Automated Molecular: The Next Steps for Liverpool Clinical Laboratories Virology

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Introduction:

Liverpool Clinical Laboratories (LCL), part of Liverpool University Hospitals NHS Foundation Trust, implemented an automated molecular solution (Roche cobas p612 + 8800) in Virology in April 2023 (Figure 1).

The intention of a Rapid Improvement Event (RIE) is to optimize the molecular virology workflow to realise anticipated automation benefits by delivering timely results usings staff resources more efficiently.

Problem: To improve efficiency of axess Sexual Health Team workflow processes from Sample Receipt through result verification ensuring 24 turn-around-time (TAT) requirements are met.

In scope:

Virology workflow from specimen receipt through result verification using cobas p612 + cobas 8800 platform (molecular assays: axess Chlamydia trachomatis & Neisseria gonorrhoea CT GC assay).

Out of scope:

Non molecular testing areas

Courier workflow prior to delivery at Specimen Receipt

Processes for RIE:

LEAN methodology principles:

Value, Value stream, Flow, Pull, Perfection (Figure's 2,5,6&7).

The Kano Model[1]:

Published in 1984 by Dr Noriaki Kano, a model to understand a customer's needs & improve customer satisfaction (Figure 2).

The 5 why's[2]:

Developed by Sakichi Toyoda in the 1930s. An effective way of identifying the root cause of a problem (Figure 3).

Figure 1: Automated Molecular Laboratory

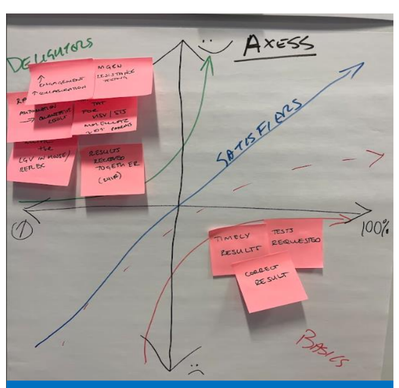

Figure 2: Value – Kano Model

Figure 3: The 5 Why's Model – Root Cause Analysis

RIE improvement themes:

a. People

Desire to enhance team member engagement. A survey has been distributed to understand baseline satisfaction

b. Quality

24 TAT performance goal for axess Sexual Health team is not realized in all testing scenarios. Impact of non-conformity test performance by assay to be measured

c. Time

Manual process steps in the workflow impact TAT. Understand waste in our current state process to redesign a more efficient process

d. Cost

Measure impact of invalid re-testing due to inefficient processes. Measure impact of time savings for staff decreasing trips between floors

e. Growth

Cobas p612 + 8800 instruments are not operating at full capacity. However, the current workflow process would not support an increased workload. Optimizing efficiency is a must.

Figure 4: Virology RIE team

Figure 5: Value Stream – Initial steps from sample to result. Pink represents issues identified

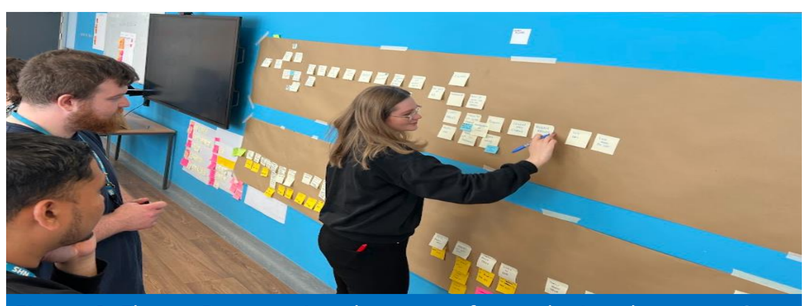

Figure 6: Flow – Re-mapping the steps after reducing the waste & resolving issues

Figure 7: Pull – New steps from sample to result showing reduced number of process steps

Results:

After a successful RIE, we were able to impressively reduce the footsteps required from sample to result by 53% (Figure 8). We have reduced our non-value added (NVA shown in red) processes down by 13, while increasing our value-added (VA shown in green) steps by 2.5%. Since implementation of the automated molecular platforms the TAT of our CT GC has greatly reduced, even more so since week 26 which was the RIE week as shown in figure 9. Furthermore, since using the automated molecular solution the RLUH (Royal Liverpool University Hospital) GUM patients have received their results quicker than previous methods. Figure 10 shows patients had waited up to 6 days (shown in red) compared to now, getting their results the same day (shown in green).

	Current	Future	Change
Flow Time	12.95 h	8.48 h	4.47 h ↓
Touch Time	12.2 h	7.95 h	4.25 h ↓
Footsteps	210	98	112 (53%) ↓
% Yield	13.54%	62.9%	49% ↑
VA	4 Steps (9.5%)	4 (12%)	2.5% ↑
NVA	42	29	13 ↓
Total Process Steps	46	33	13 Steps (28%) ↓

Figure 8: The current vs future state, demonstrating a positive change since the RIE

1st April 28th Aug 23
All sites

Week	Average of Days coll-auth
14	1.1
15	1.6
16	2.0
17	2.7
18	2.6
19	3.3
20	3.1
21	1.7
22	1.7
23	1.4
24	2.0
25	2.1
26	3.4
27	2.1
28	1.6
29	1.2
30	1.2
31	1.1
32	1.0
33	1.0
34	1.2
35	2.0
Grand Total	1.9

1st April 28th Aug 23
GUM Clinic RLUH site only

Week	Average of Days coll-auth
14	0.9
15	1.2
16	1.9
17	2.4
18	2.3
19	3.0
20	2.6
21	1.7
22	1.5
23	1.1
24	1.7
25	1.7
26	3.2
27	1.8
28	1.2
29	0.7
30	1.1
31	0.8
32	0.7
33	0.8
34	0.9
35	2.0
Grand Total	1.6

Figure 9: The average number of days it has taken from collection to authorisation for the CT GC assay

S/N	RANDOM DATES	DETAILS OF CLINICAL VISIT (PREVIOUS VISITS IF ANY)		
		DOT	DOR	TAT
1	Thursday, 1st June 2023	12.05.22 31.05.22 01.06.23	18.05.22 06.06.22 01.06.23	6 DAYS 7 DAYS SAME DAY
2	Monday, 5th June 2023	19.05.23 11.05.23 05.06.23	22/05/23 17/05/23 05/06/23	4 DAYS 8 DAYS SAME DAY
3	Friday, 9th June 2023	08.03.23 09/06/23	16/03/23 05/06/23	9 DAYS SAME DAY
4	Thursday, 15th June 2023	28/04/23 15/06/23	02/05/23 15/06/23	5 DAYS SAME DAY
5	Tuesday, 20th June 2023	14/02/22 20/03/23	17/02/22 20/06/23	4 DAYS SAME DAY

Figure 10: Patient visit dates at RLUH GUM showing many days wait for results to same day results released to patients

Conclusion:

- The RIE for Virology demonstrated great teamwork, increased confidence of staff e.g., public speaking and allowed the team to embrace new ways of working. The whole team appreciated the opportunity to take park in the RIE, thoroughly enjoyed the experience and are hugely impressed with the outcomes.
- Some take away messages for future events include having more IT support and to consider the impact on staff in the laboratory who were not actively part of the event e.g., better communication.
- The next steps for Virology are to include the LEAN methodology in other areas and ultimately increase the TAT for other assays.
  - Molecular automation can increase TAT, increase flexibility of multiplex assay testing, minimises contamination & operator error and opens cost-saving opportunities.
  - Virology are now looking at what other assays we can run on the Roche cobas p612 & 8800 to move away from our manual in-house methods.

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[1]Kano, Noriaki; Nobuhiku Seraku; Fumio Takahashi; Shinichi Tsuji (April 1984). "Attractive quality and must-be quality". *Journal of the Japanese Society for Quality Control* (in Japanese). **14** (2): 39–48.
[2]Serrat, Olivier, and Olivier Serrat (2017). "The five whys technique." *Knowledge solutions: Tools, methods, and approaches to drive organizational performance*: 307-310.