Bringing the clinical laboratory into the strategy to improve patient care excellence and healthcare system efficiency

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Clinical laboratories play important roles in supporting value-based healthcare, to improve patient outcomes while reducing overall healthcare costs. By providing accurate and timely diagnostic information, clinical laboratories help physicians and providers to make informative decisions for therapeutic options, medication dosages and monitor the progress of the treatment. There are a growing body of research that demonstrates a using clinical data to identify high risk patients for heart disease, diabetes, cancer and others, and implement early interventions led to better patient outcome with significant reduction in hospital admissions, resulting in cost saving for Health system. While the laboratory typically has rigorous practices in place to monitor the analytic phase of the test, much less control and monitoring are afforded to a healthcare systems-level that effectively integrates health care knowledge, skills, and resources for continuous and measurable improvement of outcome and decrease the cost. At the time, there were a limited number of studies on this topic.

The goal of this project is to establish a data analysis model for assessment of the total testing process, including clinical scenarios, clinical questions, and laboratory capabilities. Select proper metrics to demonstrate the measurable results of quality indicators of patient care and financial impact in our Health system.

Two testing processes are selected: 1) cervical cancer screening methods' data analysis for removing unnecessary testing. 2) methotrexate monitoring data analysis to determine if the test should be send-out or done in house. These examples demonstrate that data analysis model aids evidence-based laboratory testing decision making, which incorporated clinical goals, the cost of laboratory operation, FTE of clinical and laboratory teams, and patient outcome.

1. Cervical cancer screening: Pap smear examination was first recommended as early cervical cancer detection tool in early 1980 and still being used as primary screening method in most of Healthcare system now. Over the years, studies demonstrated that more than 95% of cervical cancers are due to HPV infection, especially high-risk HPV (16, 18, and 12 other types). Then, HPV testing was introduced as co-testing with Pap smear in 2002. With advance and standardization of HPV molecular testing, clinical studies have shown that HPV testing alone is as effective as HPV with Pap smear co-testing. Unlike pap smear that rely on visual inspection, HPV-testing is an objective test, which is also total automated. In 2020, the updated cervical cancer screening recommendations include following options: 1) high risk HPV testing using FDA approved method alone. If HPV testing positive, pap smear should be reviewed. If negative, HPV testing is repeated every 5 years. 2) HPV and cytology co-testing (every 5 years). 3) Pap smear cytology (every 3 years). The American College of Obstetricians

and Gynecologists (ACOG) joins ASCCP and the Society of Gynecologic Oncology (SGO) in endorsing the U.S. Preventive Services Task Force (USPSTF) cervical cancer screening recommendations. This cohort is to study the clinical outcomes and the costs of 3 screening methods from Oct.2021 to Dec. 2022 in OHSU clinical laboratory. Total 9213 co-tests were done, HPV and Pap smear showed similar positive rates, 12.3% vs 11.8% accordingly. Total 448 patients with positive screening results received follow up biopsy for definitive diagnosis. The patient with biopsy result of HSIL/CIN3 would need surgical excisions for therapy. Therefore, HSIL/CIN3 was selected as the indicator of screening effectiveness. HPV demonstrated 76% of sensitivity and 86% specificity; pap smear review showed much lower sensitivity (28%) with 100% specificity, corroborating with published data. The results support that HPV testing is a more sensitivity screening method. Comparing to HPV-Pap smear co-testing, 88% of the pap smear reviewing could be eliminated if HPV testing first and only HPV+ sample followed by Pap smear screening. The cost saving using Medicare rate would be $418,682 in 14 months. The cost of Healthcare system for Pap smear is higher than Medicare rate, since the cost of clinical FTE for sample collection, pap smear collection kits, sample processing instrument and reagents, cytotechnologist FTE and pathologist FTE are all need to be included. With current staffing crisis in healthcare, saving these FTE to serve other important clinical diagnostic testing is needed.

2. High dose methotrexate (HDMTX) is used in range of adult and childhood cancers, including leukemia, lymphoma and osteosarcoma along with leucovorin rescue. HDMTX therapy can cause significant renal toxicity, which may lead to morbidity, occasional mortality, or interrupt cancer treatment. Therefore, close monitoring methotrexate levels with accurate and timely results are critical for subsequent medications and discharging patients on time. Methotrexate monitoring is a high complexity testing performed by trained laboratory technologist. It is also a low volume and non-automated test. It had been a send-out test for >20 years with turnaround time (TAT) ranging 8 to 20 hr. As the medical director of the laboratory, I received complaint from clinicians about MTX send-out test. Then, I reviewed commonly used HDMTX protocols, which require MTX level monitoring at 24hr, 36hr, 48hr, and 72hr (if needed). Any delay, therapeutic window could be missed, which associated with delayed therapy, increased toxicity, and prolonged hospital stay. We collected one-month MTX testing data from reference lab including cost of the laboratory testing, reimbursement, TAT, and delayed discharge days, which were compared with planned in house testing budget and TAT. We realized that in house testing would significantly improv of TAT (2-4 hours), which could decrease therapeutic delay and shorten hospital stay, we decided to bring test back to the lab even though lab will lose money. After one-month operation, in house testing data analysis already demonstrated measurable cost saving for the Health system by nearly eliminate delayed discharge and improved patient care with evidence of 0 patient safety incidence report related to delayed therapy.

In summary, the clinical laboratories play vital rule in delivery of quality healthcare and the maintenance of public health. Leveraging clinical and laboratory data derived from the electronic health record to improve diagnoses is necessary. Clinical test utilization directed by integrating clinical needs, evidence-based laboratory operation, test selection, and patient-care

quality management approaches would provide a strategy to support excellency and efficiency among healthcare systems.