Executive Summary

Improved screening and early detection of cervical changes with the Pap test have helped to greatly reduce the incidence of cervical cancer over the last 40 years. The improved early detection has also reduced cervical cancer mortality rates by 50%, but over 13,000 women are diagnosed annually with cervical cancer and over 4,200 cases will result in death. Most often a Pap test is performed as the primary test with HPV co-testing or reflex testing based on the Pap test results and both tests can be performed on the same sample. Internationally, there is a growing trend to utilize the HPV test alone for primary screening. Not all cervical changes will result in cervical cancer and over treatment can be stressful for patients, effect fertility and are costly, so clinicians are using HPV testing to help ensure the appropriate level of treatment and frequency of future screening tests to improve patient outcomes and experience while also reducing costs for unnecessary treatment procedures and testing.

The problem: Despite the HPV and Pap tests being performed on the same specimen, these tests are often performed in different lab departments and are accessioned and resulted in separate result reports. Clinicians need to review both the Pap test and HPV test results to make informed recommendations, so Sunquest Information Systems (Sunquest) and its sister company, Data Innovations are enabling automation and integration of HPV tests to improve internal lab and clinician workflow as well as patient outcomes.

The solution: Sunquest and Data Innovations developed an interface solution to improve overall instrument coordination with Data Innovations’ Instrument Manager™ automation of orders and results, including reflexed testing and customized rules using Sunquest’s PowerPath® laboratory information system (LIS) for anatomic pathology. HPV test results are automatically sent, via Instrument Manager, to Sunquest PowerPath and integrated with Pap test data, in an information-rich report to ordering clinicians. Instrument Manager, leveraging rules, enables automatic sign-out of cases that are negative for HPV, speeding results to patients and saving pathologists’ time, too. Laboratories implementing the new gynecology molecular interface have seen dramatic improvements with boosted efficiency and an estimated savings up to $44,000 in annual costs. It has also improved HPV test turn-around time and increased customer and staff satisfaction.

“Clinicians really appreciate having both the Pap and HPV results in one report. It saves valuable time in only going to one report in the electronic health record,”

- Cytology Supervisor
Challenges in HPV testing

With the increased value and reliance on HPV testing in the screening of cervical cancer, pathology laboratories are wanting to enhance HPV testing and reporting to improve integration with Pap test results—both critical diagnostic information for physicians to assess and to make treatment decisions related to cervical cancer. Opportunities for improvement lie in test accessioning, automating orders and results for HPV tests, turn-around, optimizing pathologists' time with automatic report sign-out, patient safety and enhancing customer and staff satisfaction.

Prior to the combined Sunquest / Data Innovations solution, a typical outline of HPV test workflow often included the following:

- Each Pap test, with a HPV test, was accessioned twice: the Pap as a cytology case and the HPV as a molecular case;
- Specimens were also double-labeled with a cytology label and a pre-printed HPV instrument label;
- When HPV tests were completed on instrumentation such as Roche cobas® 4800, a medical technologist reviewed the results and printed them out. Then, technologists manually entered results data into the HPV molecular case in Sunquest PowerPath;
- Pathologists needed to sign-out cases before test results could be released to ordering physicians and patients. This took about one hour each day, but the more serious impact was that HPV results could be back-logged one to two days (during times of high molecular test volume, for instance), requiring pathologists to spend three hours to catch up on sign-outs.

Solution: Sunquest PowerPath and Data Innovations Instrument Manager

Sunquest Information Systems and its sister company, Data Innovations, enable automation and integration of HPV testing and reporting to address the workflow challenges with the release of Sunquest PowerPath 10.3 and the Data Innovations Instrument Manager integration.

Sunquest is the leader in laboratory innovation and renowned for its enterprise laboratory information solutions, which leading laboratories across the globe rely on to meet challenges of multi-disciplinary workflow, multiple performing labs, and optimal test utilization, among other goals.

For the complex diagnostics and pathology workflows specific to anatomic pathology laboratories, Sunquest offers the robust AP LIS, Sunquest PowerPath. This highly sought-after information technology helps lab leaders worldwide manage patient cases and automate diagnostics—from test orders and specimen accessioning to reporting on complex anatomic pathology issues such as cervical cancer. Sunquest PowerPath also enables interoperability with the clinical LIS (Sunquest Laboratory™ LIS or others), electronic health record systems, cancer registries, instrumentation such as stainers, digital pathology systems and more.

Data Innovations, an international laboratory enterprise connectivity company, offers Instrument Manager, one of the company's stellar solutions aimed at improving lab workflow and efficiency by enabling connections to interface extensive and sophisticated automation, instrumentation and information systems.
at multiple locations. One of Data Innovations’ robust offerings is the interface for molecular diagnostics in gynecology, which automates orders and results for HPV, gonorrhea, chlamydia and trichomonas testing.

Implementation: Sunquest PowerPath and Data Innovations Gyn Molecular Interface

The Sunquest PowerPath AP LIS and Data Innovations’ Instrument Manager gynecology molecular interface, together with lab instrumentation, enable significant shifts in cytology accessioning, molecular and pathologist workflows:

- Pap tests are only accessioned once, and HPV tests are part of the same case (with the Pap test).
- An instrument-ready label, produced from Sunquest PowerPath, is used instead of pre-printed labels;
- HPV test results are released from the instruments and automatically file to the Pap report, thereby creating an integrated report, making it possible for medical technologists to address other challenges as opposed to manual tasks and reducing the risk for manual data entry errors;
- Data Innovations’ rules enable automatic sign-out of results and delivery to ordering physicians and patients through the cytology report. Pathologists no longer need to sign-out separate HPV reports.

The Results: Lab Efficiency, Better Reports, Costs Savings

Essentially, Data Innovations’ Instrument Manager—together with the Sunquest PowerPath AP LIS—helps to create a new world of integrated reporting of gynecological cytology and molecular testing.

“Today, they come in and release HPV results from the instrument, which immediately cross over to Sunquest PowerPath due to connectivity provided by Instrument Manager, and the case is signed out. No one has to manually enter or result it in Sunquest PowerPath,” said Amanda Coble, Product Manager, Sunquest PowerPath.

Lab personnel would prefer to spend their time focused on the science and bench work and not result entry, one medical technologist reported, “The transition to the HPV workflow with Data Innovations was fairly seamless and easy. It definitely improved turn-around time, because I don’t have to find time or someone to manually enter test results. I am happy to focus on my bench work—instead of manual data entry of results.”

Organizations that implement Sunquest PowerPath can experience the following benefits:

1. **Introduction of a new automated workflow for HPV tests:** Data Innovations’ Instrument Manager interfaces with Sunquest PowerPath and molecular testing instruments to help transform workflow from one with various manual steps to a highly streamlined and automated process.

"The Pap and HPV tests are both important tools in cervical cancer screening and treatment decisions, and they need to be reported and reviewed together in one integrated report. Clinicians are happy with the new workflow.”

Amanda Coble
Product Manager, Sunquest PowerPath
Rules driven test orders and reporting: New algorithms and test rules enable gynecology molecular test processing with automatic reflexing such as: HPV testing based on a Pap interpretation; additional HPV genotyping pursuant to an initial HPV result; and reflex to Pap from the primary HPV screening. Also, doctors get reports on results as they wish: preliminary (Pap only) or consolidated (HPV and Pap tests).

Accessioning accelerated: Only a single case is accessioned and both Pap and HPV test are included.

Instrument-ready labels: Sunquest PowerPath makes possible instrument-ready barcode labeling and eliminates time and expense of pre-printing a separate label as well as paper and staff time to do so.

Valuable integrated reports and increased clinician satisfaction: Instrument Manager enables HPV test results to populate completed Pap test reports in Sunquest PowerPath, creating a valuable integrated report that provides clinicians the complete picture of gynecological cervical testing in a single place within the EHR / EMR.

Test results reported automatically and pathologist cost and time savings: Data Innovations' Instrument Manager makes it possible to enable rules for automatic sign-out of cases based on the lab's preferences, i.e. all HPV results, only negative HPV results, etc. Savings of about five hours, or $700 per week, have been attributed to less time spent by the pathologists in sign-outs.

Elimination of manual tasks by medical technologists and relative cost and time savings: Medical technologists are no longer weighed down by manual entry of test results. Savings of about five hours of tech time, or at least $146 per week, have been attributed to elimination of manual steps.

Faster test turn-around: Laboratories reported a reduction in HPV test turn-around time.

More work satisfaction, less stress: Laboratory professionals report more satisfaction in their positions as they take on more challenging responsibilities for the lab.

Less overtime: The lab has less overtime expenses associated with medical technologists' work on HPV testing.

Less possibility of error and improved patient safety: With elimination of manual tasks and extra steps, there is less possibility of error, too.

Overall efficiency and big annual savings: Greater efficiency, made possible by the new Sunquest PowerPath and Data Innovations' Instrument Manager gynecology molecular interface, is saving one lab about $44,000 a year.

“The Pap and HPV test are both important tools in cervical cancer screening and treatment decisions, and they need to be reported and reviewed together in one integrated report. Clinicians are happy with the new workflow,” Coble said of her work with Sunquest PowerPath customers.
About Sunquest Information Systems and Data Innovations

Lab leaders throughout the world recognize Sunquest as the one laboratory information technology expert with a high-level, industry-leading AP LIS, as well as other solutions—notably the Sunquest Laboratory LIS—that can deliver labs to new heights. The Sunquest AP LIS’s impressive capabilities—rules-based accessioning, streamlining orders, specimen tracking, results reporting and more—are especially key to serving providers in diagnosing cervical cancer, a disease on the rise in the U.S.

Data Innovations enables interfaces that establish a link with sophisticated instruments such as those for molecular gynecological real-time PCR testing. Such connections have the propensity to change a lab’s laborious, manual workflows to efficient, automated processes and enabling integrated results for pinpointing disease and launching patient treatment.

Healthcare system leaders and lab executives are invited to contact Sunquest and Data Innovations for more information on solutions briefly described above.

References