IMPLEMENTING NEW POINT OF CARE TESTING

A PRACTICAL GUIDE

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TRICORE

TRICORE REFERENCE LABORATORIES

- Regional medical laboratory providing diagnostic testing for patients and providers
- Located throughout New Mexico
- 13 Million Test Per Year (does not include POC tests)
- 99% Volume Performed On-site
- 85+% of Clinical Data for NM
- 1.3 Million interfaced POCT tests per year

TRICORE

TRICORE POINT OF CARE PROGRAM

3 SEPARATE HOSPITAL SYSTEMS

16 hospitals

160 clinics/Urgent Care

2 hybrid ED UC

18 instrument types

16 manual kits/tests

10,000 total operators

1200 non-waived operators

800+ individual devices

1.3 million tests/year (interfaced only)

TRICORE

POCT STAFF

POC manager

6 POC technical supervisors

21 POC techs

TRICORE

POINT OF CARE COMMITTEES

One committee per system

POC staff

Medical directors

Hospital and Tricore Quality

Infection Prevention

Purchasing

Hospital administration

Unit/clinic directors

POINT OF CARE COMMITTEES

Tricore POCT Workgroup

POC supervisors

POC medical directors

Tricore Quality

Assay development

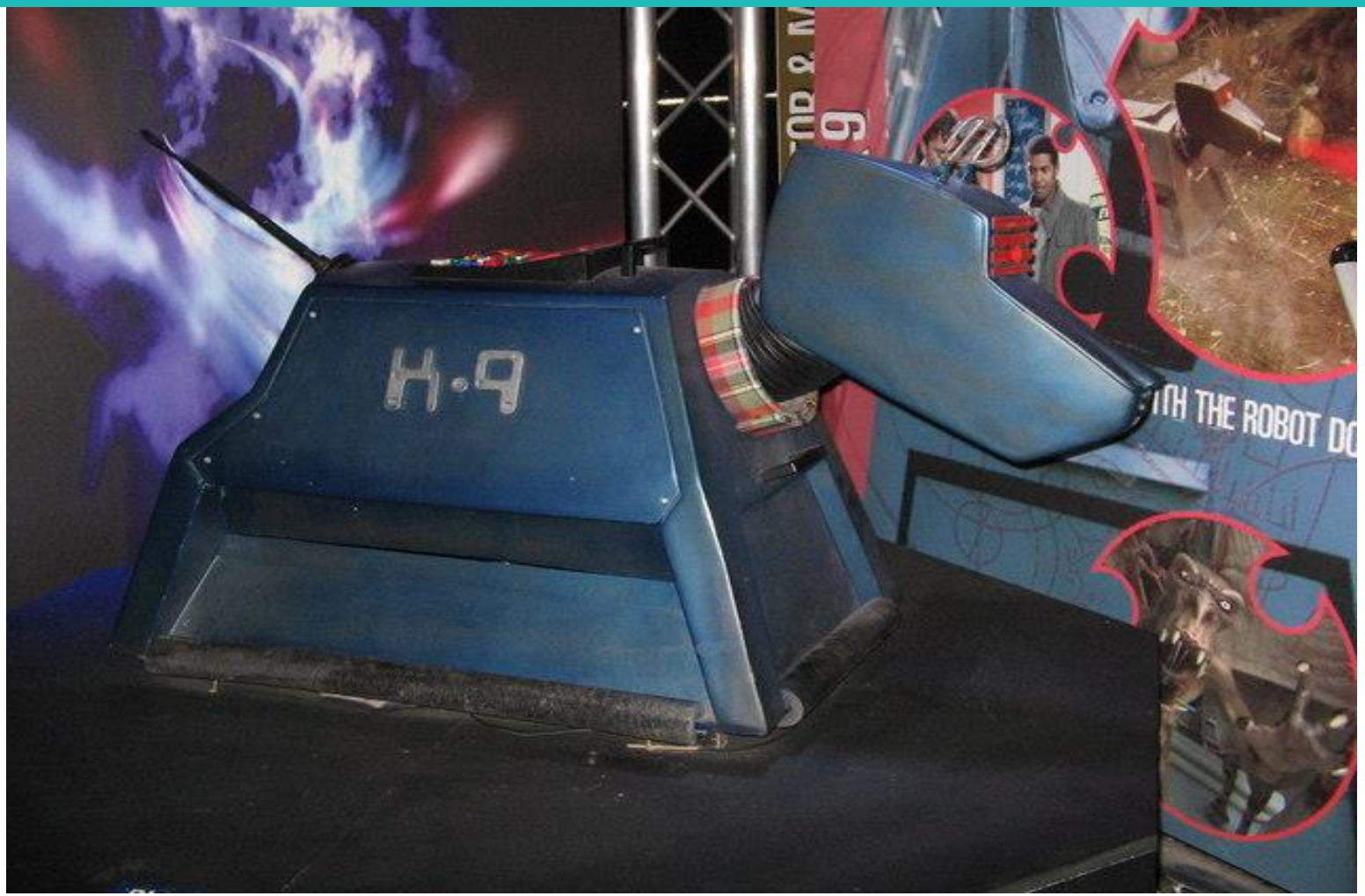
HAS THIS HAPPENED TO YOU?

Unknown to you, the cardiac cath lab director has a meeting with Sam Salesrep to see their latest device, and now wants to bring it into her department

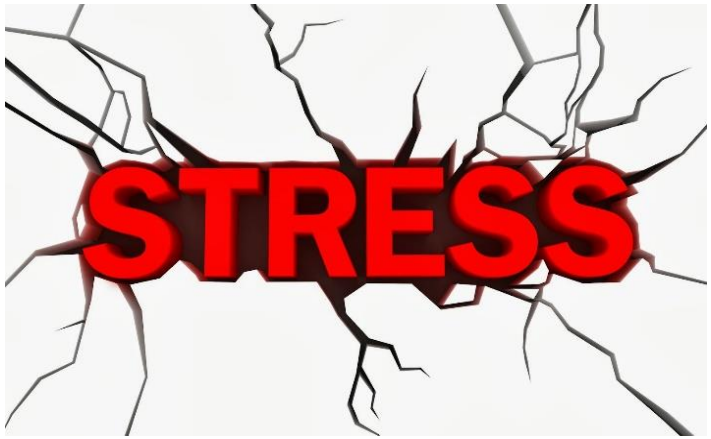
Poctalyzer Ultra Pro Plus-Enzymatic

or

PUPP-E!



NOW WHAT?!



FIRST THINGS FIRST

- Check FDA website for approval and CLIA complexity, EUA
- Do research on device, methodology, limitations
- Ask for package insert, user's manual, other information from manufacturer
- Physical specs-will it fit? Temp/humidity?
- Is renovation needed in the department?

POCT REQUEST-SAY PLEASE!

- Do you have a form for all POC testing requests?

- Should contain:
  - Test requested (device, kit, etc.)
  - Justification for testing-why the test is needed
  - Who will be responsible for testing (nurses, perfusionists, etc.)
  - Capital approval obtained?
  - Signature of unit/clinic director
  - Space for POCT committee approvals

HAVE YOU CONSIDERED?

- How will the device be connected?
- New server or device management system needed?
- Does it fit with the rest of the POCT program?
- Can the central lab do the test as quickly and accurately?

DO YOU HAVE A PROCESS?

A checklist makes sure none of the steps are missed

- VAT or Products & Standards Committee
- IT Security
- Capital/budgeting
- POCT committee
- Administrative approval
- Standardization
- Medical Director approval

PUPP-E IS APPROVED!

Checklist for implementation

- Procedure
- Electronic learning program
- Ports, wifi, IT infrastructure
- IT build: middleware, LIS, HIS, EMR
- QC process; IQCP if indicated
- Logs

PUPP-E IS IN THE HOUSE!

- Determine placement
- Environmental concerns
- Electrical
- Connect to ports/wi-fi and test

INFORMATION TECHNOLOGY

- Build test(s) in middleware
- Build test(s) in LIS
- Build test(s) in EMR
- Determine date of go live

NEXT STEPS

- Instrument clinical validations
  - Vendor assistance
  - Gather and crunch data
  - Medical director sign-off
- IT testing
- Interface validation
- Medical director approval

DOES EVERYONE KNOW HOW TO DO THE TEST?

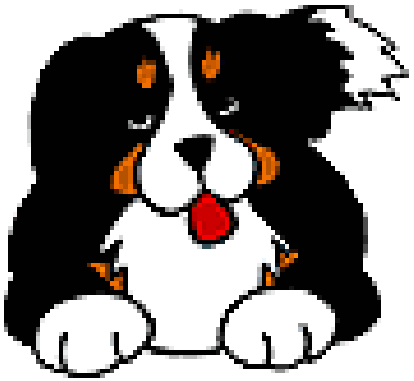
- Vendor training assistance
- Manufacturer's resources: videos, checklists, etc.
- Train the trainer model
- Ensuring access to the new device

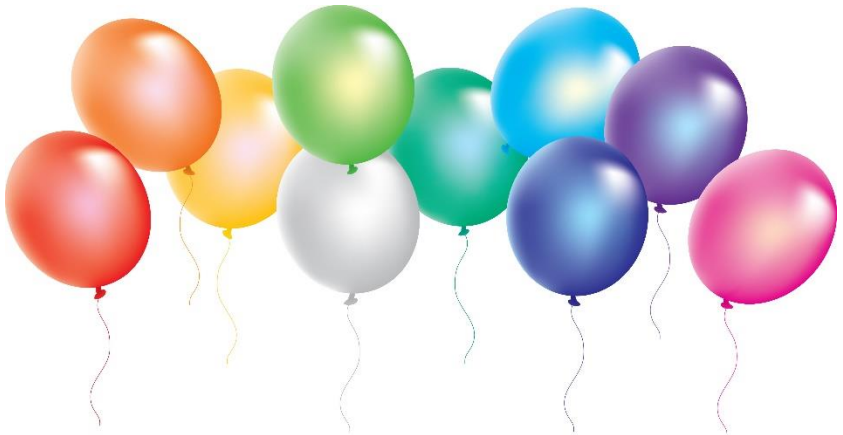
ALMOST THERE!

- Plan post go-live IT validation
- Establish ongoing competency schedule
- Add to Activity List
- Purchase proficiency testing

CELEBRATE!

PUPP-E is implemented!





Questions?
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