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Brief Communications

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Laboratory information system requirements to manage the COVID-19 pandemic: A report from the Belgian national reference testing center

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ABSTRACT

Objective: The study sought to describe the development, implementation, and requirements of laboratory information system (LIS) functionality to manage test ordering, registration, sample flow, and result reporting during the coronavirus disease 2019 (COVID-19) pandemic.

Materials and Methods: Our large (>12 000 000 tests/y) academic hospital laboratory is the Belgian National Reference Center for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) testing. We have performed a moving total of >25 000 SARS-CoV-2 polymerase chain reaction tests in parallel to standard routine testing since the start of the outbreak. A LIS implementation team dedicated to develop tools to remove the bottlenecks, primarily situated in the pre- and postanalytical phases, was established early in the crisis.

Results: We outline the design, implementation, and requirements of LIS functionality related to managing increased test demand during the COVID-19 crisis, including tools for test ordering, standardized order sets integrated into a computerized provider order entry module, notifications on shipping requirements, automated triaging based on digital metadata forms, and the establishment of databases with contact details of other laboratories and primary care physicians to enable automated reporting. We also describe our approach to data mining and reporting of actionable daily summary statistics to governing bodies and other policymakers.

Conclusions: Rapidly developed, agile extendable LIS functionality and its meaningful use alleviates the administrative burden on laboratory personnel and improves turnaround time of SARS-CoV-2 testing. It will be important to maintain an environment that is conducive for the rapid adoption of meaningful LIS tools after the COVID-19 crisis.

Key words: COVID-19, laboratory information system, health information technology implementation, computerized provider order entry, change management

INTRODUCTION

Background and significance

The novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus has caused a pandemic with unprecedented medical and socioeconomic adversity. Second- and third-wave outbreaks are becoming a reality in several countries, at least partially, due to low herd immunity.[1] Laboratory testing to rapidly detect SARS-CoV-2 using polymerase chain reaction (PCR) is essential to guide proper patient management,[2] while serological assays will soon be required to assess population immunity (eg, antibody tests) and guide national coronavirus disease 2019 (COVID-19) pandemic policies.[1]

The increased demand for round-the-clock laboratory testing during the COVID-19 pandemic has surpassed surge capacity in many clinical laboratories, resulting in significant strain on laboratory personnel and infrastructure.[3,4] These developments are especially undesirable when laboratories already have to process a large numbers of potentially biohazardous samples every day, and delays in testing directly translate into delayed clinical decision making and consequently congest emergency departments and isolation units.[3] Therefore, leveraging the capabilities of electronic laboratory information systems (LIS) to streamline all phases of laboratory testing (preanalytical, analytical, and postanalytical) has proven essential.

To our knowledge, only a single report has been published that discusses the implementation of health informatics to support clinical management of the COVID-19 pandemic through novel electronic health record (EHR) functionality.[5] COVID-19 is a laboratory diagnosis with immediate consequences in the health sector (hospitalization, patient isolation, postponing surgery, etc.). Therefore, clinical laboratories face specific challenges that require dedicated LIS functionality to ensure safe, reliable testing and acceptable turnaround times.[3] However, no literature exists on tools that leverage the LIS in order to alleviate burden on laboratory personnel, streamline laboratory testing, improve test reporting, facilitate epidemiological and translational research, and enable data-driven policy making.

OBJECTIVES

Here, we describe the challenges faced by the Belgian National Reference Center for COVID-19 testing when demand passed allocated surge capacity during the initial phases of the COVID-19 pandemic. We used Kotter's principles as a framework to rapidly develop and implement additional LIS functionality (Table 1).[6] We implemented tools to manage sample and data streams, and detail functionality to improve (1) the prelaboratory phase (test ordering, sample packaging, and shipping), (2) the preanalytical phase (sample registration, tracking, and test prioritization [triaging]), and (3) the postanalytical phase (automated reporting and facilitating data-driven policy-making). We also briefly discuss unexpected opportunities in which the COVID-19 crisis accelerated the adoption of practices that promote the meaningful use of LIS systems.

MATERIALS AND METHODS

The University Hospitals Leuven is a 2000-bed hospital providing nationwide services via approximately 700 000 consultations, 55 000 admissions, 60 000 emergencies, and 55 000 surgeries annually. The hospital uses a fully in-house–developed EHR that is also commercially available[7] and used in approximately 50% of hospitals in the Flemish Region of Belgium. The clinical laboratory department annually performs around 12 000 000 tests and has national reference functions for several infectious diseases, including the respiratory disease COVID-19. The laboratory performed a total of >25 000 SARS-CoV-2 PCR tests on respiratory samples between February 1 and April 20, 2020. Samples were sent to the reference laboratory from across Belgium, and once analyzed, results were reported to referring clinical laboratories as well as to hospitals and primary care physicians. The LIS is in-house developed and maintained by a dedicated team of computer science engineers and implementation staff. Our LIS includes a computerized provider order entry (CPOE) module for in-house test ordering, which is fully integrated into the EHR.

The LIS automatically sends all validated results to a national EHR database that is directly connected to patient-accessible Web-based and mobile applications. All external orders, including those for reference testing, are paper-based and require that request forms accompany the sample. LIS development is directed by a clinical pathologist, allowing for rapid signaling of practical bottlenecks and guidance on the development of health information technology (IT) tools.

RESULTS

COVID-19–specific challenges to laboratory management

During the early stages of the COVID-19 outbreak, our laboratory was the only SARS-CoV-2 testing center in Belgium. The first case of COVID-19 in Belgium was confirmed by our laboratory on February 3, 2020. The following month, SARS-CoV-2 PCR testing grew exponentially to >750 tests/d, at which point both traditional analytical infrastructure and reagents became limiting factors (Figure 1). To manage the acute crisis, we established a crisis management team (CMT) consisting of clinical pathology staff specialized in microbiology and in LIS development. The CMT readily implemented a triage system to reduce stress on reagents, and addressed key bottlenecks in the preanalytical and postanalytical phase. Maximum upscaling in terms of full-time equivalents (FTEs) was estimated to be an additional 20 FTEs for the preanalytical phase, 5 for the analytical phase, and 13 for the postanalytical phase (Figure 2). These FTEs were divided among 3 different shifts. After stabilization of the sample flow, a fraction of staff was reallocated to perform test validation and scientific and to engage in epidemiological studies.

Notably, the large majority of our expanded workforce (30 of the 38 additional FTEs) was assigned to help with administrative tasks (sample reception, triaging, patient registration, result validation and reporting, and epidemiological studies), and was not directly involved in expanding analytical capacity (ie, PCR analysis) (Figure 2). By April 2020, reagent supply and machine capacity were more adequate (Figure 1), but pre- and postanalytical bottlenecks could only be resolved by the implementation of dedicated perianalytical IT solutions that reduced administrative burden on laboratory staff by streamlining data flows (Table 2).

COVID-19 test panel–based CPOE tool

During the early stages of the COVID-19 pandemic, laboratory tests (SARS-CoV-2 PCR) were requested via paper forms and entered into the LIS by dedicated administrative personnel. To capture any accompanying clinical information and contact details of the requesting physicians, which were handwritten on the forms, each

Table 1. Kotter's principles applied to laboratory informatics change management during the COVID-19 crisis

Kotter's principles	Change management in response to the COVID-19 crisis
Phase 1. Creating a climate for change	
Step 1. Establishing a sense of urgency • Comfortability with the known and fearfulness of the unknown hampers innovation • Convey why the change is needed and why does it need to occur now	• The COVID-19 pandemic put a tremendous burden on the medical administration staff • Manual registration of order forms into the LIS system from external laboratories was highly labor intensive • Sample reception, triage, and patient registration at the laboratory were overwhelming • Only one-third of results is automatically reported • Together, these issues clearly conveyed the necessity to implement IT tools

Step 2. Building a powerful guiding coalition
• Identify key staff members
• Eager, people-oriented, and real leaders
Step 3. Creating a clear vision
• Define what the future state should look like
	• We established a CMT
	• The CMT consisted of a goal-oriented group of expert staff
	• Include IT managers in CMT—not only focus on analytical and human resource
	• Capitalize on pre-existing and newly developed health IT platforms to:
	  • Decrease the burden on clinical, administrative, and scientific staff
	  • Reallocate technical staff to the tasks related to the analytical phase
	  • Support COVID-19 crisis management
	• Focus on innovation and scientific advances

Phase 2. Communication and empowering others	

Step 4. Communicating the proposed vision
• Communicate how this change will affect everyone
• Provide much-needed emotional support
	• Schedule weekly meetings to brief staff on:
	  • Emerging problems and bottlenecks
	  • Proposed solutions and expected benefits

Step 5. Empowering others to act on the vision
• Delegate leadership roles (workflow redesign)
	• Invite staff to propose alternative and additional solutions
	  • Explore possible IT solutions by including IT professionals in any discussion
	• Delegate responsibilities to staff beyond the CMT to proactively solve problems in line with the vision
	  • IT professionals
	  • Lab technicians
	  • Clinical pathology residents

Step 6. Planning and creating short-term gains
• Promote good ideas
• Celebrate success as often as possible
	• Communicate success regarding the following achievements:
	  • Improved efficiency in ordering COVID-19 laboratory testing
	  • Reduction in workload (improved work schedules)
	  • >98% of analytical results were automatically reported
	  • A reduction in the number of phone calls to the COVID-19 call center
	  • A lean and easily adaptable database for fully automated reporting
	  • Automated reporting of summary statistics reporting with attractive data visualizations to all stakeholders

Phase 3. Implementation and sustaining changes	
Step 7. Consolidating improvements • Continue on problem solving and promoting solutions	• The successful implementation of COVID-19 solutions resulted in a gain in workflow efficiency and...
Step 8. Institutionalizing new approaches • Focus on changing interpersonal work dynamics to organizational culture	• ... reducing the administrative burden caused increased engagement of all laboratory staff to remedy problems through novel IT solutions

CMT: crisis management team; COVID-19: coronavirus disease 2019; IT: information technology.

document was digitized using an image scanner and uploaded to the LIS in PDF format.

Limitations of paper-based order system

The on-paper request system proved a major bottleneck to the COVID-19 sample flow. First, critical clinical information and contact details were often not provided, significantly delaying sample triaging and reporting, respectively. Second, because clinical information and triage categorizations were not registered into our LIS database, epidemiological and research studies were only possible after additional administrative personnel retrospectively entered those data using an ad hoc–developed structured data entry module Third, too often, preanalytical and shipping biosafety procedures (triple packaging) for suspected SARS-CoV-2–infected specimens were not strictly followed. Fourth, the paper-based order system did not allow to rapidly and immediately change test ordering behavior in function of evolving criteria and scientific insight.

Evidence-based COVID-19 test panel

To address problems stemming from paper-based ordering systems, we designed a CPOE-based COVID-19–specific order set in joint collaboration with the CMT, the directors of infectious disease, and

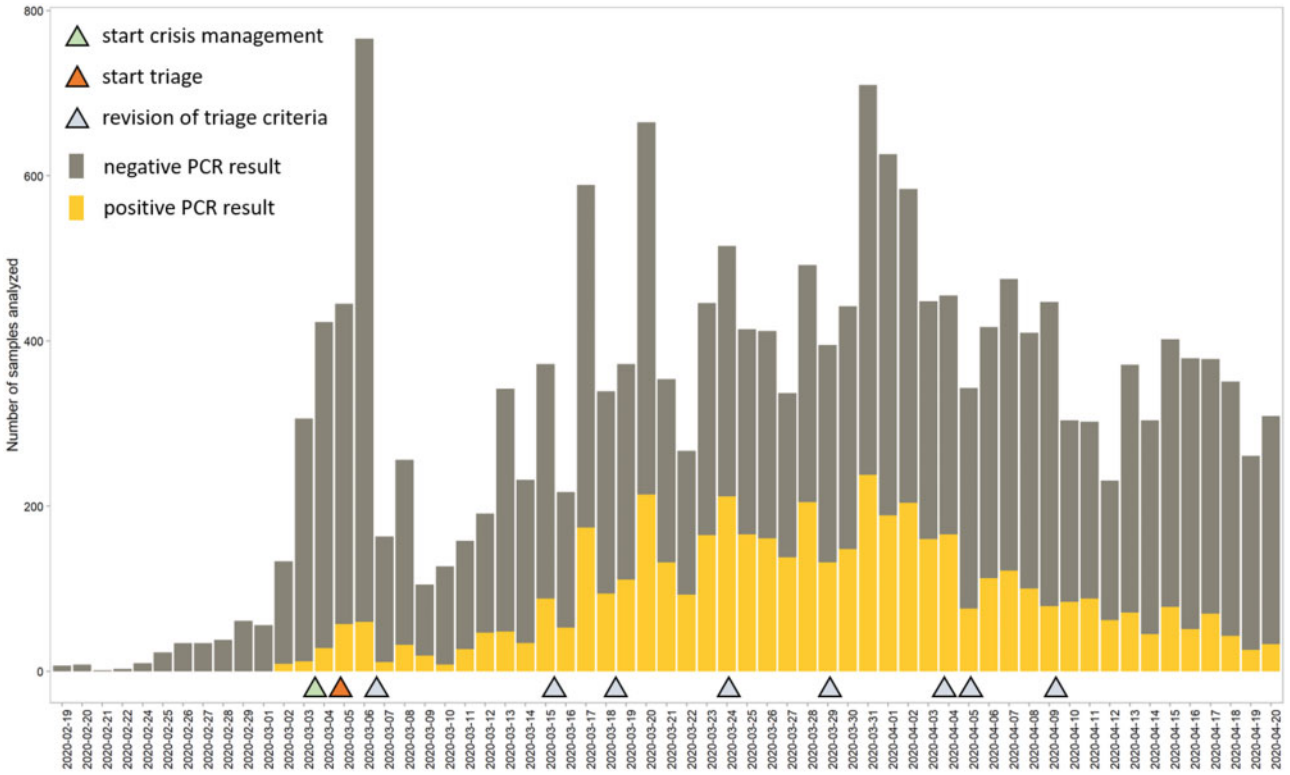

Figure 1. Evolution of coronavirus disease 2019 (COVID-19) laboratory testing and triage criteria. The number of severe acute respiratory syndrome coronavirus 2 polymerase chain reaction (PCR) tests (y-axis) per day (x-axis) from February 19 to April 20, 2020. Gray bars indicate the number of samples with a negative PCR result, yellow bars indicate positive PCR results. Triangles on the x-axis indicate key decisions made by the crisis management team that affected sample triaging or processing. Samples analyzed before February 19 were not registered in the laboratory information system.

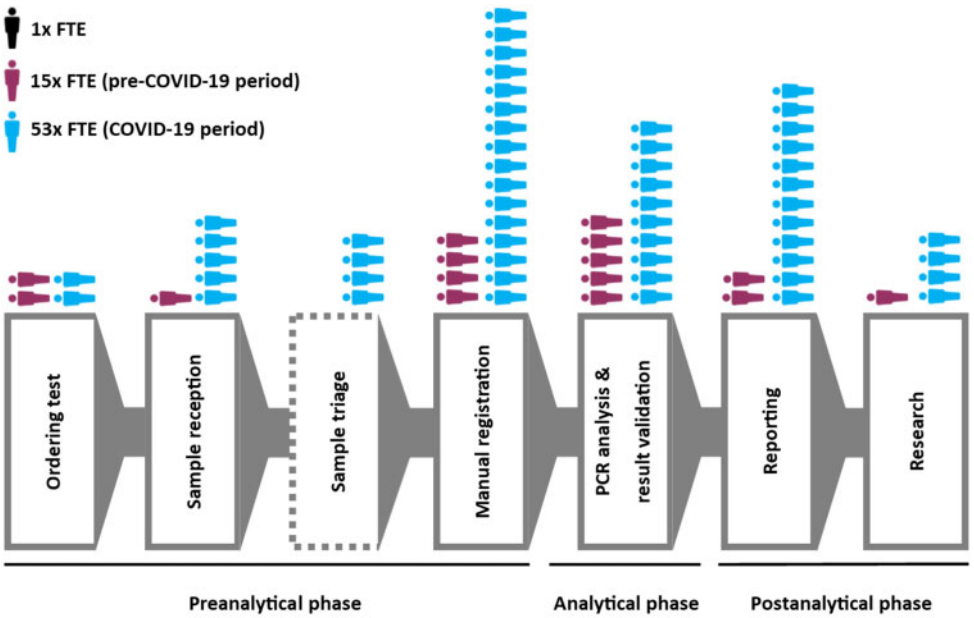

Figure 2. Graphical representation of key bottlenecks in coronavirus disease 2019 (COVID-19) sample flow. Gray boxes represent different stages in the laboratory analysis of COVID-19 samples. Stages have been group as preanalytical, analytical, and postanalytical phases. The box demarcated with a dotted line was newly implemented during the COVID-19 period. Maroon icons represent staff allocation before the COVID-19 pandemic, blue icons represent staff allocation during the COVID-19 pandemic (1 icon corresponds to 1 full-time equivalent [FTE]). Note, 30 of 38 additional pandemic-associated FTEs were assigned to administrative pre-analytical– and postanalytical–related tasks. PCR: polymerase chain reaction.

Table 2. Laboratory challenges and IT solutions during the COVID-19 crisis

Challenge	LIS solution	Advantage over paper-based systems
Prelaboratory phase		
Standardized order forms	Computerized order entry	Quickly adaptable
Standardized ordering	COVID-19 order sets	Quickly adaptable and uniform test ordering
Emergency laboratory order	COVID-19 as emergency laboratory test	Alleviates burden on medical staff in COVID-19 departments during busy shifts
Sample collection and shipping instructions	Digital notifications	Improve sample collection and shipping to reduce biohazards
Preanalytical phase		
Sample registration	Computerized order entry	Alleviates burden on medical administration staff
Triaging	Automated scripted triaging	Quickly adaptable and uniform triaging, alleviates burden on medical administration staff
Sample tracking: storage	Sample tracking	Easily retrieve samples for rapid testing, select samples for scientific studies
Real-time sample tracking	Sample tracking	Estimate individualized turnaround time
Analytical phase		
LIS interface	Bidirectional interfacing	Alleviates burden on laboratory technicians
Postanalytical phase		
Automated validation	Statistical flagging of outliers	Alleviates burden on clinical chemists
Automated reporting	Automated fax, encrypted email	Alleviates burden on medical administration staff
Reporting intermediary or invalid results	Automated fax, encrypted email	Alleviates burden on medical administration staff and call center
Postlaboratory phase		
Epidemiological reporting	Automated email and text messages	Alleviates burden on medical administration staff
Communication	Searchable database	Easily retrieve detailed information of each sample
Epidemiological studies	Sample tracking	Select samples for scientific studies
Crisis management	Daily summary statistics	Data-driven adjustment to triaging
Index patient tracking	Computerized order entry	Complete digital order forms that include all necessary information for index patient tracking

LIS: laboratory information system.

emergency departments. This laboratory set could be ordered for COVID-19–positive patients (Supplementary Table 1). The COVID-19 set contained classical pneumonia-associated parameters (C-reactive protein, white blood cell count), parameters associated with COVID-19 pathophysiology (prekallikrein, complement), and exploratory study parameters for follow-up and correlation with clinical progression (human chorionic gonadotropin, itraconazole). These tests were integrated into a predefined set that could be ordered directly from the EHR via an easy-to-use point-and-click interface. The COVID-19–specific CPOE module was linked to both the LIS and EHR, allowing to automatically retrieve demographic information such as age, birth date, sex, residence, nationality, etc., which dramatically improved metadata completeness.

Metadata recording and automated triaging

After selecting the COVID-19 test panel, physicians were prompted a discrete data entry field (DDEF) consisting of check boxes that corresponded with up-to-date triage criteria. The DDEF not only was easy to use for physicians, but also effectively functioned as a structured data entry system, thereby automating triaging and allowing clinical metadata to be stored into our LIS database for subsequent secondary analysis and epidemiological research.[8]

Preanalytical decision support

The COVID-19 ordering tool not only improved data quality, but also allowed the laboratory to proactively guide sample preparation and shipping procedures through automated notifications. For example, the system algorithmically calculated the minimum number of blood tubes required to perform all analyses (taking into consideration not only the total volume of blood, but also intralaboratory sample handling and aliquoting). The tool then notified the phlebotomist on the optimal sampling strategy. The tool also prompted the phlebotomist with packaging instructions, explaining triple packaging requirements. Finally, the COVID-19 ordering tool was effectively used by the CMT to implement updated triage criteria with immediate effect (Figure 1). This was an especially useful functionality, as both laboratory and governmental test criteria were adapted frequently in function of the developing COVID-19 pandemic, while clinical staff rotated with high frequency.

Postanalytical decision support

In our hospital, patients were categorized as cases not suspected for COVID-19, cases suspected but not confirmed for COVID-19 (test results were pending), and confirmed COVID-19–positive cases. Patients were hospitalized in different units according to this categorization in order to minimize intrahospital disease transmission. Consequently, rapid and effective communication of SARS-CoV-2 testing was required to ensure adequate patient allocation. Therefore, we displayed a "COVID-19 status" button on the main page of the EHR of each patient. This button indicated, in real time, the results of for SARS-CoV-2 laboratory testing and allowed physicians to quickly triage and (re)allocate patients, based on PCR and computed tomography scan results.

Automated reporting of referred SARS-CoV-2 reference testing

Our laboratory has national reference functions for respiratory pathogens and several other specialized in vitro tests but does not

perform referred testing for routine parameters. Under normal circumstances, approximately 2.5% of our testing is performed for external laboratories or healthcare professionals outside of the hospital, and consequently our laboratory did not invest in, nor does it have access to, a Web-based CPOE that could have been be utilized to streamline test ordering during the COVID-19 pandemic. Therefore, we implemented an alternative system to manage data streams for referred testing.

We developed an LIS-specific DDEF tool that allowed administrative personnel to register clinical information that was written on request forms. We also compiled a database with contact details and preferred reporting methods (fax, email, electronic mailbox system, etc.) of every laboratory in Belgium, to enable automated test reporting. Using this ad hoc system, we were able to automatically report the large majority (>98%) of test results. Although technically simple, this system dramatically reduced the number of patients and physicians that called our laboratory to inquire about test results, in turn significantly reducing administrative burden on our call center and staff.

Automated epidemiological reporting of COVID-19 statistics

Epidemiological reporting of clinically relevant pathogens is a key function of clinical laboratories. Reporting of epidemiological and clinically relevant pathogens as SARS-CoV-2 is mandatory in Belgium. Under normal circumstances, epidemiological reporting is centralized and represents only a limited administrative burden. However, during the COVID-19 pandemic, all laboratories were required to report daily summary statistics not only to government bodies, but also to a variety of policymakers and medical and hospital directors. These laboratory-provided statistics were required to effectively monitor and manage the SARS-CoV-2 outbreak and indeed directly affected national lockdown policies.

Our LIS was designed to enable structured data entry into an underlying Structured Query Language (SQL) database, and to efficiently visualize those data through a graphical user interface. However, the system had neither data mining nor data visualization functionality. To meet epidemiological reporting requirements, we had to develop custom-tailored SQL queries, retrieve the data in flat file format, subsequently analyze the data in a spreadsheet program, and then generate several individualized reports that were emailed to specific stakeholders. Consequently, epidemiological reporting and generating infographics quickly became a significant burden requiring full-time staff (Figure 2).

As an extension of our LIS, we developed a tool for automated report generation and emailing. Briefly, the tool accepted output from SQL queries, interfaced with Google Sheets to access reported statistics from other laboratories, automatically compiled and processed all data, and then sent customized emails or text messages to predefined recipients, including national governing bodies and policymakers. Automating the full epidemiological reporting process allowed us to send updates with higher frequency and significantly alleviated administrative burden on scientific staff.

Facilitating scientific research

Projections of the transmission dynamics of SARS-CoV-2 through the postpandemic period predict recurrent wintertime outbreaks after the current first wave.[9] Absent of any other interventions, prolonged intermittent social distancing may be required for the next 24 months, with active SARS-CoV-2 surveillance for at least 48 months.[9] Such measures will inevitably result in significant economic adversity, with fears of a recession growing.[10] Correlating data from clinical laboratories (PCR, serological testing, inflammatory parameters, etc.) with clinical data, diagnostic imaging, and molecular (omics) profiling data have the potential to significantly accelerate the development of predictive models and in vitro diagnostics and provide insight in the mechanism of SARS-CoV-2 spread and infection.

As a first step to facilitate scientific research, we developed a separate database that included results for all parameters in the COVID-19 test panel for all COVID-19–suspected patients (defined as all patients tested by PCR) evaluated in our hospital. As an extension of our previous work in making large biomedical datasets accessible to nonbioinformatician scientists,[11–14] we used the R/Shiny Web framework to develop an easy-to-use standalone data mining application. This application allowed selected staff and researchers to quickly interrogate and visualize the data in order to identify previously unknown correlations, without additional informatics support. This tool not only accelerated research, but also alleviated the burden on IT staff, who could then focus on the development and implementation of increasingly tailored COVID-19–related LIS functionality.

DISCUSSION

We have identified key bottlenecks in the laboratory management of the COVID-19 pandemic. The administrative burden on all staff increased exponentially with peaks in sample volume. IT solutions could effectively reduce administrative burden and streamline sample flow, resulting in higher staff engagement and reduced turnaround times.

Opportunities to promote the meaningful use of health IT

Our COVID-19–specific tools not only addressed immediate needs, but also highlighted opportunities to leverage the meaningful use of LIS systems to guide policymaking and advance biomedical science. So far, the meaningful use of health IT is lagging,[15] despite widespread implementation and adoption of electronic systems. Consistently, in our hospital, the COVID-19 crisis contributed to the accelerated the meaningful use and full advantages of the CPOE-associated tools.

One of the key hurdles in promoting the meaningful use of health IT is the resistance of healthcare professionals to change their daily procedures. The implementation of electronic systems temporarily increases stress (emotionally and organizationally) for medical and nonmedical staff, adding to resistance to rapidly adopting technological advances. Therefore, a key aspect of successful health IT implementation is effective change management. Practical strategies to proactively plan organizational change in the context of health IT are largely derived from the Kotter framework of change management.[16] Kotter proposed a 3-step change model.[6] The first step, establishing a sense of urgency, is the most difficult but is absolutely required to create an environment that stimulates the meaningful use of health IT.

The COVID-19 crisis has put tremendous administrative burden on our staff due to initial shortcomings of our LIS. The realization that digitalization, automation, and meaningful use of our LIS could alleviate some of the most important administrative bottlenecks provided a sense of emergency, which accelerated the development, implementation, and adoption of new functionality (Tables 1 and 2) It would be beneficial to maintain such dynamics after the COVID-19 crisis to advance LIS functionality that may ultimately increase efficiency and quality and improve employee engagement by removing

repetitive and administrative tasks. We anticipate that applying the Kotter principles for consolidating a dynamic environment, or similar change management strategies, can significantly accelerate health IT implementation and adoption.

Key recommendations

The development of robust IT solutions typically requires several months to implement, which is not sufficiently fast for the acute phases of crisis management. However, it is important to immediately develop a near-term (days to weeks) plan for the implementation of IT tools that can alleviate the administrative burden on personnel and facilitate epidemiological and scientific research and reporting. Therefore, we recommend that any CMT consists of not only staff focused on increasing analytical capacity, but also dedicated staff responsible for IT. We further recommend using a change management framework (eg, Kotter's principles) to effectively implement these new IT tools (Table 1). We found that in our scenario the most effective solutions were to streamline sample ordering through a CPOE system, and reporting by developing a database with contact details of all laboratories in Belgium. The implementation of the R/Shiny-based statistical tools facilitated epidemiological reporting and enabled explorative data mining.

CONCLUSION

The COVID-19 pandemic is especially challenging for clinical laboratories that are tasked with rapid and reliable testing of a significantly increased number of samples. Demand above surge capacity readily clogs standard infrastructure. Alleviating personnel from repetitive and administrative tasks via digitalization and automation using ad hoc–developed LIS functionality and reporting tools significantly streamlines sample processing and reduces turnaround time, features that are also beneficial after the initial phases of the COVID-19 crisis. Indeed, lockdown exit strategies will critically depend on laboratory results, including emerging antibody tests. We hope that sharing our experiences in developing these tools will help other LIS implementation teams facing similar challenges.

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AUTHOR CONTRIBUTIONS

MW, SM, and JG conceptualized the study; MW assessed key administrative bottlenecks and aided in the implementation of the computerized provider order entry module; SM performed comparisons with Kotter's framework of change management and developed the database for automated reporting; LC, SW, EH, KJ, LL, KBr, and KBe organized sample flows, managed human resources and were responsible for statistical reporting. JW and RG guided the implementation of information technology solutions. JVE and KH also assisted in development of the database. EA, MD, SD, KL, MVR, and AKLCV formed the crisis management team. MW, SM, and JG wrote the manuscript; AKLCV supervised the implementation of the computerized provider order entry module and all COVID-19–related tools, provided advice, and helped improve the manuscript. All authors commented and contributed to the manuscript.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Journal of the American Medical Informatics Association* online.

CONFLICT OF INTEREST STATEMENT

None declared.

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