Changing my laboratory: drivers and critical parameters of the process

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ECCMID2019 session ME059

Disclosures

Speaker	Type	Companies/funders
Dr. Suzan Pas	Honorarium or other endorsement for participation in advisory boards or education	• QCMD • Luminex Corp.
Prof. François Vandenesch	Research fee / Honorarium or other endorsement for participation in advisory boards or education	• Pfizer • bioMérieux • Accelerate

None of the above mentioned were paid to the speakers in person, all expenses were paid to the speaker's employer.

Session overview

- Aim of this session:

  To discuss the ever-changing environment (hospital demands, medical needs, new technologies, automation) of medical microbiology laboratory.

- Short introduction of the SP and FV
- Some slides on what drives a changing process
- Discussion

Short introduction

François

- Clinical Microbiologist /researcher
- Merger of 7 laboratories in Lyon (FR)
- ISO15189:2012 in process
- Catchment area ~1 million people
- Total Lab automation bacteriology cultures

Suzan

- Medical molecular biologist
- Microvida: a merger of 3 labs in South-Netherlands
- ISO15189:2012 accreditated
- Catchment area ~450.000 people
- Lab automation: molecular diagnostics

Changing laboratories: Drivers

- Time to result
- 24/7 service
- Reducing costs (cheaper assays, “optimal economical care”, larger scale)
- Automation
- New techniques and new demands

Point of impact vs point of care tests

Point of care

@ bedside
(biochemistry)

@ Emergency room

@ Clinical chemistry lab

Point of impact

Microbiology laboratory

For virology:

- resp: FluA/FluB/RSV
- HIV at anonymous testing site

Model for the microbiology service is changing

INFECTION HOT TOPIC 10.1111/1469-0691.12692

Clinical microbiology laboratory: from the Pasteur model to the 24/7 clinical chemistry concept

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Parameters to take into account

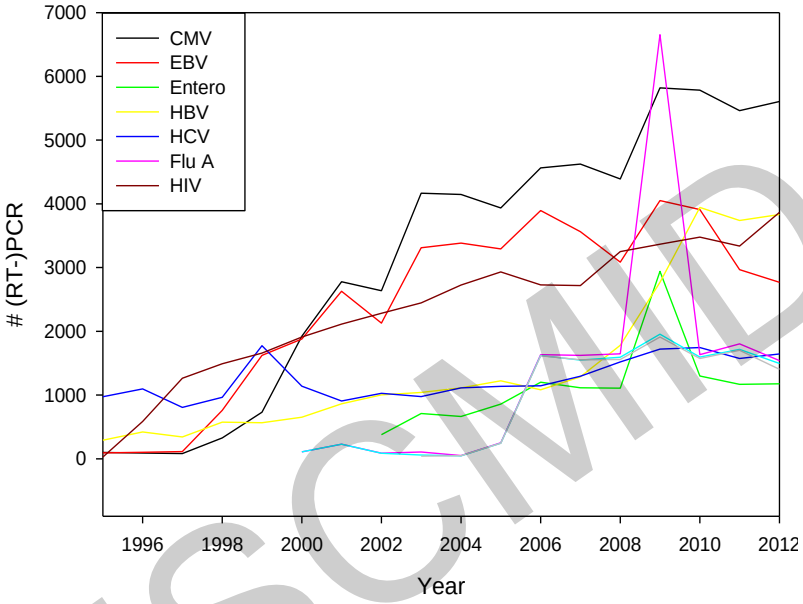
- Logistical issues (distance between core lab & clinical unit) → POI / not POI
- Number of samples (threshold for efficiency)
- Availability of clinicians to adjust patient treatment
- Financial aspects
- Political issues

Merging: New Lab = a 24/7 platform

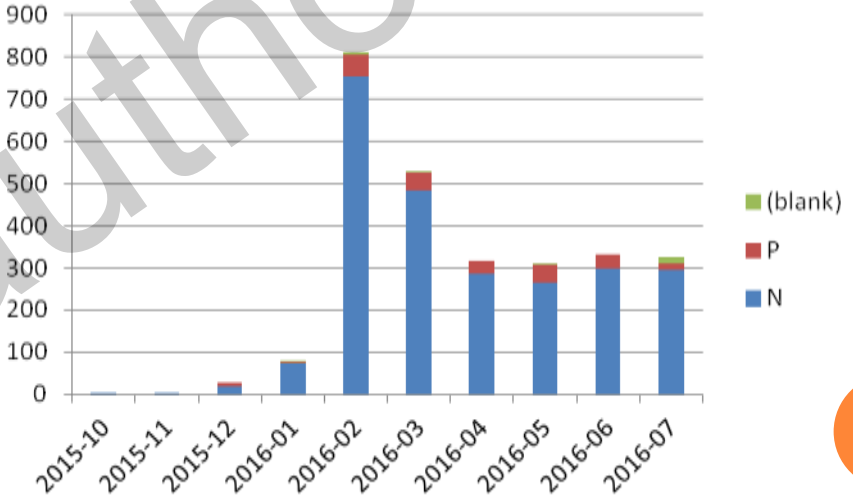
- Central area: dispatch and ON activities
- Adjacent BC instrument room
- Vicinity to conventional lab for manual processing
- Vicinity to lab automation instruments
- Not far from Point of Impact Lab

(MOLECULAR) LABORATORY AUTOMATION

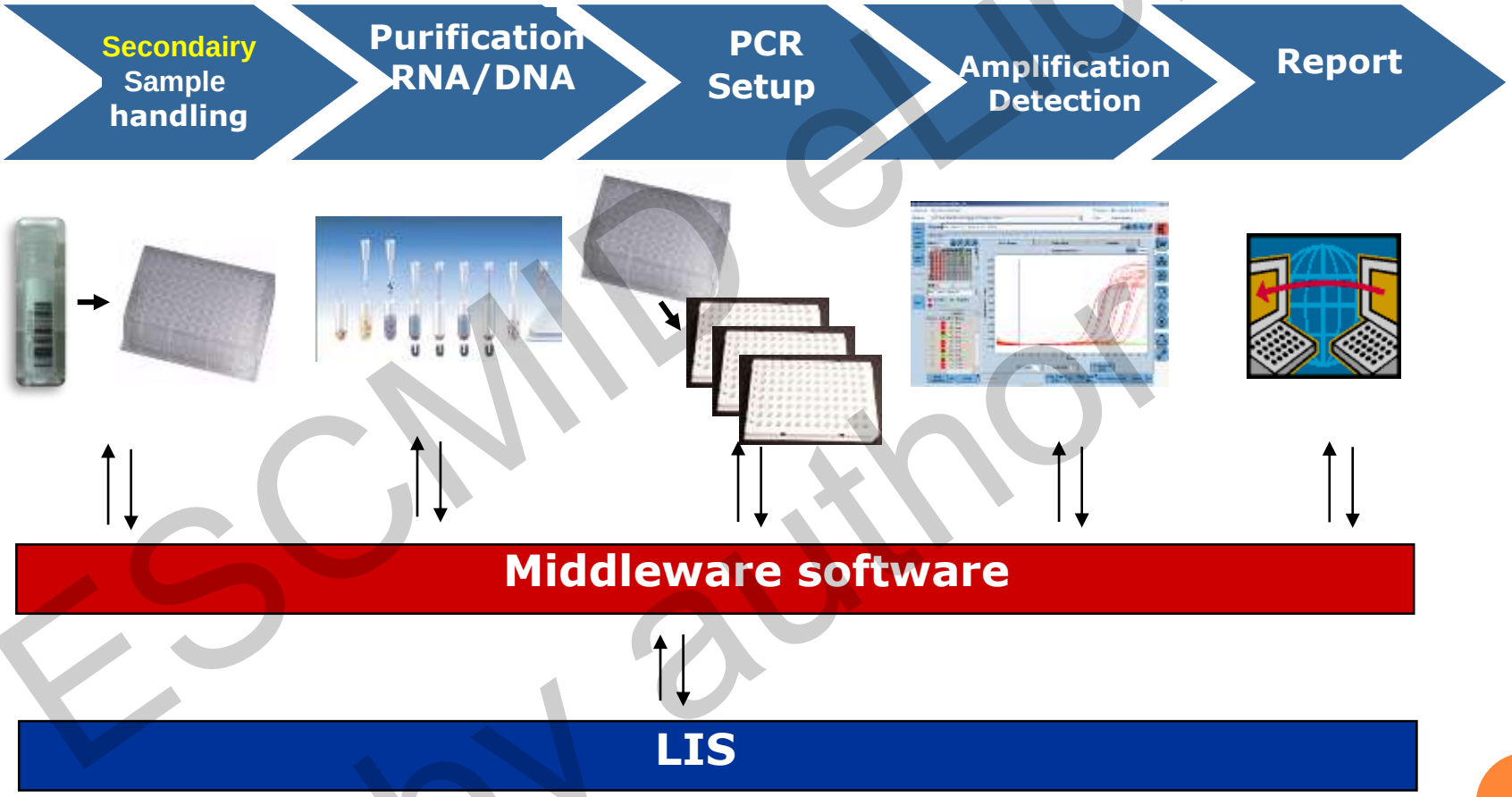
Steady increase in production Mol Dx…



…or sudden increase in production Mol Dx due to outbreak (2016 Zikavirus)



Automated molecular diagnostic work-flow



Lab automation is needed

- Pandemic preparedness, quick up scaling
- Data management
- Quality improvement
  - → Prevention of sample exchange
  - → Prevention of human re-writing and pipetting errors

- Increased efficiency, less hands-on time
- Time saving ?

Is your lab work flow efficient enough for automation?

Poll

1. What is your educational background?

A. Medical Doctor
B. Scientific
C. Technician
D. Other

2. In what facility do you work?

A. University hospital
B. Peripheral hospital
C. Private laboratory
D. Industry
E. Other

3. Is your laboratory in a changing process?

A. Yes, merging labs
B. Yes, automation
C. Yes, 24/7 service
D. Yes, combination of A, B, C
E. Yes, other
F. No, just changed
G. No, no need
H. No, other

4. What is your learning goal from this session?

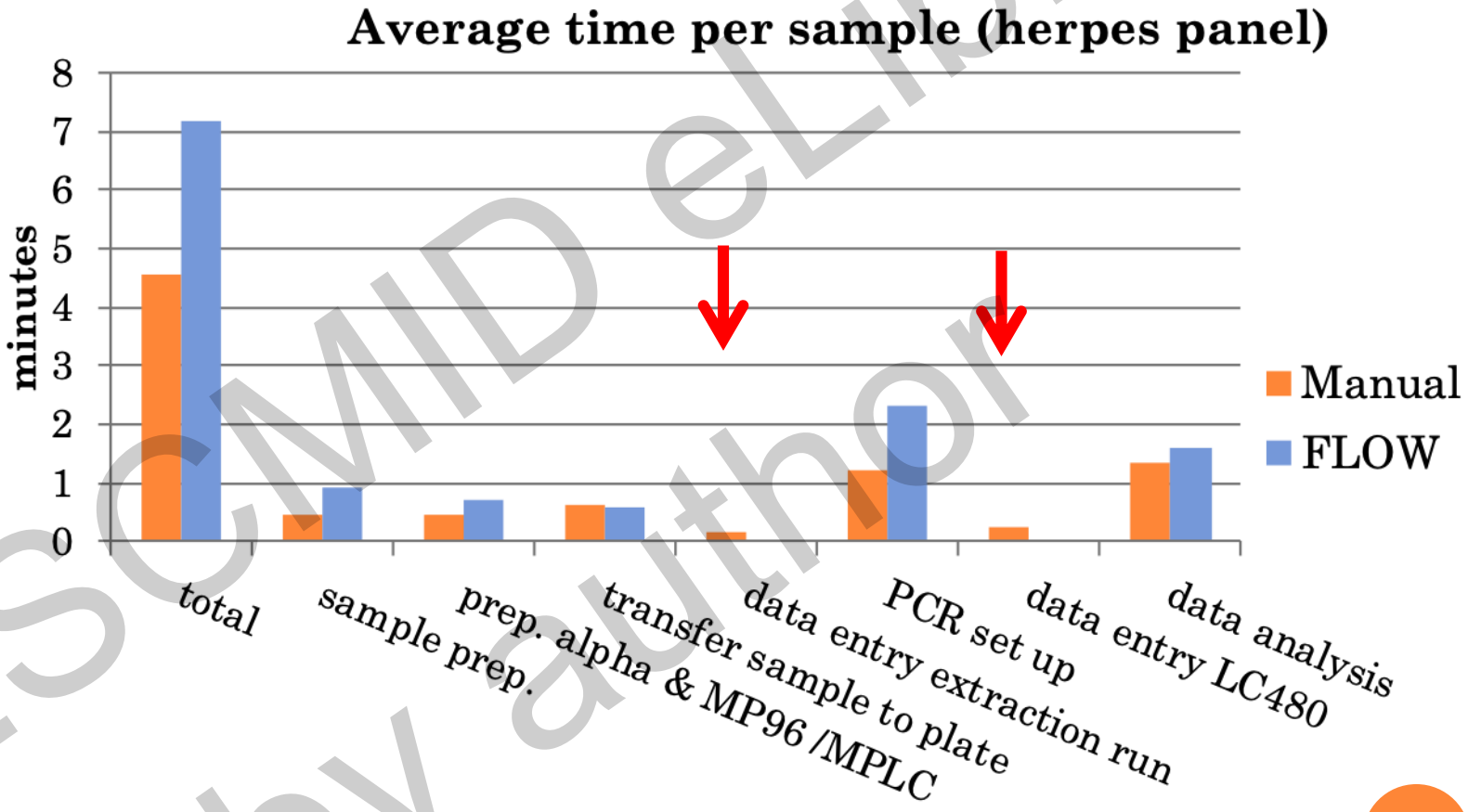
A. Decision for automation or not
B. Decision for 24/7 service
C. Choosing between true POC
D. High efficiency logistics
E. Merger of laboratories
F. Other

Statements

5. The goal of lab automation is to have higher turn around times.

A. Yes
B. No
C. Don't know

Is lab-automation faster?



Not per se quicker!
Time saving slots: data entry in MP96 en LC480 !

Comparison of TTR (before and after)

Sample type and results per sample	Number of samples 2017 vs 2018	TTR between "final confirmation" by LT and sample arrival Difference 2018 – 2017 in minutes	TTR between "final validation" by medical microbiologists and sample arrival Difference 2018 – 2017 in minutes
Urine sample			
Global	2588 vs 2093	+96	+73
Negative & non-significant	1182 vs 785	+172	+125
Contamination	564 vs 484	-153	-91
Positive	843 vs 827	-66	-208
Urine (incubation > 1200 min)			
Global	2015 vs 2093	**-142**	**-110**
Negative & non-significant	842 vs 785	**-7**	**-23**
Contamination	466 vs 484	**-332**	**-254**
Positive	707 vs 827	**-337**	**-339**
Blood culture			
Global	3821 vs 8293	**-218**	**-259**
Negative	3438 vs 7788	*Automatic validation*	*Automatic validation*
Positive	363 vs 504	**-242**	**-504**

Wasp Lab + standardisation of reading time point + extended reading time (8-16h to 8-20h):

-> overall TTR shortening: 1 to 5 hours for urine, and 3 to 5 hours for BC samples

Dauwalder O. Poster #O0222

6. Automation leads to improved quality

A. Yes
B. No
C. Don't know

Automation: quality improvement?

- Yes!
  - Standardisation
  - Tracability
  - Reproducibility
  - No human pipetting errors with complex pipetting schemes
- Know the limits of the robots!
  - e.g. What is the min. amount of samples the PCR set-up robot can handle?

Lyon

- Standardisation of sample collection device
- Standardisation of inoculation : automated streaking
- Automated reading
- Traceability, reproducibility, objectivity

7. I DON'T NOT NEED TO CHANGE PROTOCOLS FOR LAB AUTOMATION

A. Yes
B. No
C. Don't know

Labour intensity / Robustness

Old generation

Some real time mixes have up to 9 tubes!

New generation

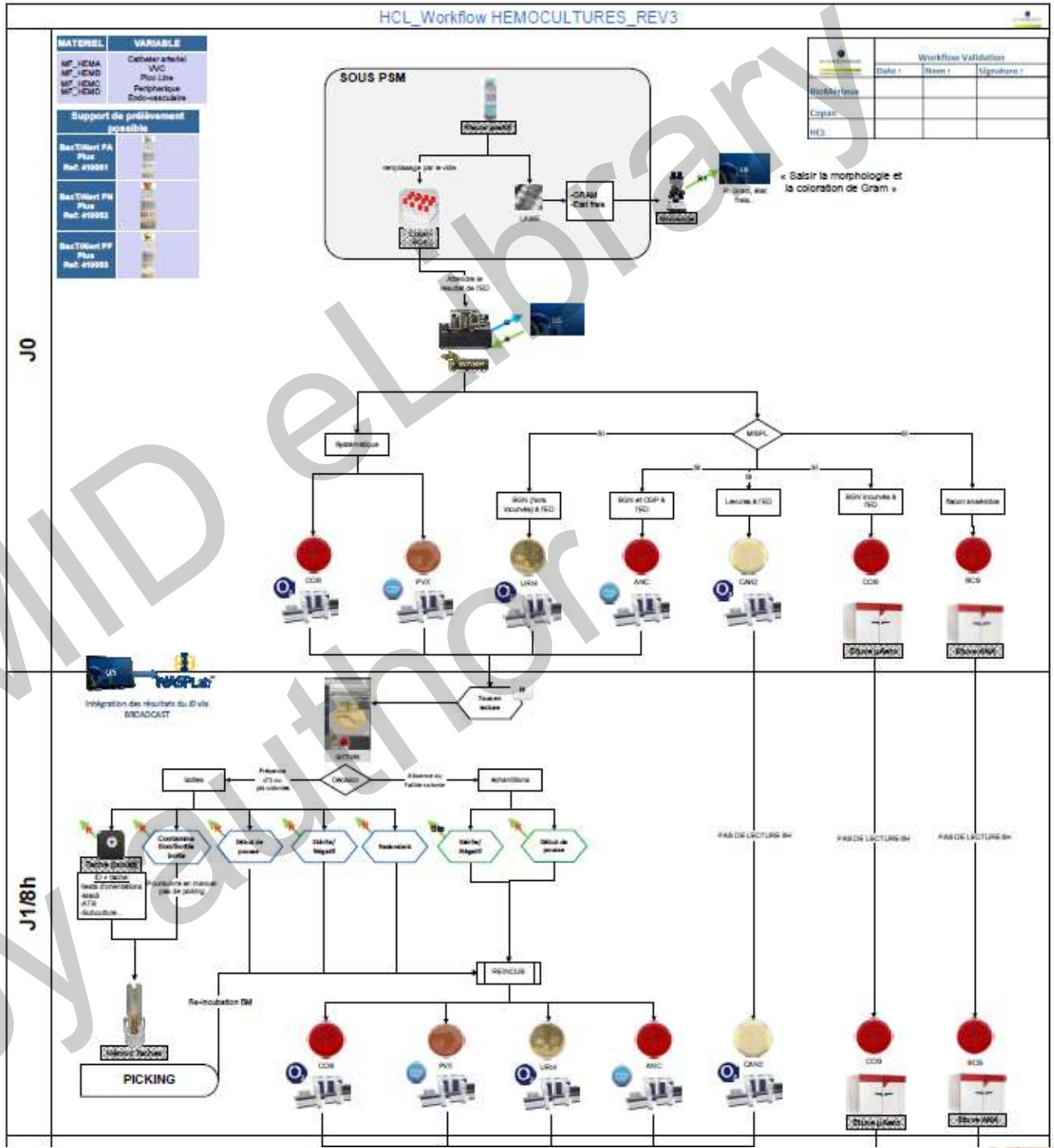
Mastermix: 1 tube + pp mix
Advantage : quicker & more robust!

Efficiency increase by consolidation of PCR (DNA) and RT-PCR (RNA) profiles

Mergin laboratrories and Introducing automation in Bacteriology

- Need to precisely describe each step of pre-analytic, analytic and post-analytic process
- For all type of samples
- In the context of your laboratory
- For all steps
- For all circumstances even those you did not think they could exist !
- example: BC process

BC PROCESS



8. POC / POI IS SUFFICIENT TO PROVIDE 24/7 SERVICE.

A. Yes
B. No
C. Don't know

Take home messages

- Changing a laboratory is a timely process, which need changing
- Automation…
  - …leads to increased quality rather than increased turn around times
  - ….should be thought of as part of the whole proces, with consequences up and down stream which need to be anticipated.
  - ….automation is only cost-effective beyond a certain production threshold
- POC / POI is not per sé the magic solution