

March 20–23 | Indian Wells, CA

PCRS 2024

INNOVATION AND INTEGRATION

THE FUTURE OF REPRODUCTIVE MEDICINE

Disclosures

Neither I nor members of my immediate family have any actual or potential financial interests to disclose relating to the content of this presentation.

Troubleshooting in the IVF lab: Why we should go beyond the basics

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Needs Assessment Statement and Expected Learning Outcomes

The dynamic and complex nature of assisted reproductive technologies, which are constantly changing, requires laboratory leaders to maintain and a comprehensive understanding of common challenges and effective troubleshooting strategies.

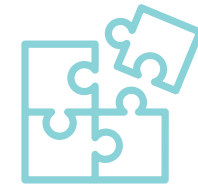
Expected Learning Outcomes:



- 1 Identify how to interpret lab performance data and identify “brewing” problems



- 2 Evaluate troubleshooting tool kit to correct, communicate, and collaborate effective solutions.



- 3 Integrate new strategies and performance indicators into a routine QA program with the goal of optimizing lab performance and culture.

Lab Troubleshooting Agenda

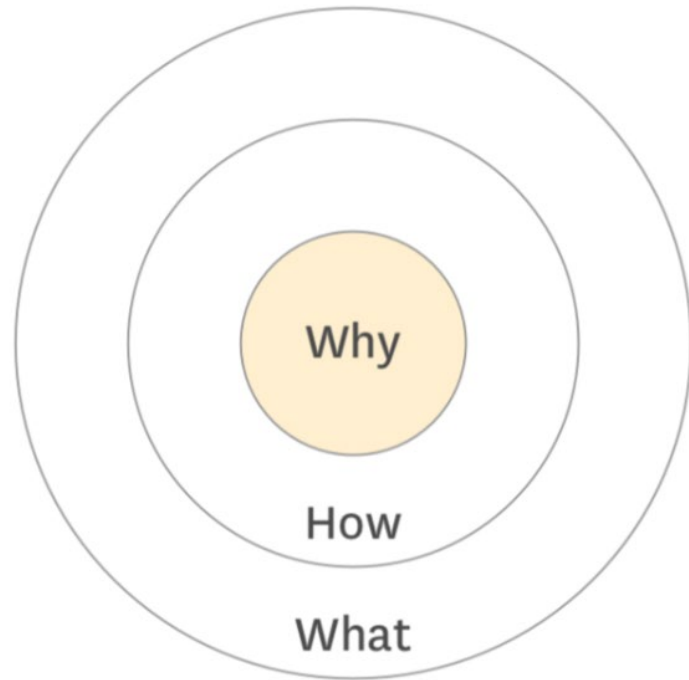
01 Troubleshooting basics

WHY? HOW? WHAT?

02 Traditional lab KPIs

03 KPIs for leadership and teams

Why How What?



WHY = Why do you look at KPIs? Why do you troubleshoot?

How = the processes and actions we take to hold ourselves and each other accountable. How do we analyze KPIs?

What = the tangible proof of the why, the results. What should the KPIs be and tell us?

Start with WHY

WHY look at KPIs? Why troubleshoot?

Our commitment to:



Patients



Safety



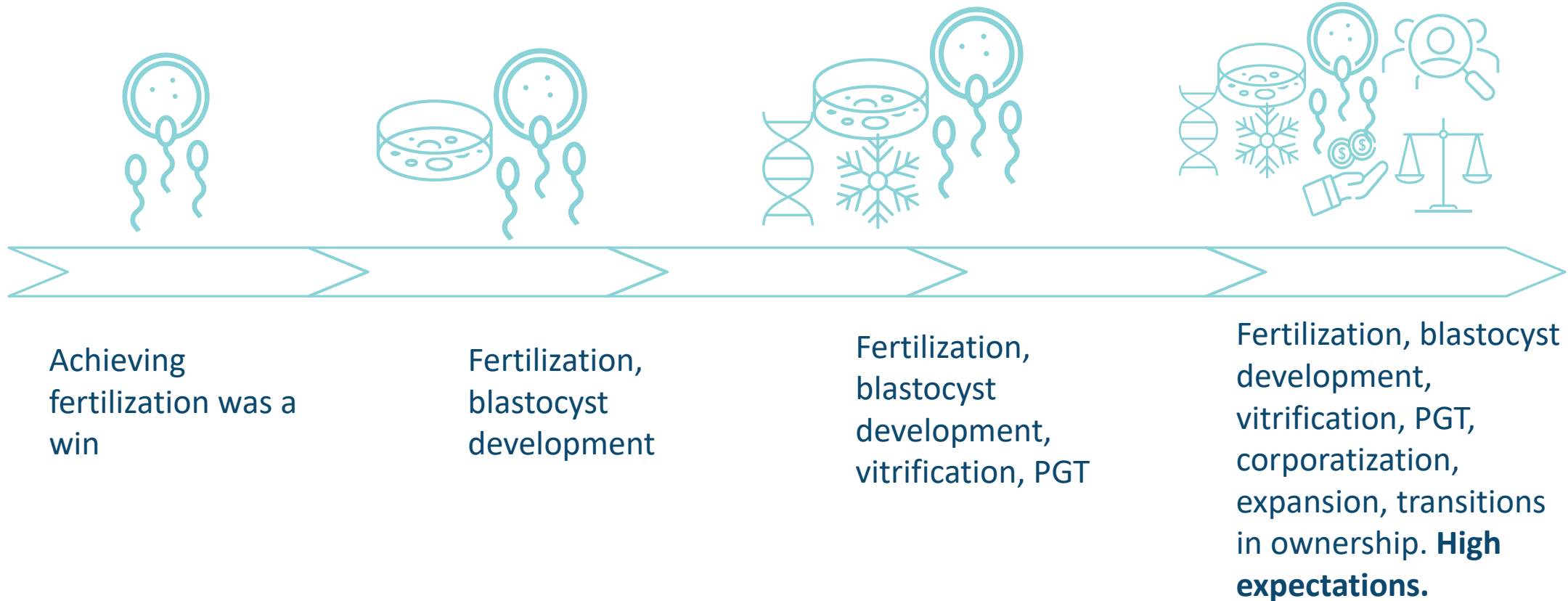
Lab staff



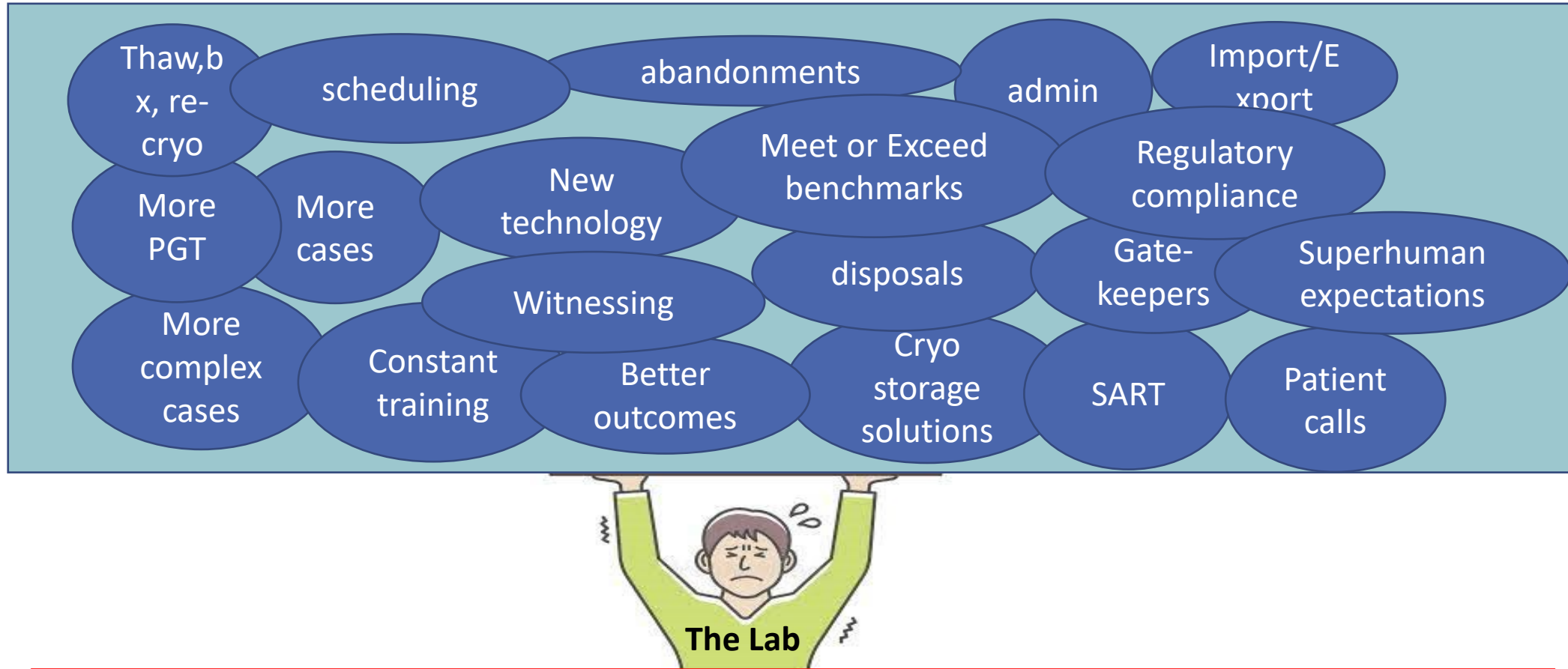
Always doing better



“Knowing better” is not as simple as it used to be

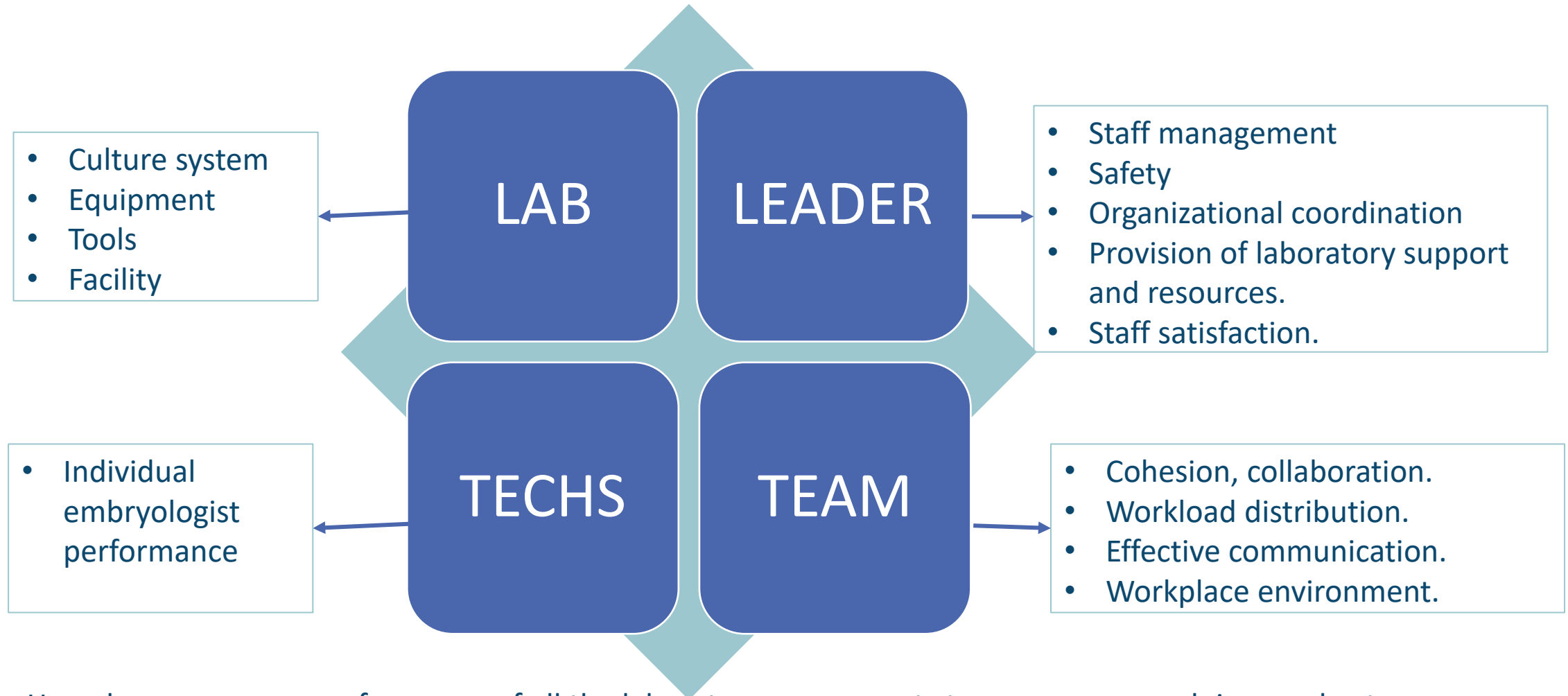


Expectations of today's ART lab



More and more factors to consider when assessing lab performance and troubleshooting

Components of laboratory performance



How do we measure performance of all the laboratory components to ensure we are doing our best and considering all variables?

Key Performance Indicators – the How to our Why



What are KPIs?

- Key performance indicators
- Top priority metrics that are analyzed as a reflection and measure of the overall performance of the lab.
- Specific, measurable, attainable, relevant, and time based



KPIs of laboratory performance

Human Reproduction Open, pp. 1–17, 2017
doi:10.1093/hropen/hox011

human
reproduction
open

ESHRE PAGES

The Vienna consensus: report of an expert meeting on the development of art laboratory performance indicators^{†‡}

ESHRE Special Interest Group of Embryology^{1,*} and Alpha Scientists in Reproductive Medicine^{2,*}

¹European Society of Human Reproduction and Embryology, Meerstraat 60, B-1852 Grimbergen, Belgium ²ALPHA Scientists in Reproductive Medicine, 19 Mayıs Mah. 19 Mayıs Cad. Nova Baran Center No:4 34360 Sisli, Istanbul, Turkey

Choose top 5

- Fertilization rate – ICSI and SI
- Blastocyst **utilization** rate – Day 5 and total
- ICSI degeneration rate
- Cryosurvival rate
- PGT read rate

Performance indicators for the ART laboratory

11

Table IV KPIs for the ART laboratory.

KPI	Calculation	Competency value (%)	Benchmark value (%)
ICSI damage rate	$\frac{\text{no. damaged or degenerated all oocytes injected}}{\text{no. oocytes injected}} \times 100$	≤10	≤5
ICSI normal fertilization rate	$\frac{\text{no. MII oocytes injected}}{\text{no. oocytes with 2PN and 2PB}} \times 100$	≥65	≥80
IVF normal fertilization rate	$\frac{\text{no. COCs inseminated}}{\text{no. oocytes with 2PN and 2PB}} \times 100$	≥60	≥75
Failed fertilization rate (IVF)	$\frac{\text{no. cycles with no evidence of fertilization}}{\text{no. of stimulated IVF cycles}} \times 100$	<5	
Cleavage rate	$\frac{\text{no. cleaved embryos Day 2}}{\text{no. 2PN/2PB oocytes on Day 1}} \times 100$	≥95	≥99
Day 2 Embryo development rate	$\frac{\text{no. 4-cell embryos on Day 2}}{\text{no. normally fertilized oocytes}^a} \times 100$	≥50	≥80
Day 3 Embryo development rate	$\frac{\text{no. eight cell embryos on Day 3}}{\text{no. normally fertilized oocytes}^a} \times 100$	≥45	≥70
Blastocyst development rate	$\frac{\text{no. blastocysts Day 5}}{\text{no. normally fertilized oocytes}^a} \times 100$	≥40	≥60
Successful biopsy rate	$\frac{\text{no. biopsies with DNA detected}}{\text{no. biopsies performed}} \times 100$	≥90	≥95
Blastocyst cryosurvival rate	$\frac{\text{no. blastocysts appearing intact}}{\text{no. blastocysts warmed}} \times 100$	≥90	≥99
Implantation rate (cleavage-stage) ^b	$\frac{\text{no. sacs seen on ultrasound}^c}{\text{no. embryos transferred}} \times 100$	≥25	≥35
Implantation rate (blastocyst-stage) ^b	$\frac{\text{no. sacs seen on ultrasound}^c}{\text{no. blastocysts transferred}} \times 100$	≥35	≥60

^aDefined as oocytes with 2PN and 2PB on Day 1.

^bBased on total number of embryos transferred to *all* patients in the reference group, not just those for whom an implantation occurred.

^cDefinition reached after discussion, as some felt that no. fetal hearts / no. embryos transferred was a more meaningful indicator.

KPI, key performance indicator.

Top 5 KPIs of laboratory performance

	S Specific	M Measurable	A Attainable	R Relevant	T Time-based
Fertilization rate	ICSI vs. Standard	#2PN/injected #2PN/insem	70-80% 60-70%	Technique culture system	Weekly, monthly
ICSI deg rate	% of injected eggs that degenerate	#degenerated/ #injected	2-10%	Technique, equipment	Weekly, monthly
Blastocyst utilization rate	% of blasts transferred and frozen	# utilized blasts/ #2PN	30-60%	Culture system	Monthly
Thaw survival rate	% oocytes, embryos surviving thaw	# survived/ # thawed	90-100%	Technique, equipment	Weekly, monthly
PGT read rate	% biopsied embryos with a PGT result	#embryos with result/ #embryos biopsied	95-98%	Technique	Monthly

Cadence and timing of KPI measurements

Fresh retrieval volume	Suggested frequency of KPI evals
< 30 cycles per month	Every 30 cases, quarterly, annually
30-80 cycles per month	Monthly, quarterly, annually
> 80 cycles per month	Weekly, monthly, quarterly, annually

Too frequent - not enough data, may be skewed by 1-2 patient variables.

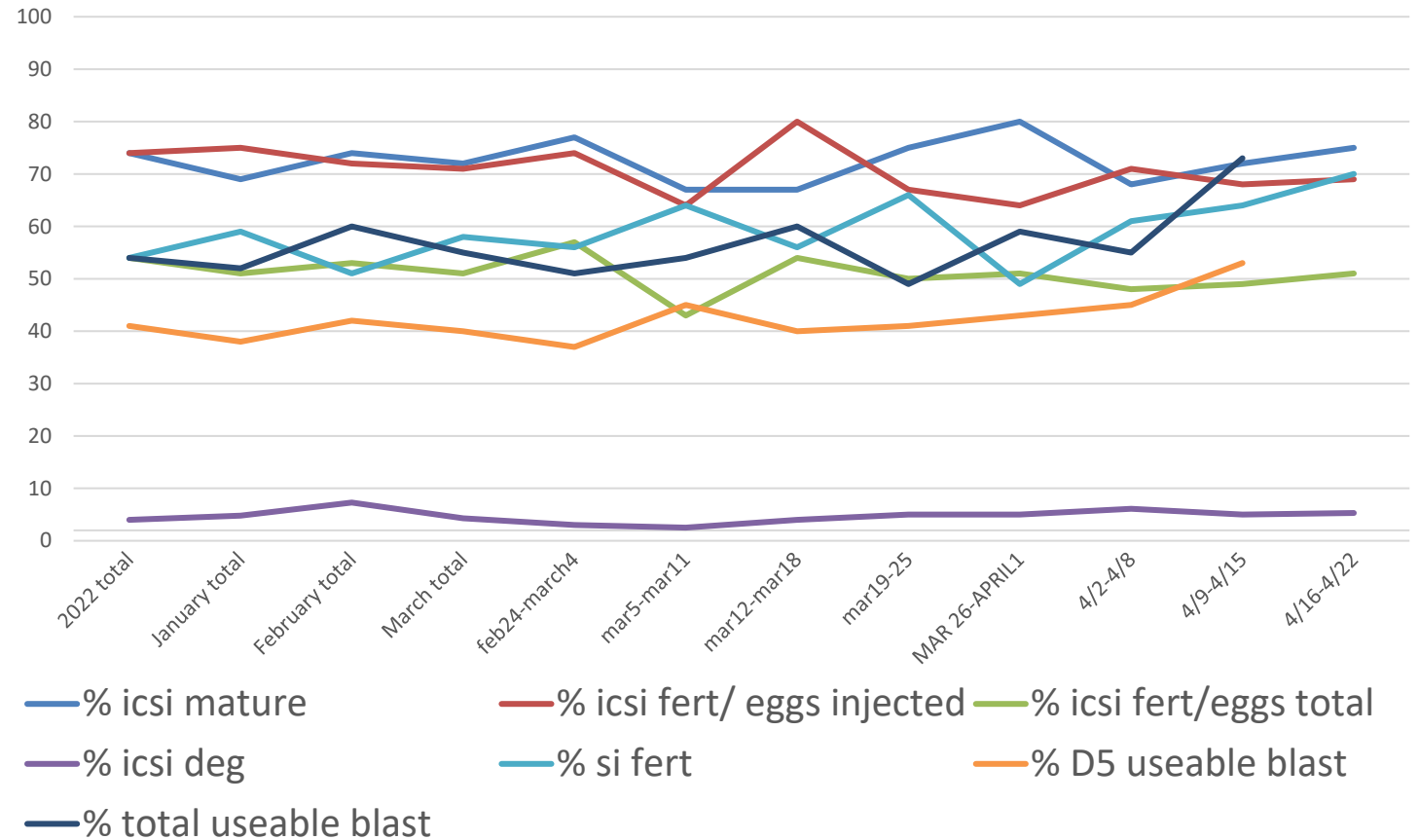
Not frequent enough - hard to troubleshoot the “damage is done”

Expert panel from Vienna consensus recommends KPIs are evaluated **monthly** or with an initial dataset of **30 cases**.

Weekly lab KPIs

Weekly Lab KPIs – example
ICSI maturity rate (#MII injected/#retrieved)
ICSI Fertilization rate (all 2pn/all injected)
ICSI deg rate (all deg/all injected)
Standard insemin fertilization rate (#2pn/#insemin)
Total useable blast rate* (#frozen+#transferred/#2PN)
D5 useable blast rate* (#frozen D5+transferred)/#2PN

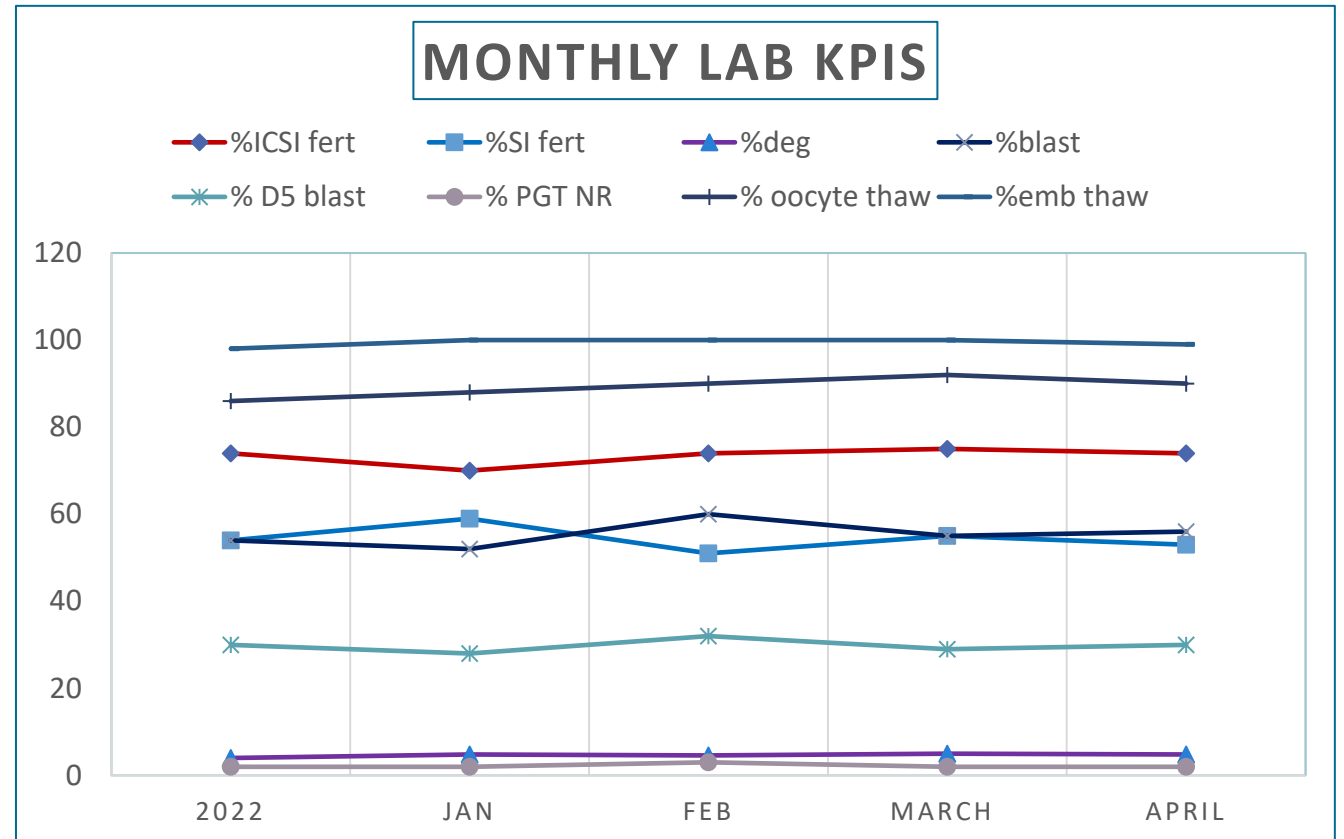
* Data added 1 week later



Used mostly to see trends and to reference for monthly troubleshooting
 Corrective actions minimal, mostly observational, discussion points

Monthly/quarterly/annual lab KPIs

Monthly/quarterly/annual KPI examples
% no eggs/no mature
% failed fert
% no blasts
% icsi mature
% icsi fert/ eggs injected
% icsi fert/eggs total
% icsi deg
% si fert
% D5 useable blast
% total useable blast
% biopsies with no results
% embryo survival
% oocyte survival

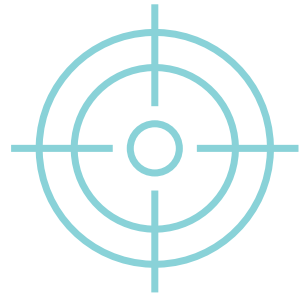


KPI Values – the What to our Why



KPI values – establishing standards and setting goals

For each KPI, there should be 2 parameters:



Competency Value

- Minimum acceptable standard
- Published guidelines good start – should not fall below



Benchmark Value

- Gold standard
- Your outcome goal for each KPI

IVF lab KPI competency and benchmark values

	Competency value	Benchmark goal
Fertilization - ICSI	70%	80%
Fertilization – standard	60%	70%
ICSI damage	<5%	<3%
Total blast utilization	40%	60%
D5 Blast utilization	30%	50%
Thaw survival	90%	99%
PGT read rate	95%	98%

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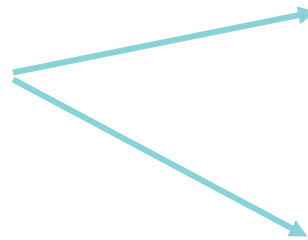
KPI, key performance indicator.

How do we determine our IVF lab competency and benchmark values ?



Look at your performance over time, establish mean, highs and lows.

Research and review published guidelines and data reported from peers and leaders



Determine competency values using your data; should not be lower than published guidelines



What are your peers and top performing clinics reporting?
Determine benchmarks based on your PR and external motivation

“Benchmarking is the best way to avoid complacency” David Mortimer

Analyzing KPIs

Scenario 1: Values always stay between competency(acceptable) and benchmark(goal).

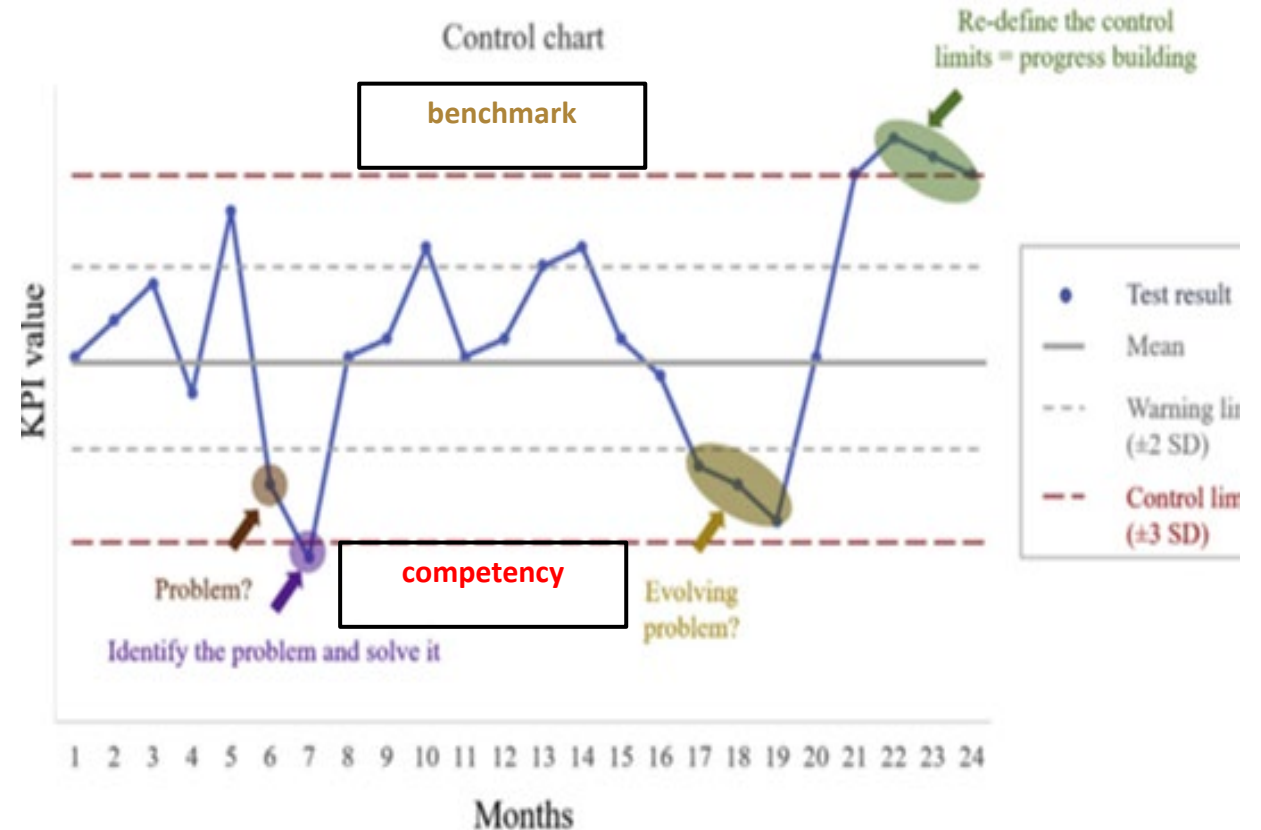
- Acceptable but opportunity to tighten up and raise the bar? Especially if this goes on for long periods of times and improvements/upgrades have been made.

Scenario 2: A single drop (1 data point) is observed.

- Caution – start looking, do some detective work, but do not make any drastic changes.

Scenario 3 – Data from multiple measuring intervals shows a trend in the wrong direction, but still above competency or there is a severe drop.

- Start trouble shooting protocol

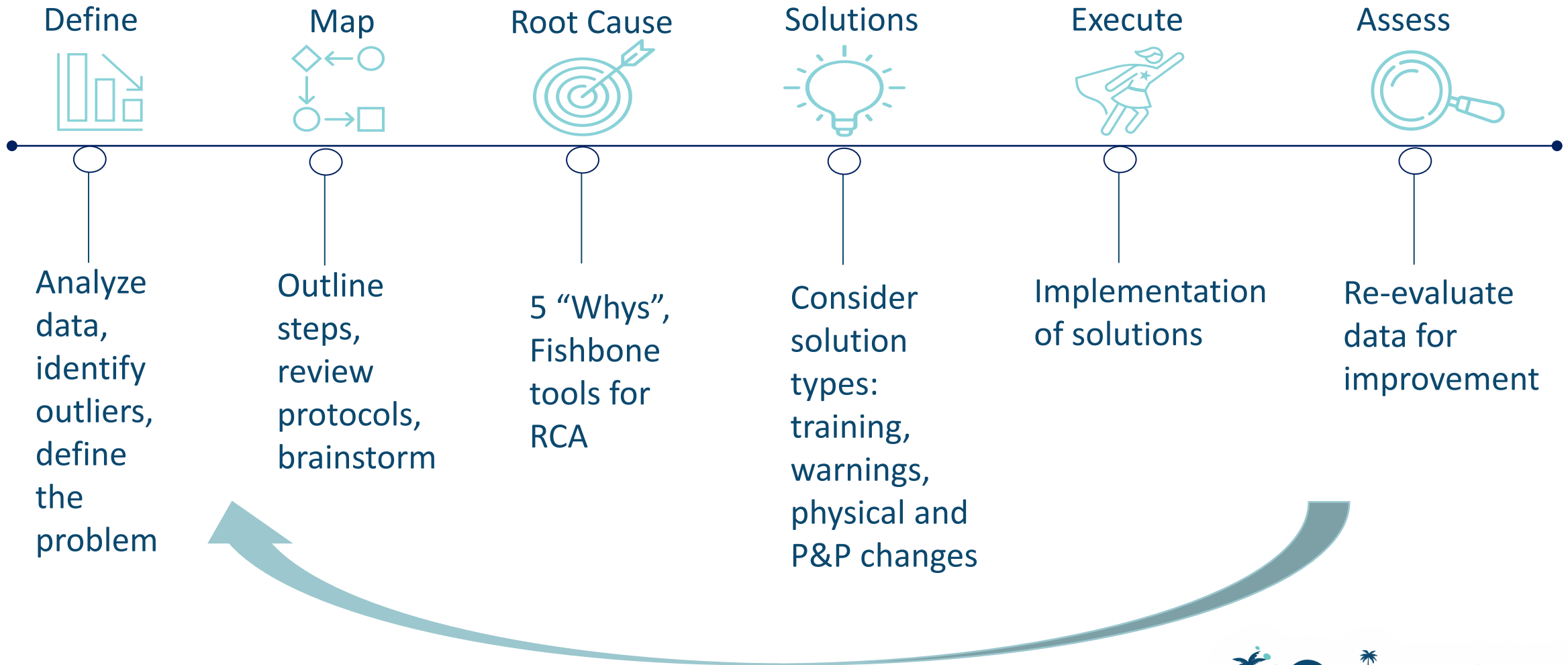


Representative scheme of a control chart and its use. KPI = key performance indicator; SD = standard deviation.

Fabozzi. KPIs in the ART laboratory. Fertil Steril 2020.

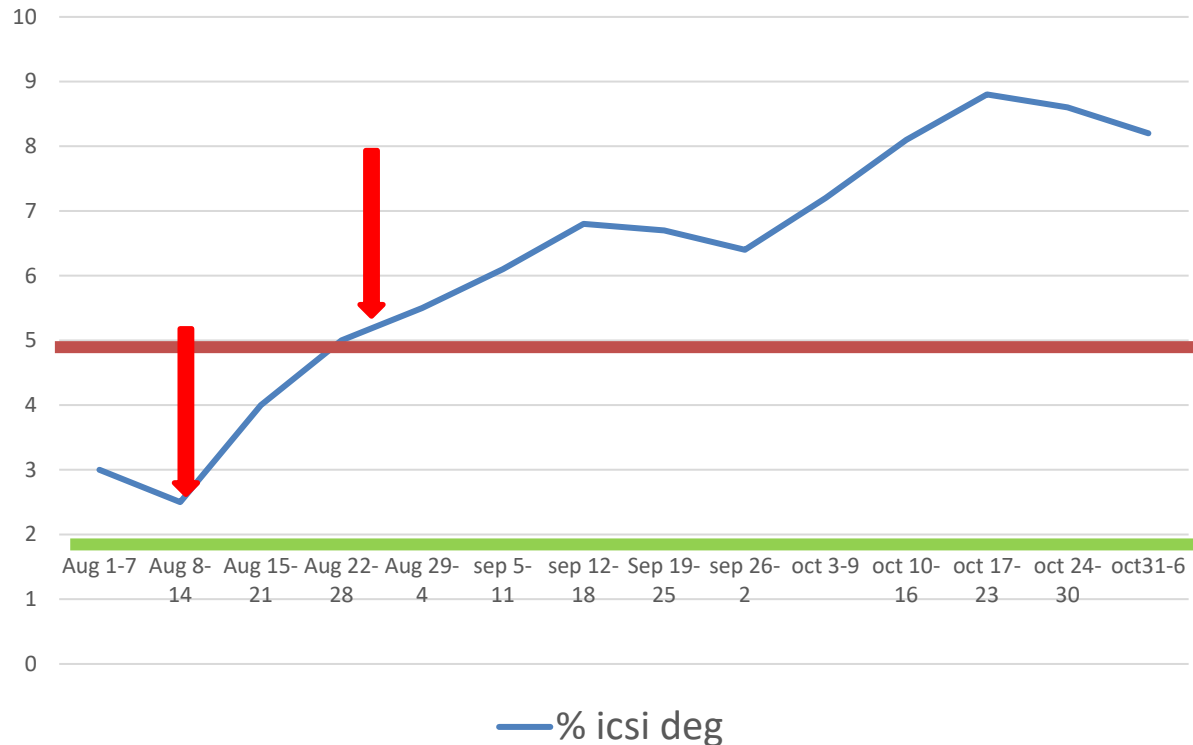
¹ Fabozzi, G., D. Cimadomo, R. Maggiulli, A. Vaiarelli, F. M. Ubaldi and L. Rienzi (2020). "Which key performance indicators are most effective in evaluating and managing an in vitro fertilization laboratory?" *Fertil Steril* **114**(1): 9-15.

Troubleshooting KPI data



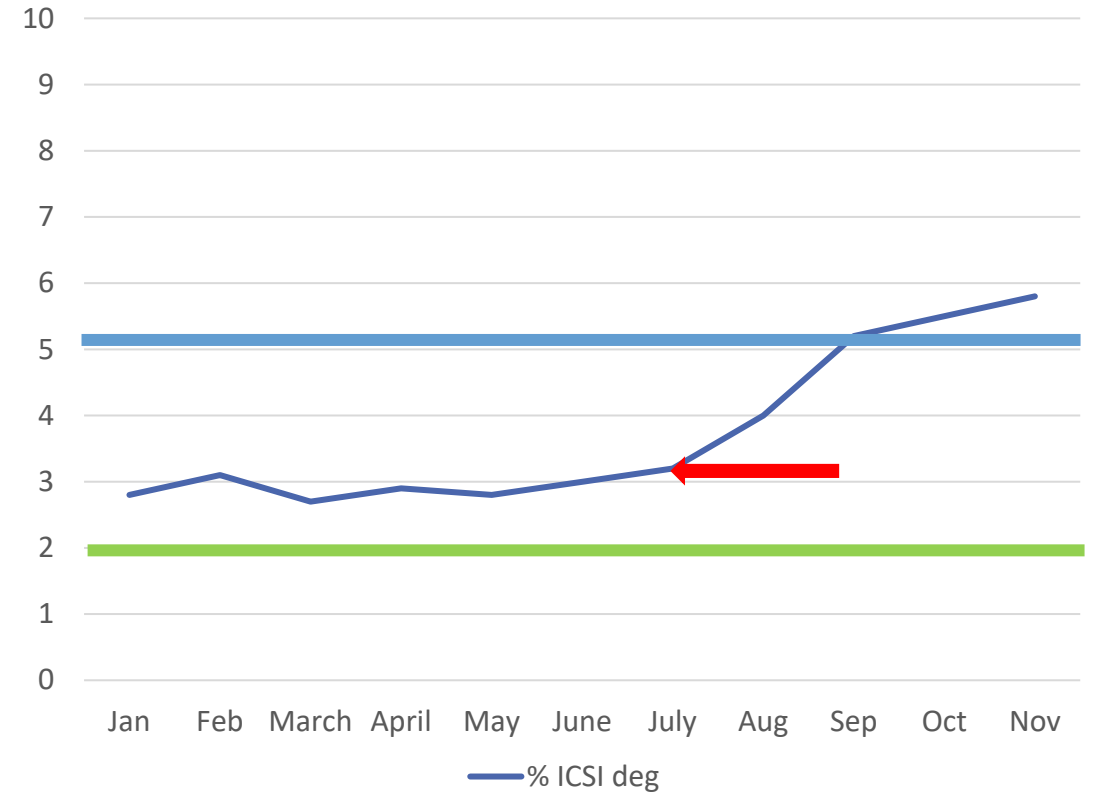
Real life problem: high ICSI deg rates

Weekly Lab KPIs - % ICSI deg



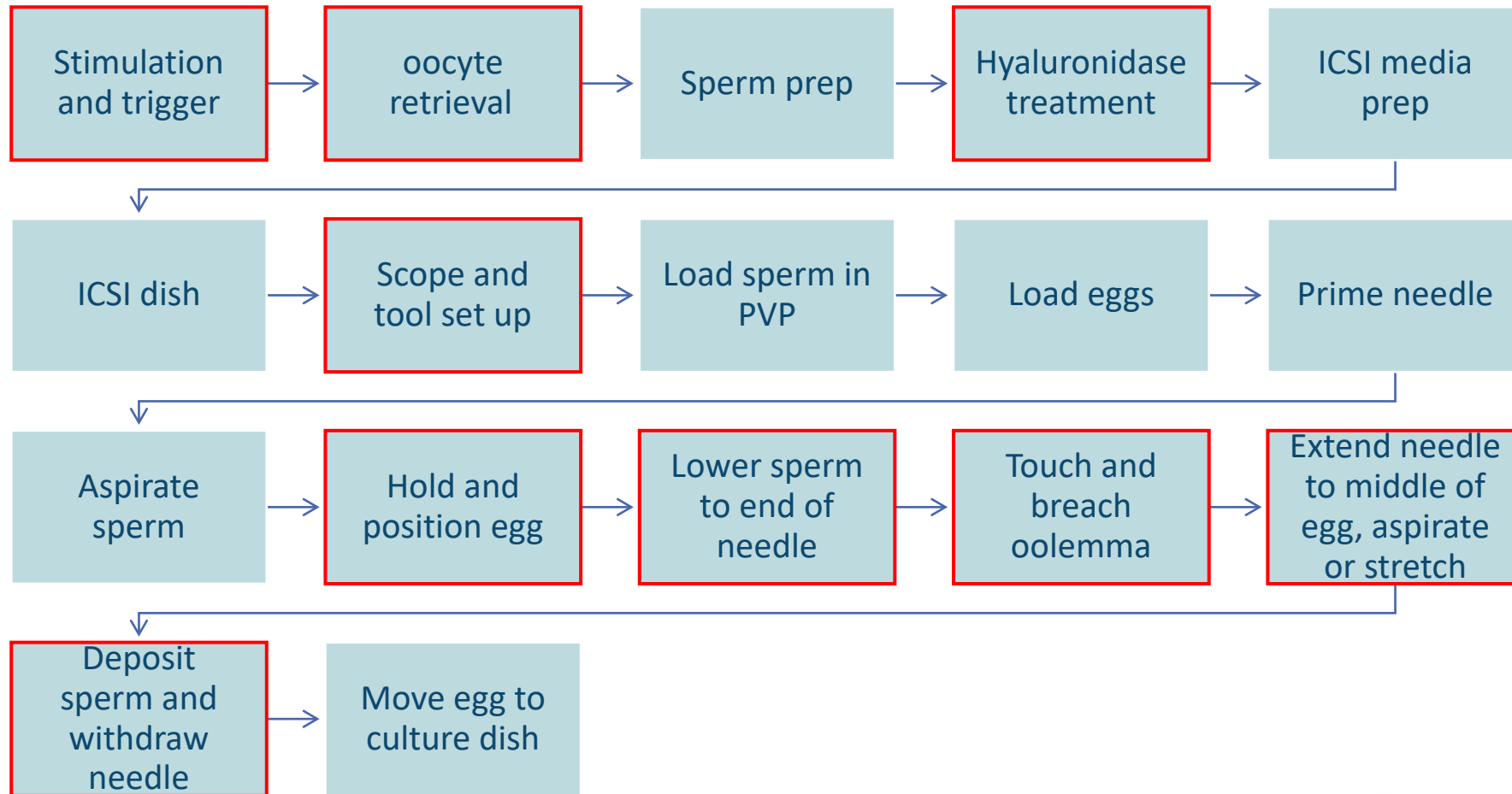
Starting in August of 2018 – Weekly and monthly KPI data showed upward climbing trend in deg rates.

% ICSI deg



Pregnancy outcomes and BUR remained high ICSI fertilization rates only slightly impacted.

Process map



Potential root causes and why

Stimulation and trigger

- Stim changes
- Length of stim

Oocyte retrieval

- Pump pressure
- MD technique
- Needles to trim cumulus

Hyaluronidase

- Diameter of stripper tip
- Technique
- Time in hyal

Scope and Tool Set up

- Vibration
- Focal alignment
- Angle of tools
- Quality of needle tip
- Injector control

Hold and position egg

- Suction pressure
- Pb position
- Position relative to bottom of dish

Breach zona and advance pipette

- Focal plane
- Funnel visualized

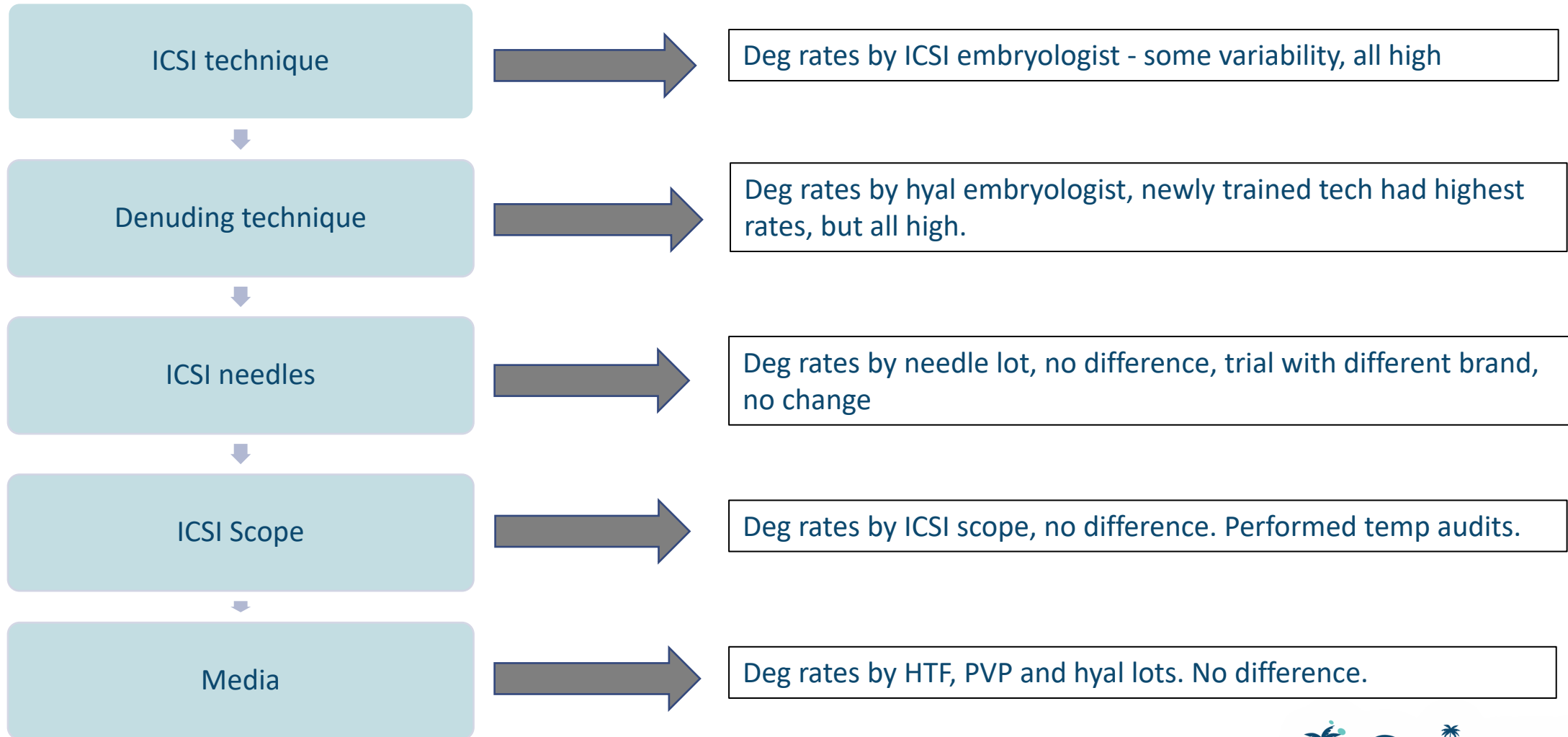
Break oolemma and deposit sperm

- Aspiration vs stretching
- PVP in cyto
- Cytoplasm leaking?

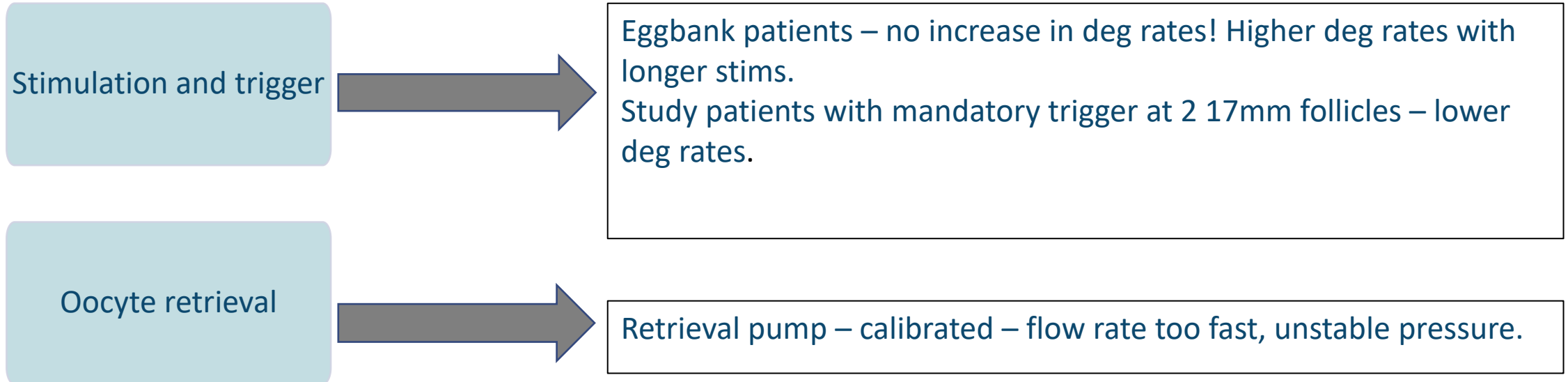
withdraw pipette, release egg and return to culture

- Diameter of stripper tip

Troubleshooting ICSI deg rates – usual suspects



Troubleshooting ICSI deg rates - not the lab?!



Troubleshooting ICSI deg rates

No “smoking gun”

Identified Source	Corrective Action	Follow-up post Implementation	Lessons learned
Newly trained embryologist – denuding technique	Re-training, started back by splitting large cases, monthly review; review of shear stress.	Individual deg rates improved. Overall rates remained high.	Track outcomes of new trainees <u>monthly</u> for the first 6 months.
Stimulation/day of trigger (research patients with “mandatory” trigger criteria had no increase in deg rates.)	“Updated” protocol re: triggering with 17mm follicles for most stims.	Temporary decrease in average stim length, technical drift still a problem; but minimal impact on overall deg rates.	Protocols are not always followed. Drift is real..
Old/faulty VOR pump	Replaced (and purchased new back-up). Implemented quarterly flow checks of pump and annual PM/calibration.	After 1 month post install, positive trend downward, rates stabilized around 3% after 2 months.	We can’t work in a silo. Investigate for yourself Be involved in anything that impacts the lab (which is almost everything).

Lab KPIs- beyond the basics



Beyond the basics - start with WHY

Why go beyond the basics?

Our commitment to:



Patients



Safety



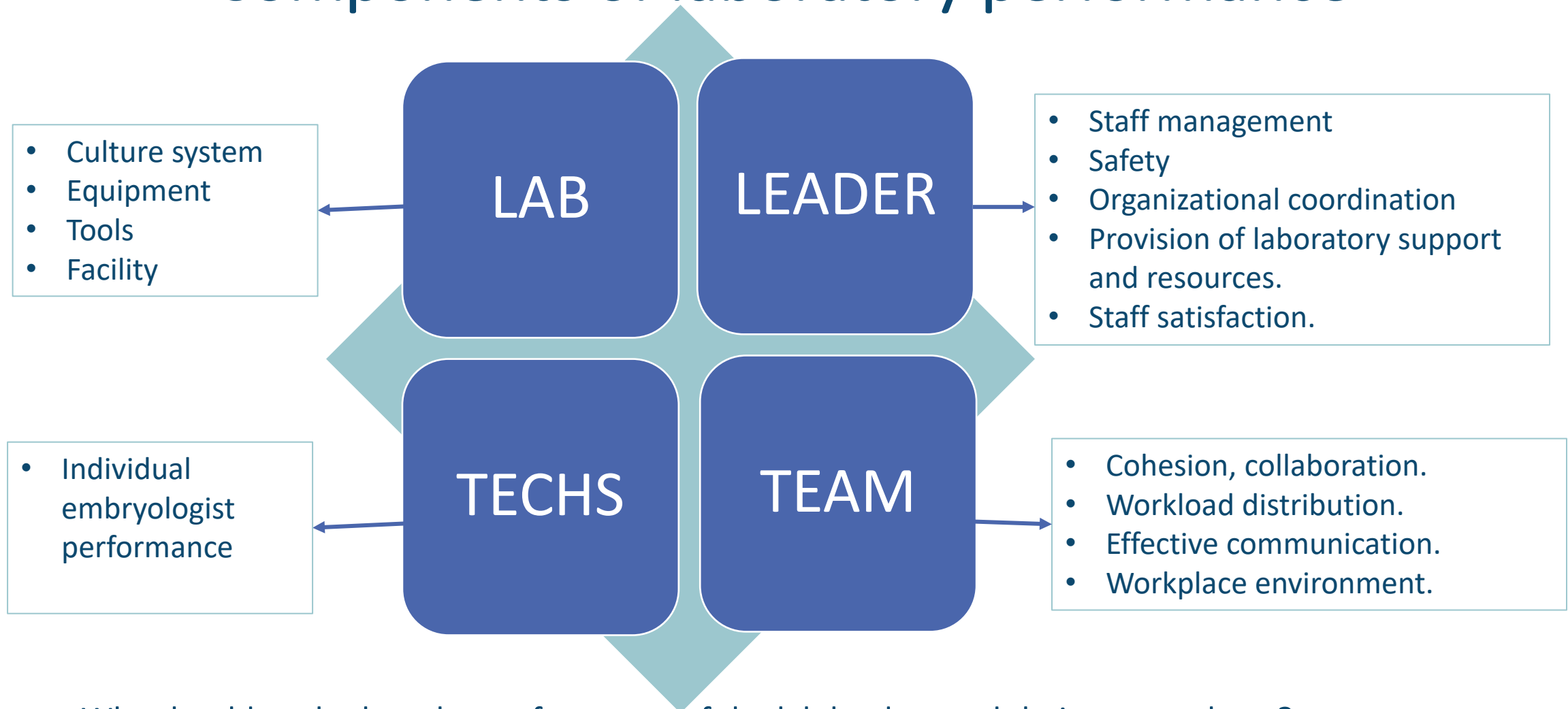
Lab staff



Always doing better



Components of laboratory performance



Why should we look at the performance of the lab leaders and their team culture?

Why assess leadership and team performance?



Leadership is at the core of overall laboratory performance



Strong leadership creates happy, successful high functioning teams.



Poor leadership has been attributed to high turnover rates, staff burnout, and increased vulnerability to lab error and safety risks.



Assessing and troubleshooting leadership and team performance is subjective and challenging.

But not impossible

How do we measure leadership?

Successful Leadership ¹		
Lead by example	Continual learning	Strong communication skills
Demonstrates integrity	Builds and maintains trust	Make hard decisions
Grace under fire	Recognizes success	Empowers and inspires others



Successful Teams ²	
Defined goals, everyone aware, shared vision	Clearly assigned roles and responsibilities
Clear and open communication	Trust
Conflict resolution	Strong outcomes

Poor team performance ¹	
Communication failures/issues and conflict	Difficult employees
Decreased productivity	Low morale/poor engagement
Increased error rate, lax safety adherence	High turnover/"quit" but don't leave

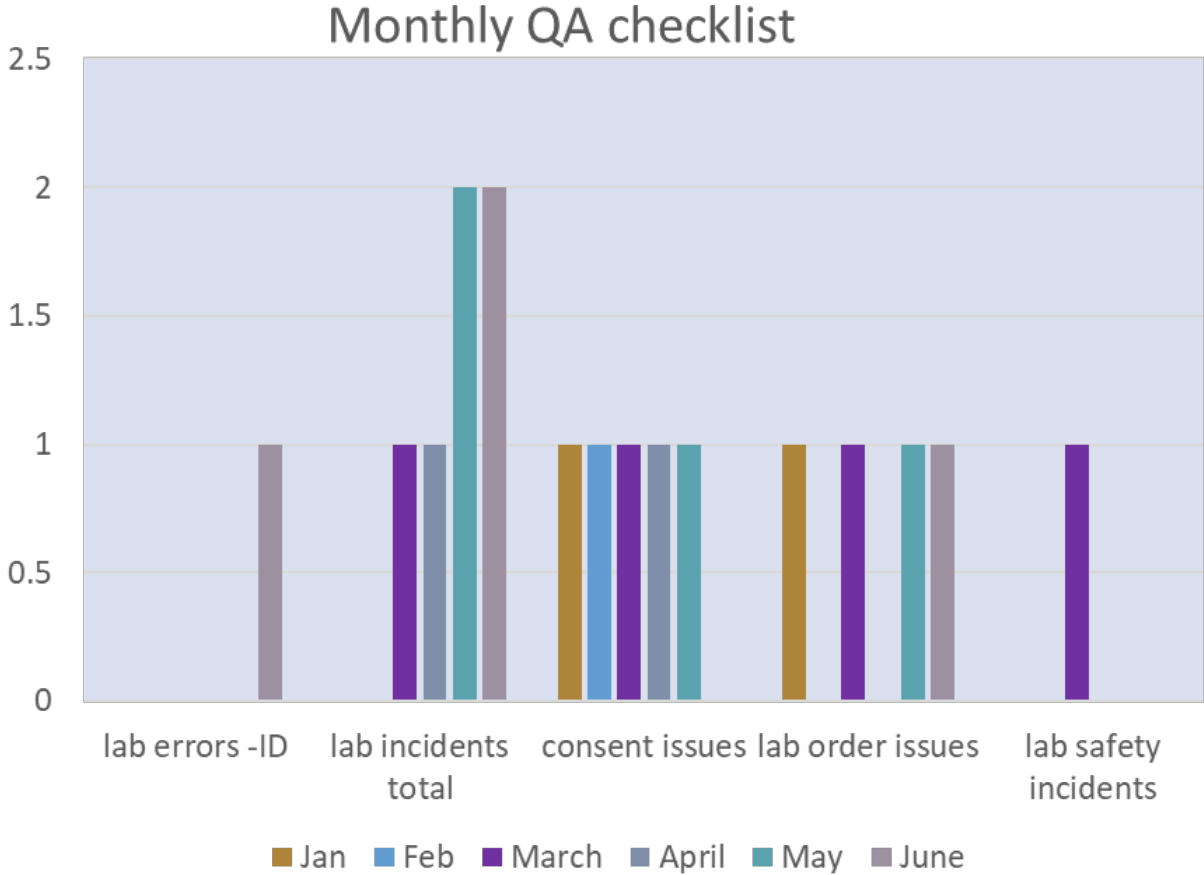
Look at the performance of the team

¹Sinek, S. (2014). *Leaders eat last: Why some teams pull together and others don't*, Penguin.

² <https://www.indeed.com/career-advice/career-development/characteristics-of-effective-teams>

Team performance - QA checklist

Item	#	Goal	Comments/ Corrections
Incident reports - total		0	
Incidents involving sample or patient ID		0	
Incidents involving communication failures		0	
Safety related incidents		0	
Missing consents/ orders		0	



Team performance - satisfaction surveys

CARS lab Staff Satisfaction Survey

Please rate your level of satisfaction with the following aspects of your work at the IVF lab using the following scale:
1 = Very Dissatisfied 2 = Somewhat Dissatisfied 3 = Neither Satisfied nor Dissatisfied 4 = Somewhat Satisfied 5 = Very Satisfied

1. Communication with colleagues and management:

1
 2
 3
 4
 5

2. Training and development opportunities

1
 2
 3
 4
 5

3. How satisfied are you with the training and development opportunities provided by the laboratory?

1
 2
 3
 4
 5

4. Quality and appropriate amount of laboratory equipment and facilities:

1
 2
 3
 4
 5

Rate on scale of 1-5

Overall job satisfaction

Support for work-life balance:

Training and development opportunities

Communication with colleagues and management:

Availability of necessary supplies and materials:

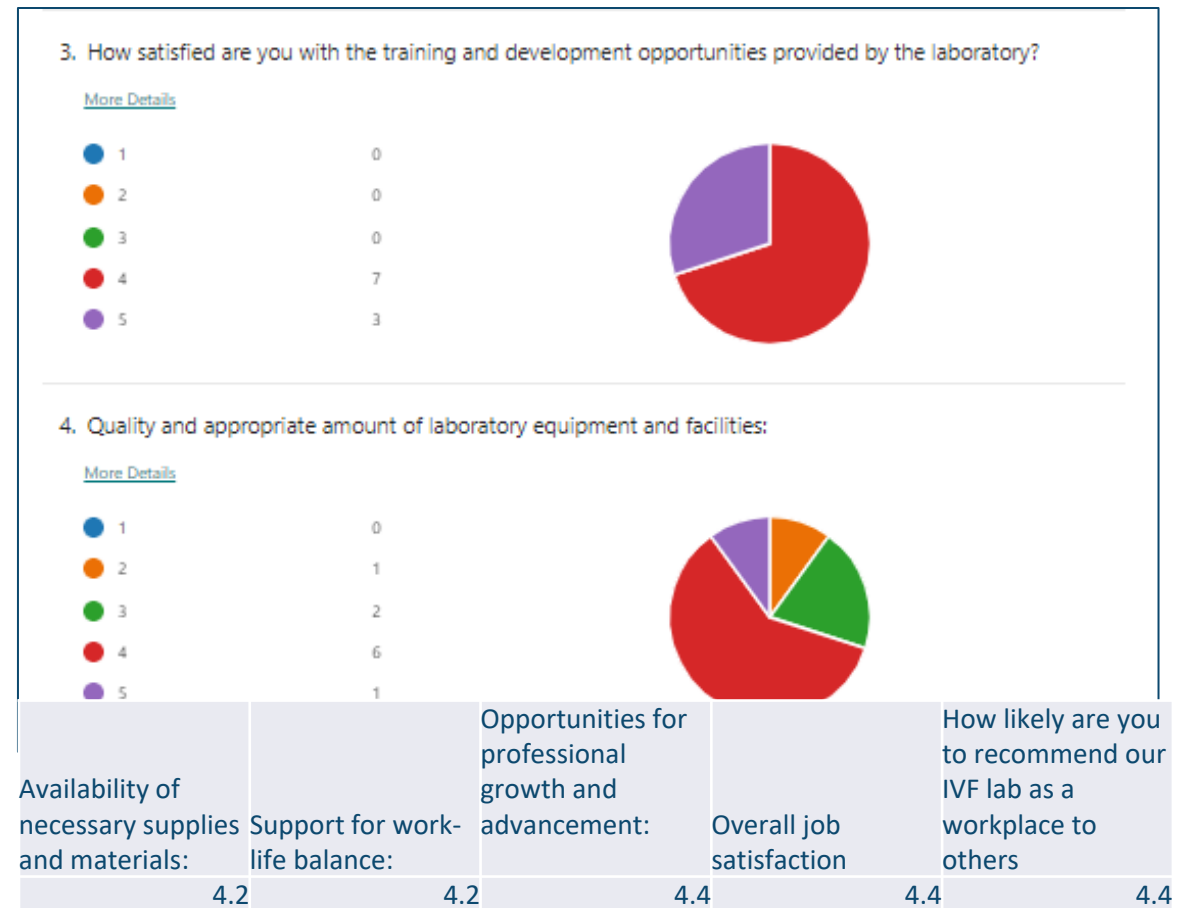
Opportunities for professional growth and advancement:

Quality and appropriate amount of laboratory equipment and facilities:

How likely are you to recommend our IVF lab as a workplace to others?

- Google or MS forms
- Use numerical scale to quantify for analysis
- Questions regarding and with insight into:
 - Leadership
 - Workplace environment
 - Scheduling
 - Task assignments
 - Continuing education
 - Professional development, etc.
 - Safety
 - Interpersonal issues/team morale

Staff surveys – data analysis



- Establish minimums and goals for average responses.
- Send results out to team with analysis/acknowledgement/actions.

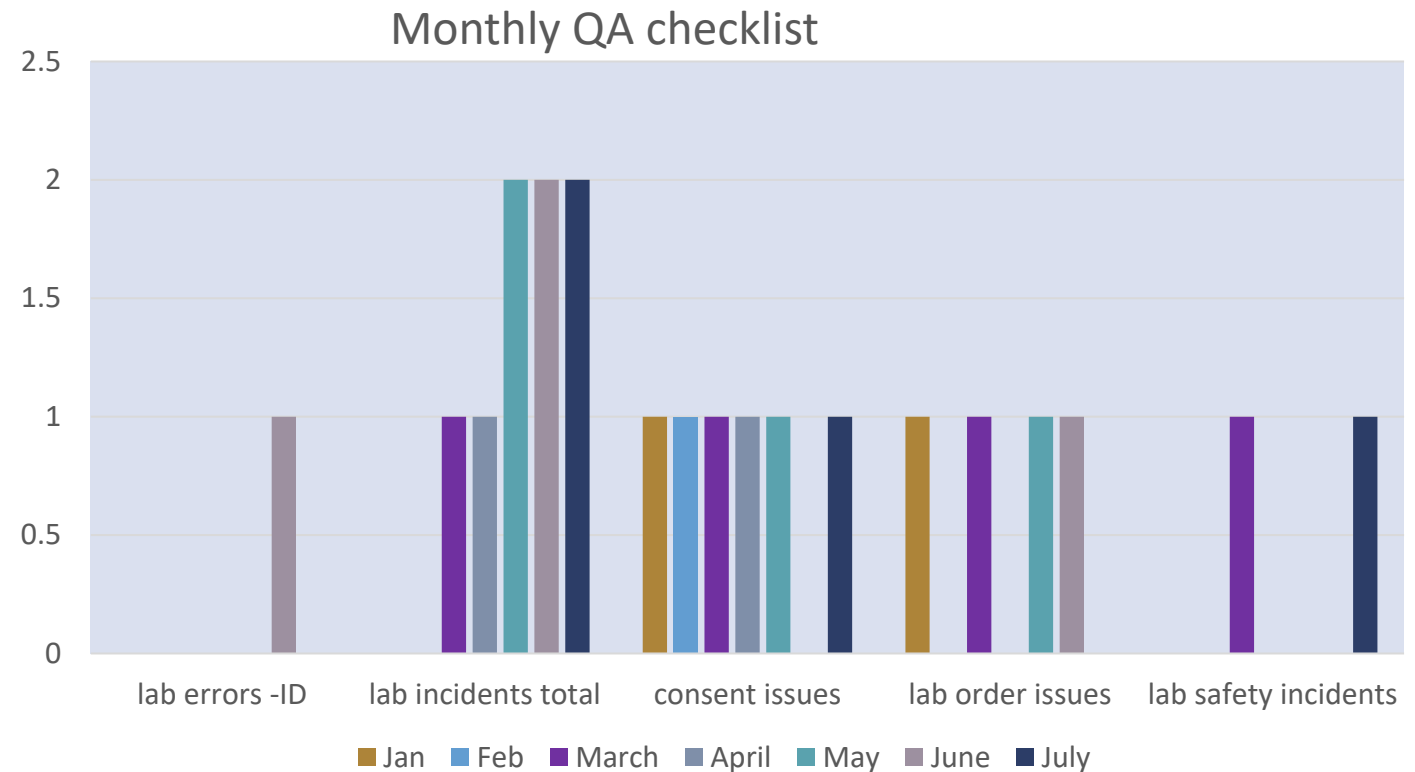
What are the benchmarks of leadership performance?

KPI	Acceptable	Benchmark goal	Cadence
Incident and error trends	Minimal incidents with proven effective corrective actions	No incidents or major lab errors	Monthly/Quarterly
Sufficient staff to support volume (metrics)	Adherence to 2022 ASRM staffing guidelines ¹ , always more than 1 embryologist. Per diem on hand/back up plan.	Acceptable metrics with administrative role/support + depth (1 extra) for crisis control/training pipeline.	Annual and/or quarterly depending on size of lab(s)
Training achievement	75% reaching proficiency goals	100%	
Staff development	≥ 1 per year where applicable (may include training up, specialty courses, etc.)		
Staff retention rates	Minimal turnover due to life changes, unrelated to lab culture or lack of advancement.		
Provision of resources to support growth/maintain performance	Incubators at capacity +1 extra Backup equipment	≤ 3 patients/incubator ≥ 3 micromanipulator/laser Bench space, computer/ FTE, innovation.	
Staff surveys	Steady/maintenance levels of response, no drastic drops.	Constantly high and improving scores.	

Real life problem: high number of lab errors

Spring/Summer 2017 – obvious trend and increase in lab errors

Item	#	Goal
Incident reports - total	2	0
Incidents involving sample or patient ID	1	0
Incidents involving communication failures		0
Safety related incidents	1	0
Missing consents/orders		0



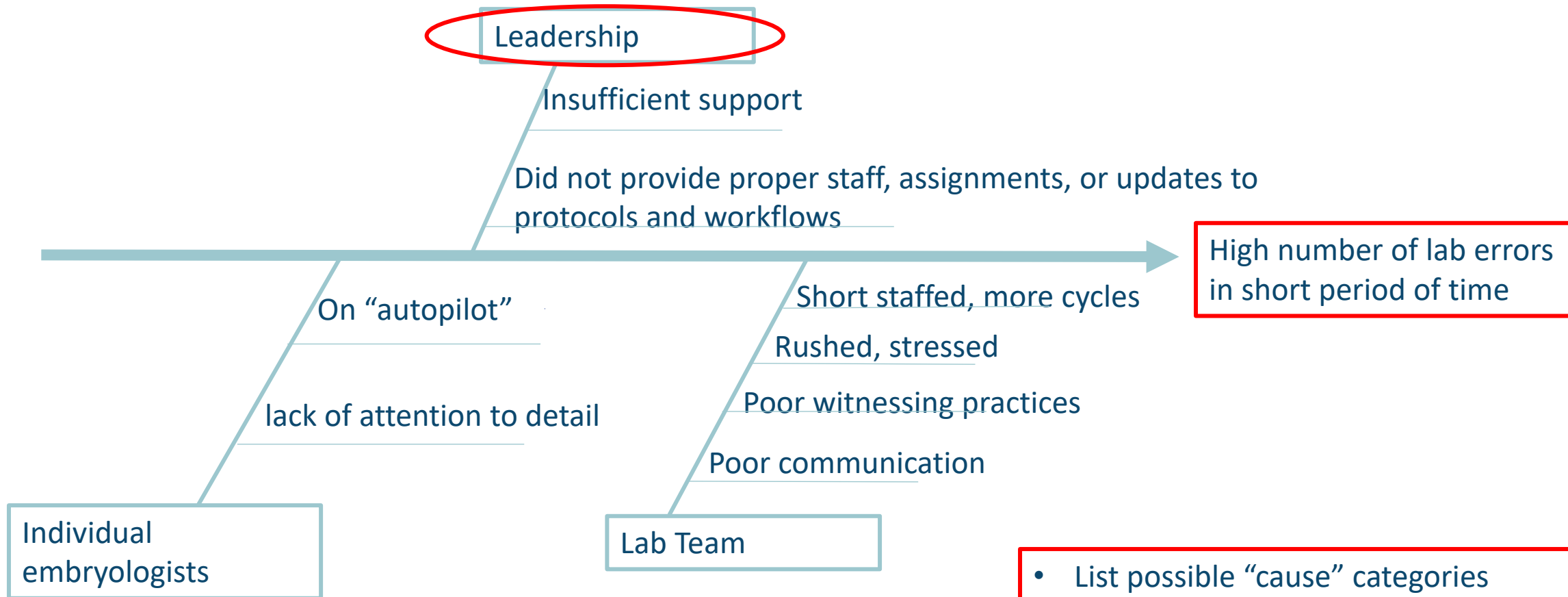
My Initial Approach



“We do not see you as the problem. We see you as part of the solution. You need to see yourself that way and go solve the problem.”

You may still be the problem – but the good news is you are also part of the solution. Be a part of the solution.

Root Cause Analysis – Fishbone



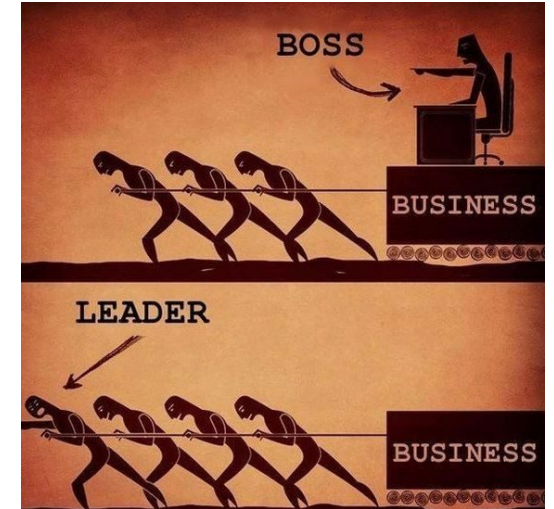
- List possible "cause" categories
- Ask "Why" and added branches.
- Identify root cause by asking "Why"

High number of lab errors—corrective actions and follow up

Findings/Root cause	Corrective Action	Follow-up post Implementation	Lessons learned
<p>Short staffed with simultaneous increase in cycle volume and complexity.</p> <p>Failure to respond to the changing needs - update protocols, reformat organizational and staff workflows, etc. and support lab appropriately.</p>	<ul style="list-style-type: none"> • Per diem support, new positions added. • Improved procedure checklists and chart prep protocol. • Reorganization of lab workflow, staff structures – assignments, sign offs, morning huddles. 	<ul style="list-style-type: none"> • Trends in lab errors improved • Staff stress level subsided (but not a quick fix). • Workflow management vastly improved but continues to be work in progress 	<ul style="list-style-type: none"> • Respond sooner – there are always little warning signs. • Never too early to address potential problems with team and leadership.

Improve leadership by focusing on the team

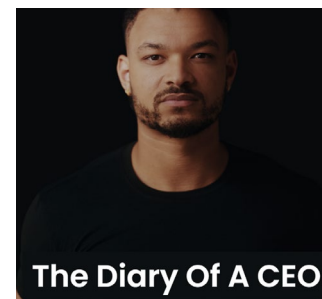
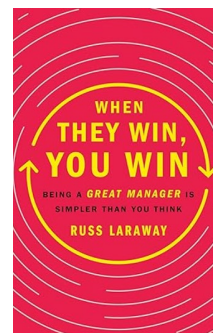
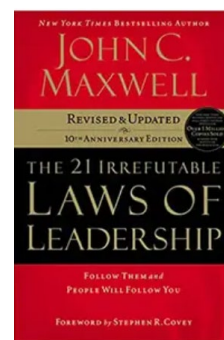
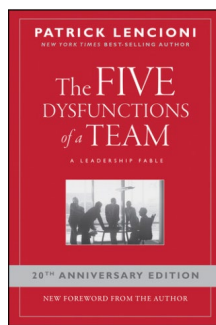
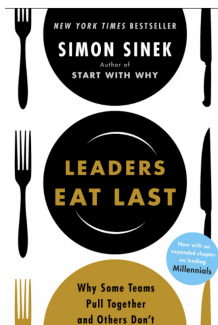
Leadership Strategy ¹	Why is it successful?	How do I implement in a lab setting?
Prioritize well being	Leaders that prioritize well being of staff are more likely to have high performing teams.	Lead by example -don't ask team to do anything you would not do. Advocate for staff – compensation, staffing levels, policies that protect the lab against burnout and error.
Trust	Trust is essential – “ A team is not a group of people who work together. A team is a group of people who trust each other” ¹	Transparency, communication The cover up is always worse than the crime Talk the talk and walk the walk Be vulnerable
Purpose and values	Successful teams have a clear sense of purpose and shared values.	Create a lab mission statement or mantra and post it.
Collaboration	High performing teams work collaboratively; will sacrifice for each other, especially when collaboration includes the leader.	Create opportunities for collaboration and recognize success. Teams for special tasks Fun fairies Recognition board



¹Sinek, S. (2014). Leaders eat last: Why some teams pull together and others don't, Penguin.

Troubleshooting leadership = teaching leadership

- Leadership classes
- Executive coaches
- Books and podcasts





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INNOVATION AND INTEGRATION

THE FUTURE OF REPRODUCTIVE MEDICINE



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Q&A