Designing Optimal Workflow in Molecular and Genetic Testing Labs: Using Lean Tools in a Dynamic Way to Support Changing Technologies

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Lab Quality Confab ■ New Orleans ■ October 18, 2016

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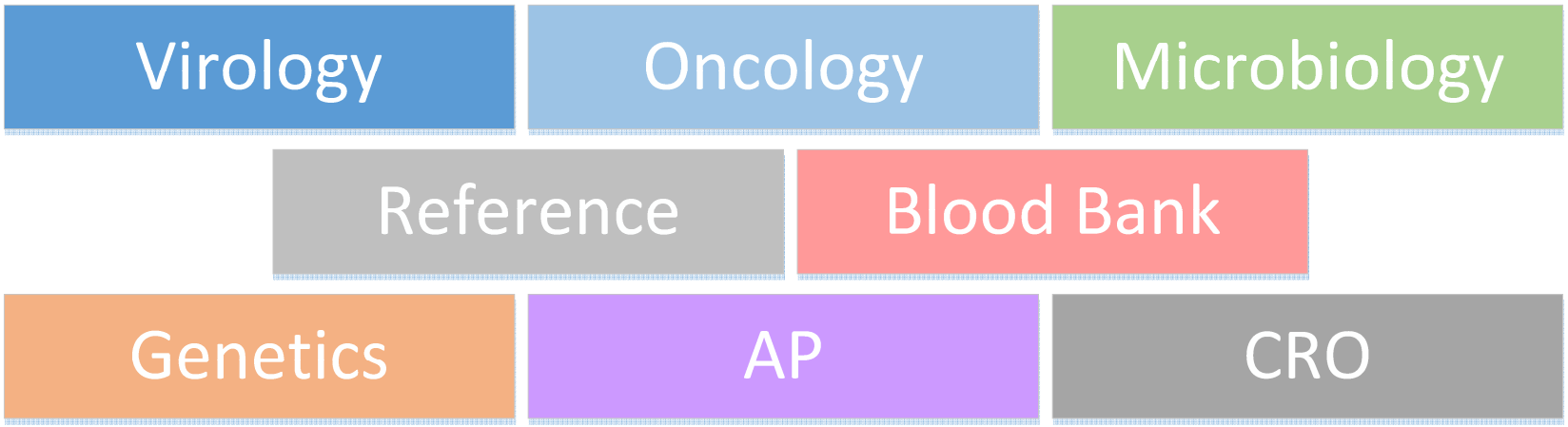
Molecular Labs

Molecular testing can be found in many different settings



Molecular Labs

- These labs tend to be very different, but the approach to designing efficient workflow is the same

- In my discussion today, we will look at how Lean tools can be used to optimize molecular workflow

Goal of Lean

- Lean is about reducing waste, continuous flow and standardized work
- Has been successfully implemented in the laboratory
- But what about Molecular?

Molecular Challenges

Why Lean is difficult in Molecular

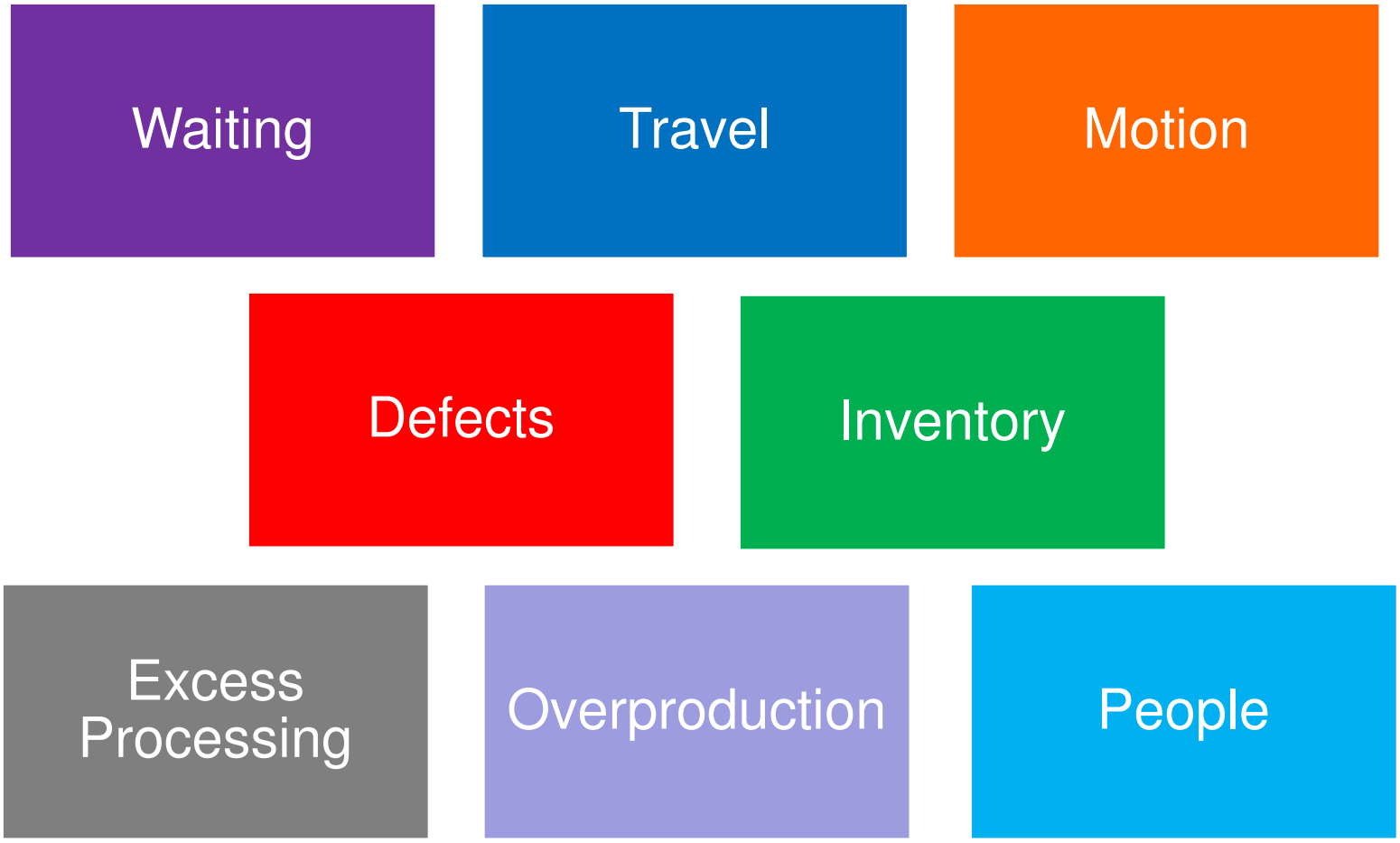
- Batch testing
- Daily testing schedules
- Multiple specimen types
- Shared resources
- Contamination concerns
- Seasonal volumes
- Mix of automation and semi-automated
- Dynamic menus and instruments

Where to Start

- When designing workflow in a molecular lab consider starting with the basics

- Recognizing the wastes and principles of Lean

The Eight Wastes of Lean



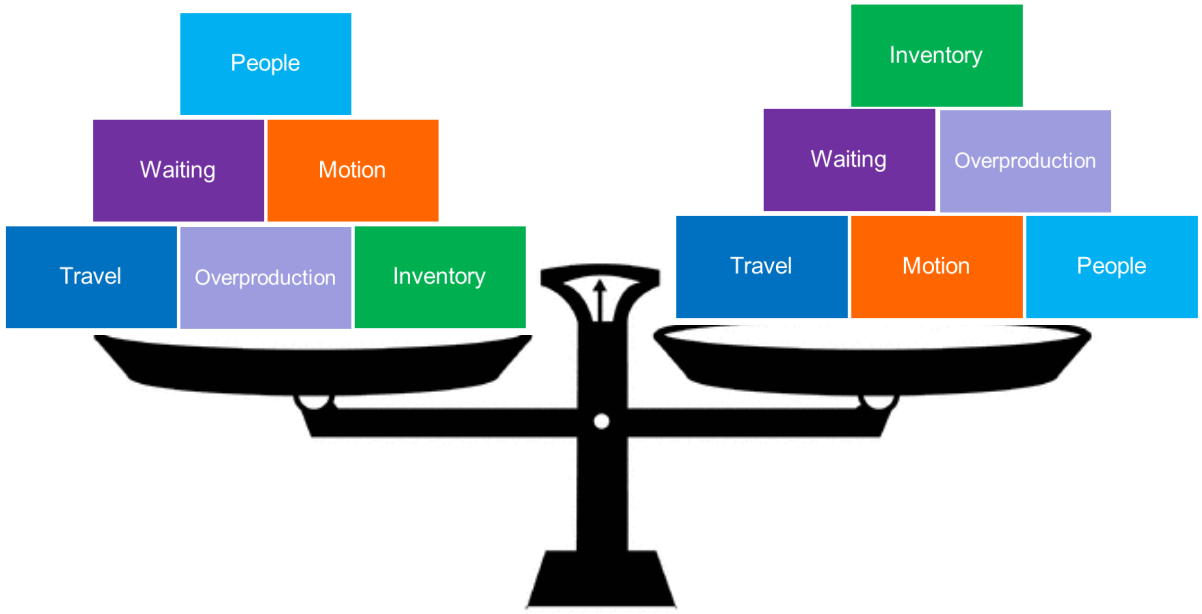
Waste

- Before Waste is removed, processes are often scattered, which can negatively affect your productivity

- After Waste is removed, processes are more streamlined, resulting in more efficiency

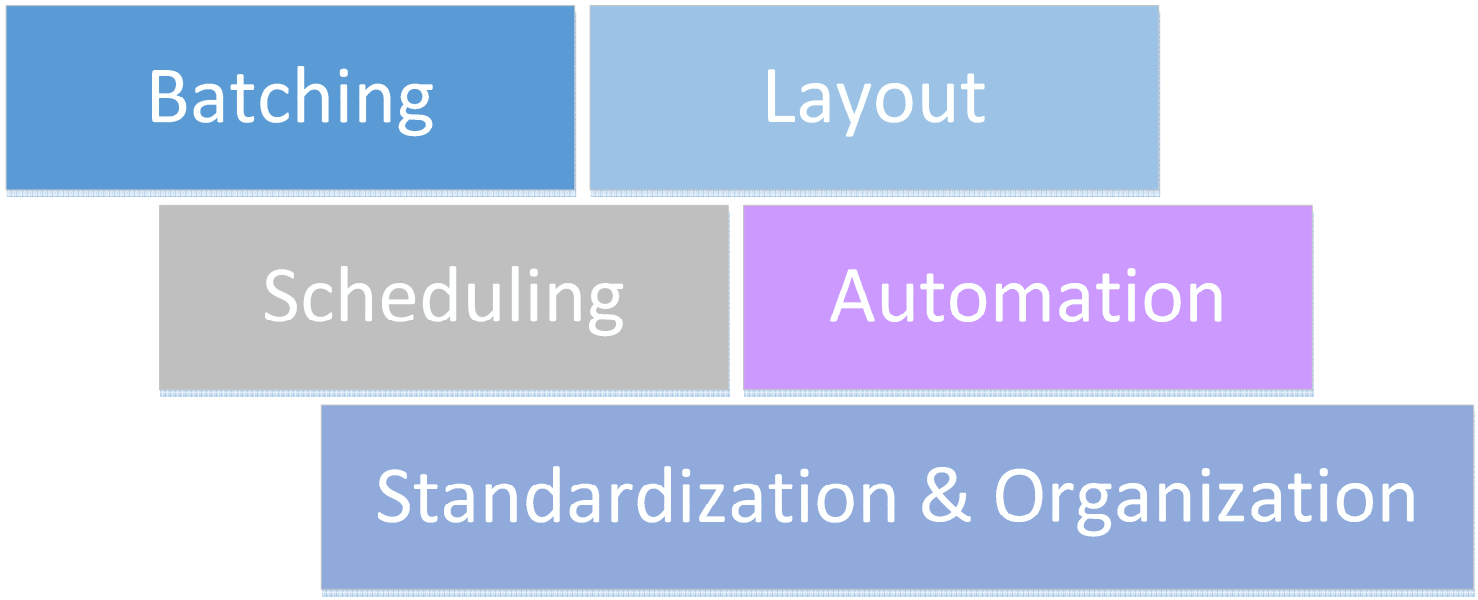
Balance the Waste

- All environments, especially molecular, will have necessary waste. Weigh your outcomes and select which wastes you can live with.



Areas of Focus

For our discussion of molecular workflow design, we will focus on these key areas:



Waste: Waiting

Waiting

Definition:

Periods of Inactivity

- Including specimens, information, equipment, people, etc.
- A specimen waiting for something to happen to it is non-value added time & pure waste

Example: Waiting

Delivered specimens waiting for receiving and accessioning at a reference lab.

Waste: Overproduction

Overproduction

Definition:

Continued production when you should have stopped

- Large batches
- Processing more, earlier or faster than is actually required by the next workstation

Waste: Inventory

Inventory

Definition:

Excess Work In Process (WIP), materials, supplies or reagents

Related to overproduction; too much WIP creates large batches. Excessive supplies consume resources and lab space and out-of-date supplies become waste.

Batch Sizes

- The traditional thought process in Lean is “single piece flow”
- Great for manufacturing, but doesn’t always work well in testing
- The key is to find the “**right-sized**” batch

Batch Size

- For many molecular systems, batches provide for better utilization of resources
  - People
  - Automation
  - Hoods/Equipment
  - Consumables
  - Time

Batch Example

Semi-Automated molecular process

# of Samples	# of Runs	Total Hands-on Time	Hands-on Mins Per Test
1	1	17.3	17.3
2	1	21	10.5
3	1	24.7	8.2
4	1	28.4	7.1
5	1	32.1	6.4
6	1	35.8	6.0
7	1	39.5	5.6
8	1	43.1	5.4
9	2	53.6	6.0

Batching

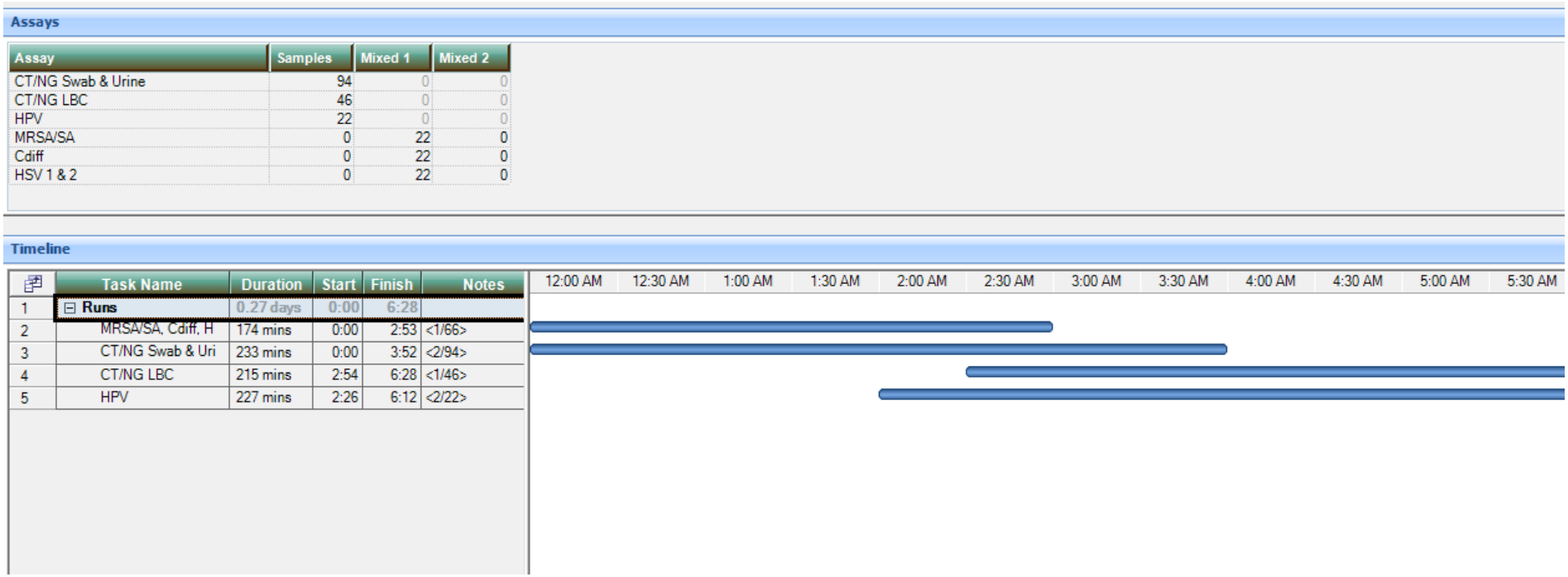
- Larger batches may be improve efficiencies in molecular testing
- Many molecular tests have relatively low volumes which can result in small runs

Scheduling

- Scheduling molecular runs is a big challenge
- There's no one "right" way to schedule
- You look at the factors and strive for a mix of efficiency and service

Scheduling Tool

- *Scheduling Tool Example*



Assays

Assay	Samples	Mixed 1	Mixed 2
CT/NG Swab & Urine	94	0	0
CT/NG LBC	46	0	0
HPV	22	0	0
MRSA/SA	0	22	0
Cdiff	0	22	0
HSV 1 & 2	0	22	0

Timeline

	Task Name	Duration	Start	Finish	Notes
1	Runs	0.27 days	0:00	6:28	
2	MRSA/SA, Cdiff, H	174 mins	0:00	2:53	<1/66>
3	CT/NG Swab & Uri	233 mins	0:00	3:52	<2/94>
4	CT/NG LBC	215 mins	2:54	6:28	<1/46>
5	HPV	227 mins	2:26	6:12	<2/22>

12:00 AM 12:30 AM 1:00 AM 1:30 AM 2:00 AM 2:30 AM 3:00 AM 3:30 AM 4:00 AM 4:30 AM 5:00 AM 5:30 AM

Scheduling Factors

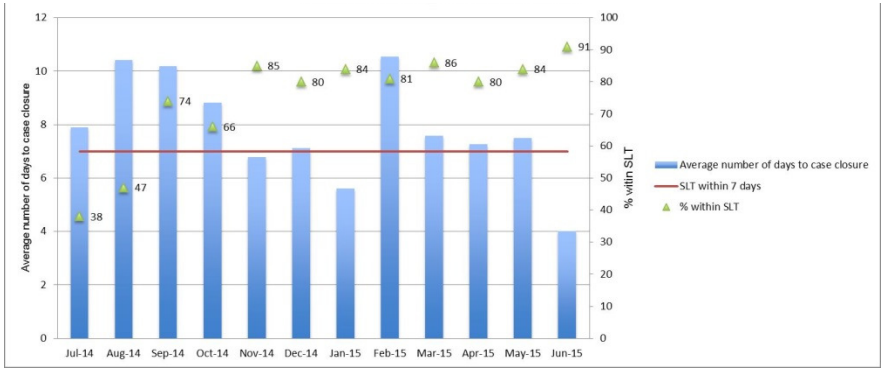
Operations:

- Hours of operation
- Specimen arrival times
- Volumes by test
- Availability of staff
- Attended completion?
- Seasonal variations

Scheduling Factors

Goals:

- Turnaround Time (TAT)
- Priority assays
- Instrument capacity / utilization
- Reagent waste allowance to achieve turnaround



Scheduling Factors

Instruments:

- # of Instruments and characteristics
  - (*Capacity, Speed, Hands-on Time, Walk-Away Time*)
- # of other instruments required for pre-processing
  - (*Capacity, Speed, Hands-on Time , Walk-Away Time*)
- Test menus
- Limitations (mixed runs vs. single assay)
- Accessibility (contamination concerns)
- Availability of hoods/cabinets

Know Your Lab

Are you utilizing your LIS data for operations management?

- Do you know your arrival volumes and patterns
- Do you know when tests are resulted
- Do you know how long all of the processes really take

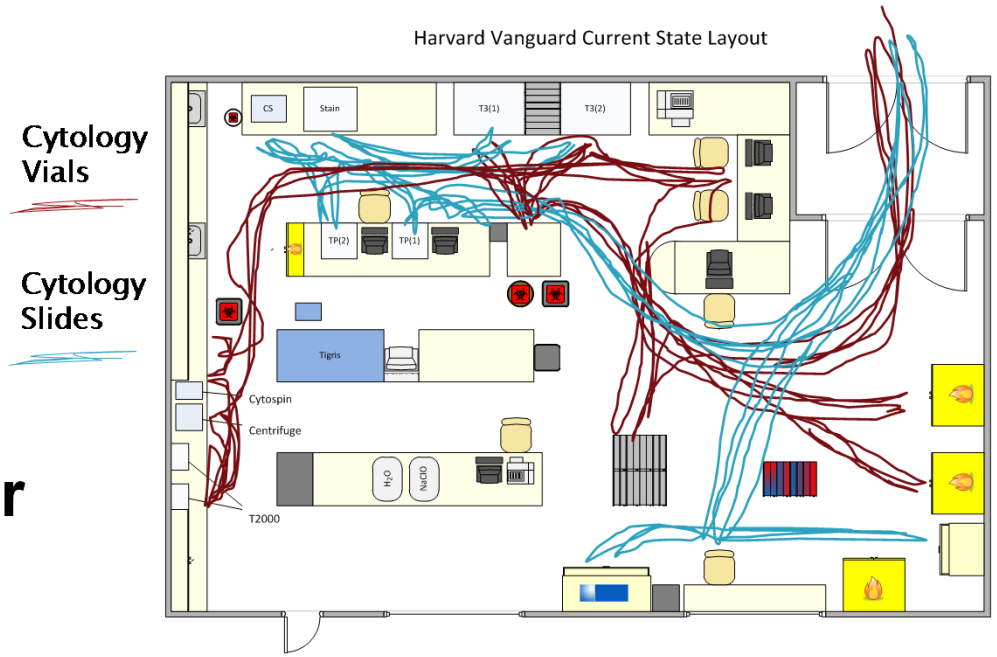
Waste: Travel

Excess Travel

AKA: Transportation

Definition:

Unnecessary movement of specimens, supplies or information around a facility



- Indicative of poor layout, inefficient processes, inappropriate storage locations etc…
- Excessive travel between work areas

Waste: Motion

Motion

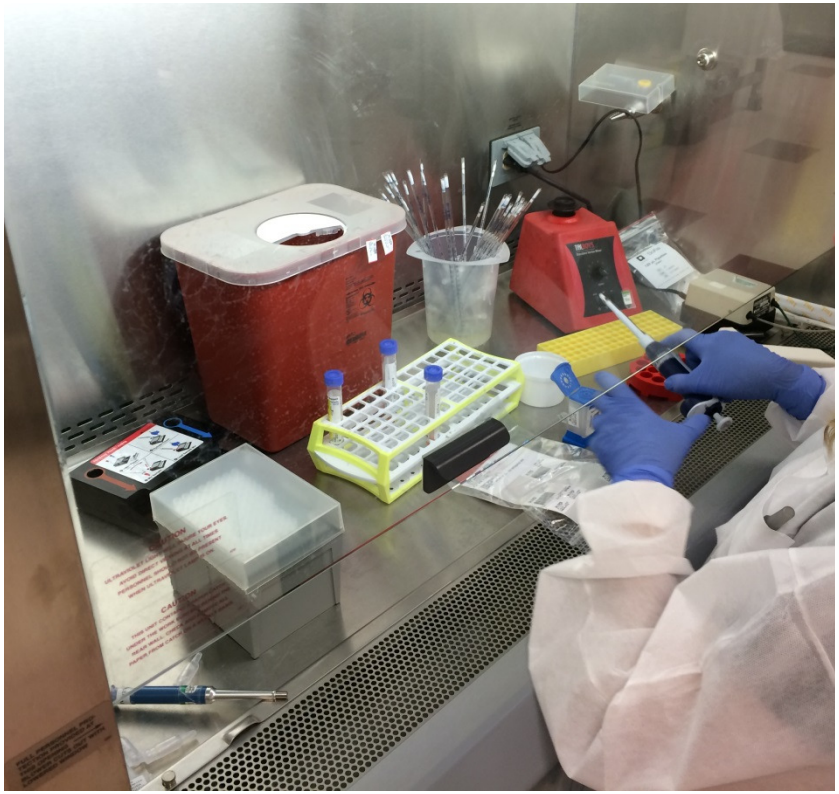
Definition:

Movement of people. Walking, hand and body movements & too many steps

Layout, work area, workstation design, manual processes, poor ergonomics, inventory placement, specimen staging, sharing tools, etc.

Example: Motion

- Manual pipette and workspace organization



Example: Motion

- Walking to supplies

Fixed, Large Storage

Movable, Modular

Layout

- Layout can have the greatest impact on molecular workflow
- How do you determine the best layout?
- Lean tools that help identify layout opportunities

Spaghetti Diagrams

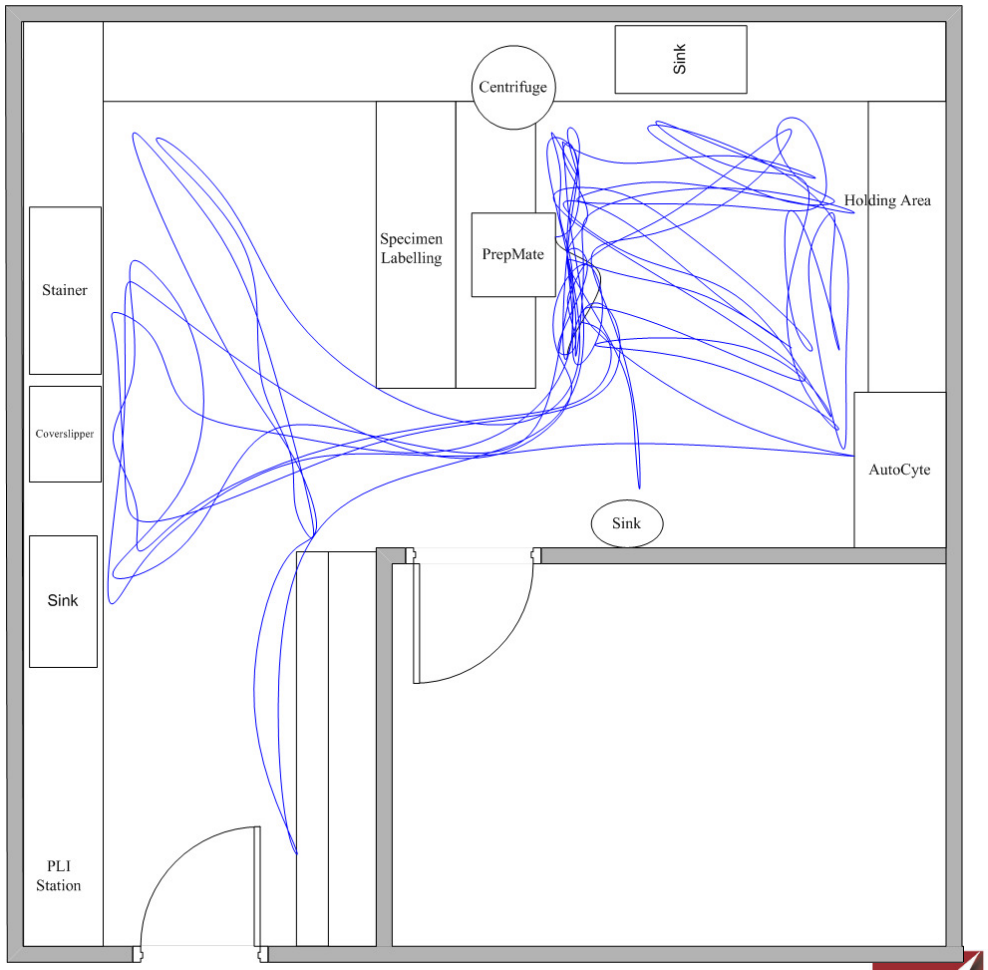
- Create spaghetti diagrams to capture the true impact of the current layout and travel
- Focus on the process steps and location of materials
- Follow lab personnel and draw a continuous line everywhere they travel to complete a task
- Or, follow a specimen through the entire testing process

Example: Travel

This is a laboratory layout that demonstrates excessive travel

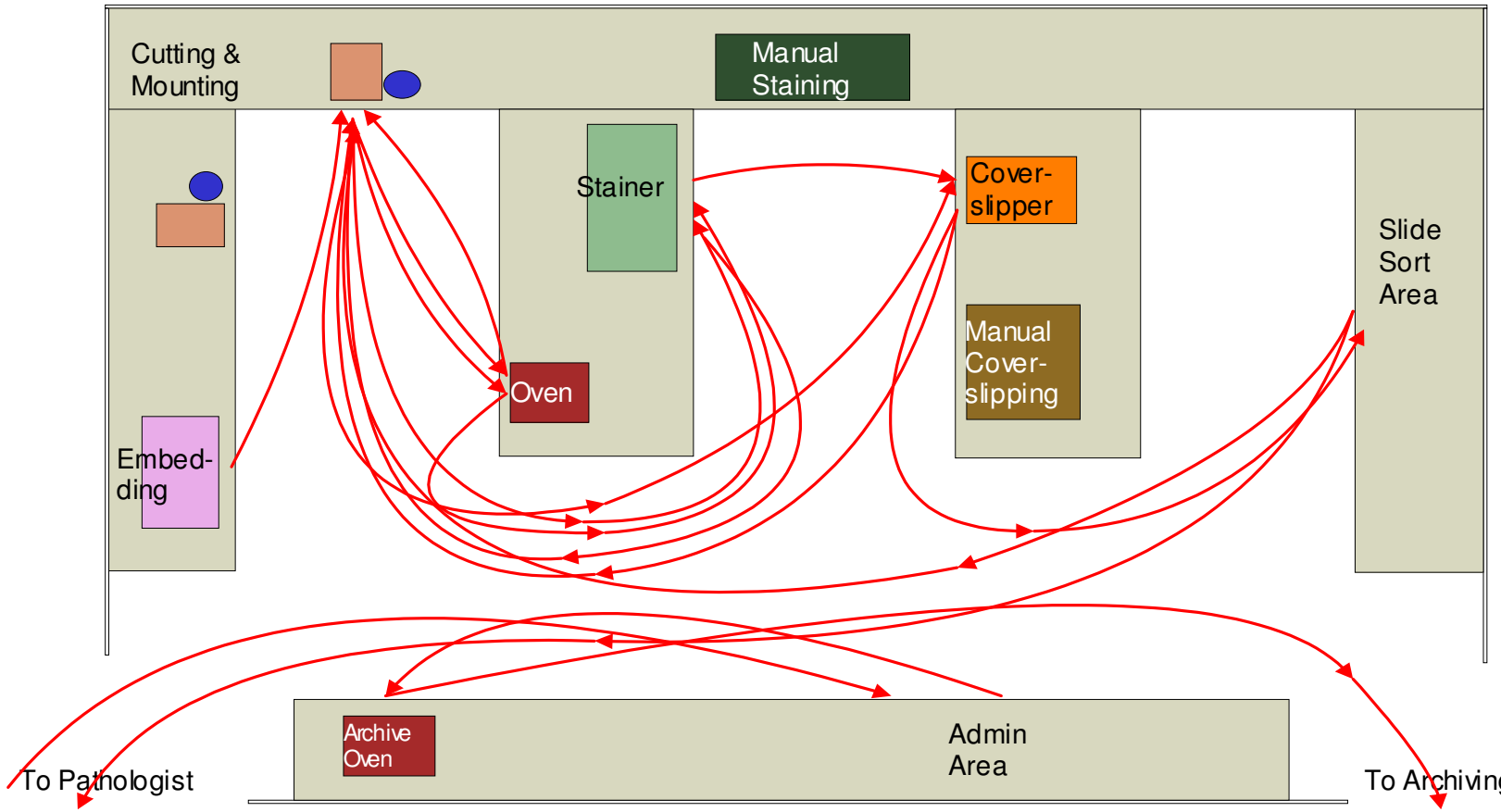
Spaghetti Diagram is a tool that shows the flow of people or specimens

This is one person's motion in a 30 min. period



Spaghetti Diagram Example

Personnel Flow



Molecular ASR Example

Process Flow

C. diff Example

Process

Flow

What Did We See?

- Recognize the limitations of contamination control
  - Multi-room, dedicated cabinets
  - What is necessary and what is over-caution
- Need to reduce travel
- Create work cells around cabinets
  - Placement of refrigerators, freezers, supplies
- LIS placement is important
  - Many systems are not interfaced

Resource Matrix

- A tool used in Lean Mfg to set up equipment and materials for work cells and product lines
- The object is to identify what key items are shared by each product line
- In the lab, the product lines are the tests or protocols that are performed
- List the tests by frequency or volume and then use the matrix to ensure that key items are placed properly to support testing

Sample Resource Matrix

Equipment	Tests			
	Test A	Test B	Test C	Test D
Workbench A	X		X	
Workbench B		X		X
LIS Station	X	X	X	X
Centrifuge	X		X	X
Vortex		X		
Pipette Station	X		X	X
Hood	X	X		
Refrigerator 1		X	X	
Refrigerator 2				X
Freezer	X			
Instrument A	X			X
Instrument B		X		
Instrument C			X	

Resource Matrix

Outcomes

- Develop a clear picture of what is needed for each test
- Identifies equipment that is shared and most used
- Facilitate placement of equipment for higher-volume testing
- The ultimate goal to reduce travel distance and congestion

Layout Tips

- Too many benches and countertops can be inefficient
- Workbenches can create barriers and generally collect clutter. Keep benches to a minimum and keep them clean and organized
- Substitute carts for benches whenever possible; they are smaller and more flexible
- Maintain uni-directional flow and avoid backtracking
- Avoid bottlenecks, dead-ends and inaccessible areas

Layout Tips

- Don’t use the entire room for testing if it is not needed
- Create efficient work cells that use less space. Use excess space for administrative purposes, storage or future testing needs
- Cabinets and shelving should be open with no doors. Open cabinets are easier to maintain and organize. Moreover, visibility of supplies and tools will lead to efficiencies

Point Of Use Storage

- Storing supplies in an organized fashion at the work location
- Right-levels and visual identification is important
- Reduces travel, motion and improves space utilization

5S System

5S: Workplace Organization & Standardization

- Used to create organized, clean and functional work areas
- Used to control supplies and materials
- Create efficient workstations
- Facilitates standardization
- Reduces unused items

1. **SORT**
2. **SET IN ORDER**
3. **SHINE**
4. **STANDARDIZE**
5. **SUSTAIN**

5S in Molecular

Use 5S for:

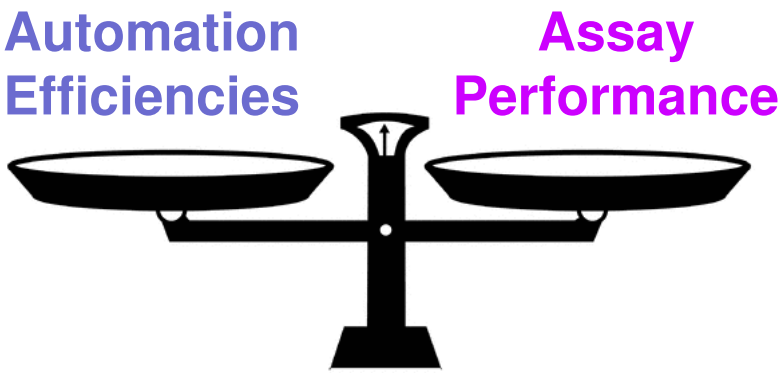
- Organizing incoming specimen refrigerators. Implement visual controls and labeling
- Organize the location of consumables and tools for bio-cabinets - Increase efficiency.
- Establish locations and quantities of Point of Use Storage (POUS)
- Reduce clutter and unnecessary items in the lab
- Create free space

Automation

- More tests move to automation
- Menu consolidation
- More “direct” tests
- Reagent kits – less prep, ready to use

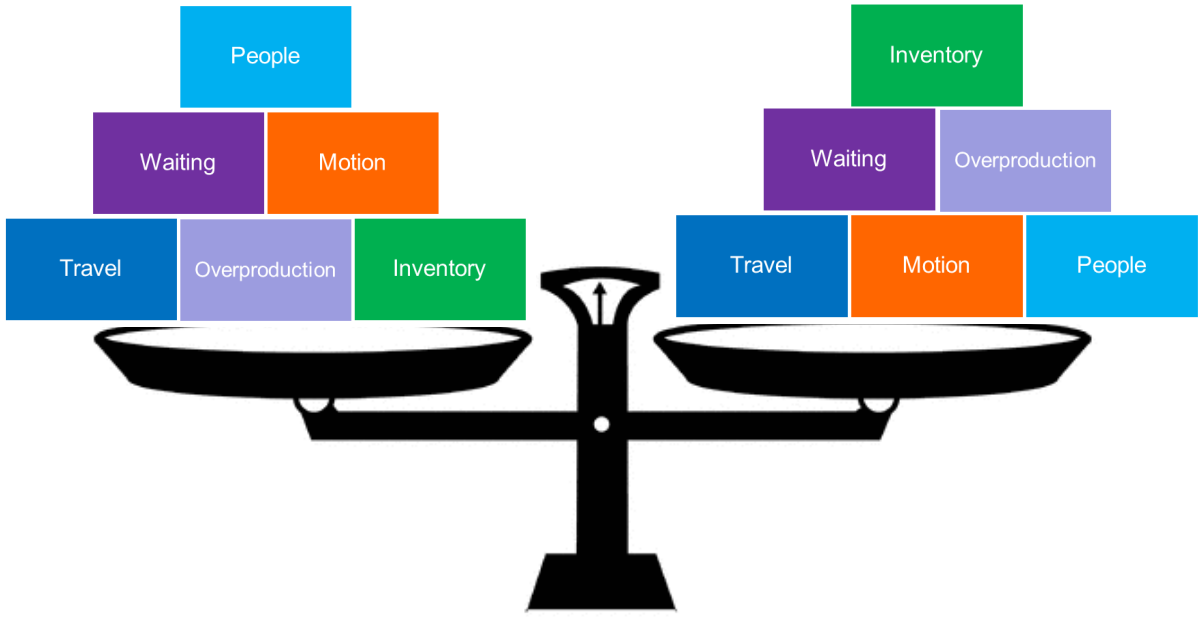
Automation

- There is a lot of workflow efficiencies to be gained from automation in molecular
- Labs will constantly need to weigh assay performance to the efficiencies



Conclusions

- Molecular is a dynamic area with great opportunity for efficiency. Understand where your opportunities lie and weigh your outcomes



Thought for the Day

Remember…

"Learning is not compulsory, neither is survival"

- W. Edwards Deming

End of presentation

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