THE QC RESPONSE TO COVID DISRUPTION: A CASE STUDY

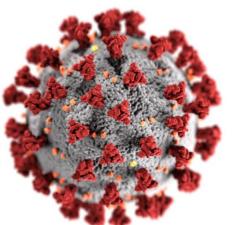
BRIAN K NUNNALLY, PH.D. 28 January, 2022



INTRODUCTION

- COVID has changed nearly every facet of society
- Like it or not, many things will never go back to what it was before
- The laboratory has a chance to evolve to a better place which could result in improved adaptability to the new demands
- Maximizing safety is the key objective
- Allowing for collaboration a bedrock of science – is the goal







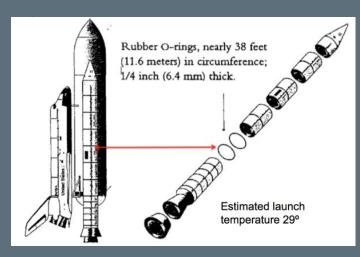
LABORATORY DESIGN



LABORATORY DESIGN

- The changes due to COVID have created a need for new ways of thinking regarding laboratory design
 - The changes have come too fast "we are fixing the plane while we are flying it"
 - The adaption is occurring but we are still learning
- No detail will be too small

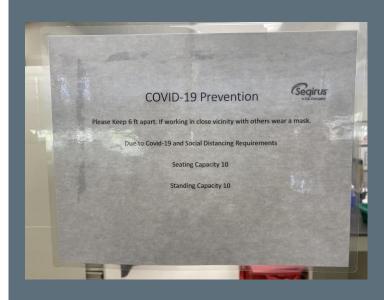






LABORATORY DESIGN – INFRASTRUCTURE

- Ensure adequate ventilation and room air exchanges
- Limit the number of personnel per room
 - Be diligent in describing <u>how</u> the work will take place
 - How many people will be allowed to work at a bench? Is there sufficient space between bench work?
 - Dividers could be placed between analysts, especially when social distancing is not possible
 - Don't forget the office/write-up space as well!
- Maintaining throughput and interaction while minimizing contact is the key



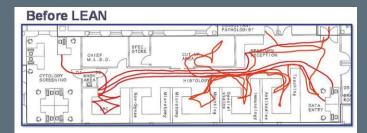


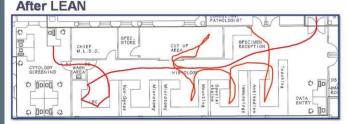
LABORATORY DESIGN – INFRASTRUCTURE

- Flexible, adaptable space
 - Mobile benches and reconfigurable space
- Unidirectional flow
 - LEAN laboratories are still an answer think 7 wastes!
- Minimize high traffic areas
 - Change your way of thinking
 - Space out high traffic equipment, e.g. balances



Reference: https://www.atvilla.com/ATVilla/Products/Benches.htm





Reference: https://www.cellpath.com/latest-news/lean-and-learn-efficiency-in-the-histology-laboratory/



LABORATORY DESIGN – PERSONNEL

- Masks required even if COVID abates?!?
- Vaccination (preferred) or testing routinely (testing on site?!?)
- Maintain social distancing at all times even if COVID abates?!?
- All of these things help with a potential flu pandemic as well

NO DETAIL IS TOO SMALL

Do not forget nonlaboratory areas. Lunch and break rooms have been the largest contributors to transmission!



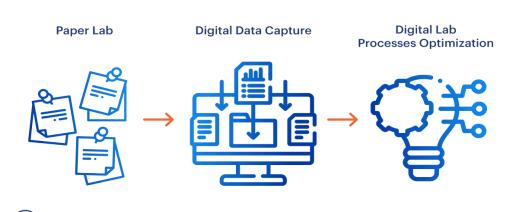


DIGITAL SOLUTIONS

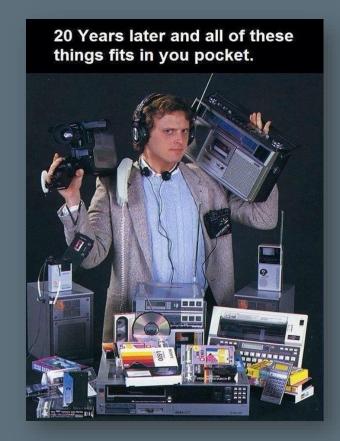


DIGITAL SOLUTIONS

- The goal is to simplify operations and minimize the need for people to be involved (allows for people to not be on site, potentially)
- Everything needs to integrate together



A LOT HAS CHANGED...



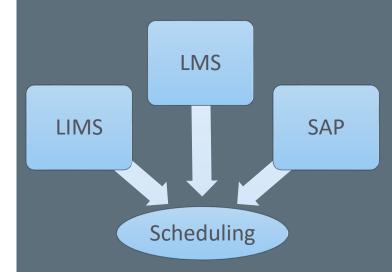


BINOCS

DIGITAL SOLUTIONS - SCHEDULING

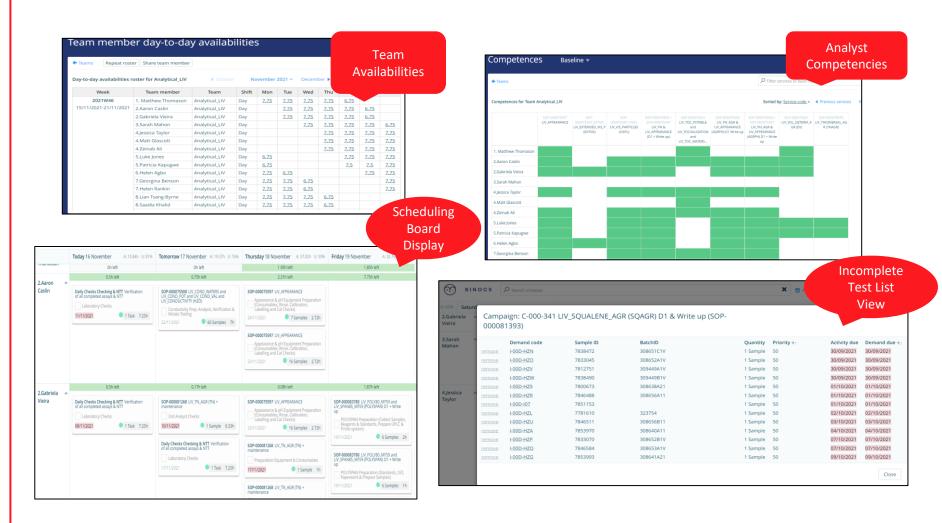
- Digital solutions for every day issues
- Laboratory scheduling, for instance, needs to be robust and automated
- Sickness can happen at any moment and staff can be removed without warning
- Integration is the key for all software but especially for scheduling software







DIGITAL SOLUTIONS – SCHEDULING





DIGITAL SOLUTIONS – METHOD EXECUTION

- Digital method execution reduces the need for paper based tools
- Reduces the potential for error and can improve the performance of the methods
- Media describing the technique can be accessed during critical moments. Operators consume demonstrations before completing a step
- Work hands-free with voice guided instructions
- Main workflow page easy to navigate with Visual queues for steps

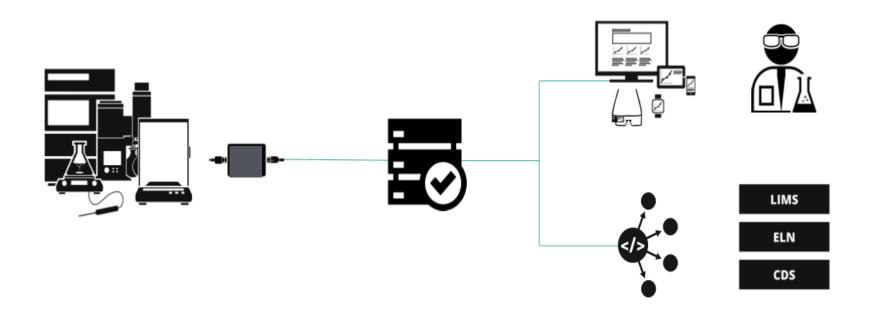




- Operator selects a step and a second screen opens which details all inputs from the augmented document
- Quick visual checks for managers/supervisors on how a procedure is going

DIGITAL SOLUTIONS – INSTRUMENT INTERFACES

- The Digital Lab is smart, integrated, safe, and efficient
- Interfacing data eliminates the need for time consuming checks, reducing the potential for close contact when verifying
- Error Proofing: transcription of data, human error; identify errors earlier



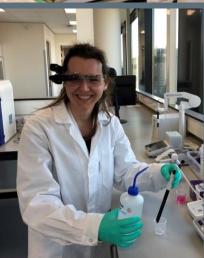


DIGITAL SOLUTIONS – SMART GLASSES

- These "Smart Glasses" allow for collaboration in real time across miles and time zones
- A person at a computer linked to the glasses and see exactly what the analyst sees
- Great tool for remote verification efforts to maintain lower numbers in the laboratory
- Has been used successfully to mitigate issues associated with travel – more on that later...











BUSINESS CONTINUITY



BUSINESS CONTINUITY – BUILD IN REDUNDANCY

- Redundancy is needed at all levels ignore it to your peril
- Back-up laboratories consider qualifying additional laboratories so samples can be quickly re-routed when illness reduces (eliminates?) capacity
- Utilize the whole QC network
- Redundant instrumentation consider having additional instrumentation to mitigate delays caused by vendors unable to come to site for repairs / maintenance (due to travel or site rules)
- Do not forget about the laboratory supply chain – back-up for reagents and supplies are needed to ensure no disruption due to supply chain snafus, heavier inventory as well



Laboratory reagent supply chains strained in the pandemic like all other supply chains. Supply issues for items like pipette tips, tubes, and other plastics were common due to numerous factors.



BUSINESS CONTINUITY – SHIFT PATTERNS

Shift	Days	Time	QC Role
Morning	Monday - Friday	6:30 am – 2:21 pm 7:00 am – 2:51 pm	5 x QC Analysts 1 x QC Team Leader
Afternoon / Weekend	Monday – Friday Tuesday – Saturday Sunday	3:00 pm - 11:00 pm 3:00 pm - 11:00 pm 3:00 pm - 11:00 pm	1 x QC Specialist 1 x QC Analyst 1 x QC Analyst
Overnight	Monday - Wednesday	9:00 pm – 5:00 am	1 x QC Analyst

SHIFT PATTERNS

Use shift patterns to reduce the number of personnel who can come into contact while still maintaining (enhancing?) throughput



BUSINESS CONTINUITY – PERSONNEL

- Work from home where possible. This limits the number of people in the laboratory and reduces the potential for spread.
- Don't come to work sick this is a change in culture. No more "toughing it out".
- Regular checks of safety protocols routine inspections run by safety officers to ensure safety protocols are being followed
- Close contact definitions ensure the definitions of close contact are consistent with the best scientific guidance and risk mitigations





https://www.verywellhealth.com/should-i-call-in-sick-770447





BUSINESS CONTINUITY – PERSONNEL

- Regular cleaning ensuring surfaces, high traffic areas are cleaned and sanitized regularly
- "Virtual everything" use of virtual meetings to replace face to face contact or to limit the number of in person attendees, digital trackers (instead of manual), etc.
- Over-hiring of staff, supplemental staffing –
 this can be difficult to do from both a
 budgetary scenario and finding people to
 fill the roles in the era of the "Great
 Resignation"
- More cross-training mitigate the risk of losing a cohort of people
- Better on-boarding to get (and keep) people engaged









ONBOARDING

- Research indicates that people leave jobs because:
 - Not valued by organization (54%)
 - Not valued by manager (52%)
 - Lack a sense of belonging at work (51%)
- Challenges
 - Ever increasing digital environment
 - Remote working makes it much more difficult to stay connected
 - Increases in length of time to get new employees "up to speed" and contributing
 - This adds stress to current employees as work load imbalance within group
- Mitigations
 - Developed group specific checklist for buddy and new employee
 - Validation execution completed: 31Oct2020
 - Validation report approved: 15Nov2020

ONBOARDING

Onboarding has always been a challenge, one made more difficult due to COVID





ONBOARDING - MITIGATIONS

- Developed group specific checklist for buddy and new employee
 - Most efficient order for training
 - How to get access to various systems including who to talk to
 - Checklist is a living document that gets updated regularly
- Daily "touch-base" meetings
 - Teams still largely working from home except for essential activities
 - Virtual meeting designed to be short, quick discussions with team (5 minutes)
 - Intent is to provide opportunity for employees to ask for assistance (not an update/status meeting)
- "Stay" conversations
 - Purpose is for leaders to listen and understand what motivates employees
 - Outcome are actions to be taken based upon the conversation (For example-new development plan)











TRAVEL DISRUPTIONS



TRAVEL DISRUPTIONS – USE TECHNOLOGY

- Virtual will never be as good as face to face – accept this and move on to make the virtual experience as good as possible
- When travel is restricted, Smart glasses can be used as a supplementary option
 - For example, for a new laboratory being opened in another country, training was conducted remotely using Smart glasses technology
 - Performance of the laboratory was excellent, despite the challenges associated with the non-traditional way of training











TRAVEL DISRUPTIONS – INSOURCING?

- Travel disruptions can affect your ability to get vendors on site – consider insourcing of maintenance to eliminate reliance on vendor maintenance
- This is not possible for all instrumentation or all situations



Good reasons for both insourcing AND outsourcing as strategies. Creating business continuity utilizing both options is likely a good idea.



CONCLUSIONS

- Changes we are making due to COVID will linger once COVID is endemic
- These are opportunities to remake the laboratory into a new and better image
- Attitude will play a large part in how the laboratory grows through this challenge
- Cloud laboratory?!?



ACKNOWLEDGEMENTS

 Seqirus QCLT: Eric Blaesing, Becky Elliott, Simon Harwood, André Johnson, Helen Mihaljevic, Leonora Pancho, Jeff Pederson, and Andrea Pickering



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