specific diagnostic categories. Our workflow eliminated patient complaints of receiving partial information, and increased provider satisfaction by providing linked reports that allow for accurate interpretation of integrated data.

IMPLICATIONS

A variety of pediatric tumors, particularly brain tumors, are characterized by distinct molecular alterations. Additionally, identical molecular alterations can be seen spanning distinct histopathologic entities. Diagnostic molecular pathology findings can be used to assign a WHO grade to certain tumors. Molecular findings when taken in context can portend critical diagnostic, prognostic, therapeutic, and familial cancer risk information. Accurate tumor characterization is thus dependent on a combination of molecular and histopathologic findings.