IMPLEMENTING CONNECTIVITY SOLUTIONS IN POINT OF CARE TESTING ACCURACY

Brigitte Wierer

15-10-2025

Disclosure

I declare that I have had no financial or other relationships with commercial interest groups in healthcare in the past to years

Public Health Care Company

7 Hospitals

10 000 employier

- 1 500 physicians
- 3 700 nurses
- 2 200 health technicians

Cost estimate 2025: € 1.8 billion

Inhabitants 550 000

Tourists arriving year 8.5 million

THE PROJECT

Open procedure for the five-year supply from 2024 October to 2029 October of a **diagnostic system for blood gas analysis/POCT**, with the provision of blood gas analysers in full-service to the Azienda Sanitaria dell'Alto Adige.

7 Hospitals	Hospital Beds: 1339
Hospital Units	42
Blood Gas Analysers	46
Tests per year	1.5 Million
Health care workers to train	1000
Laboratories	4

THE PLAYERS

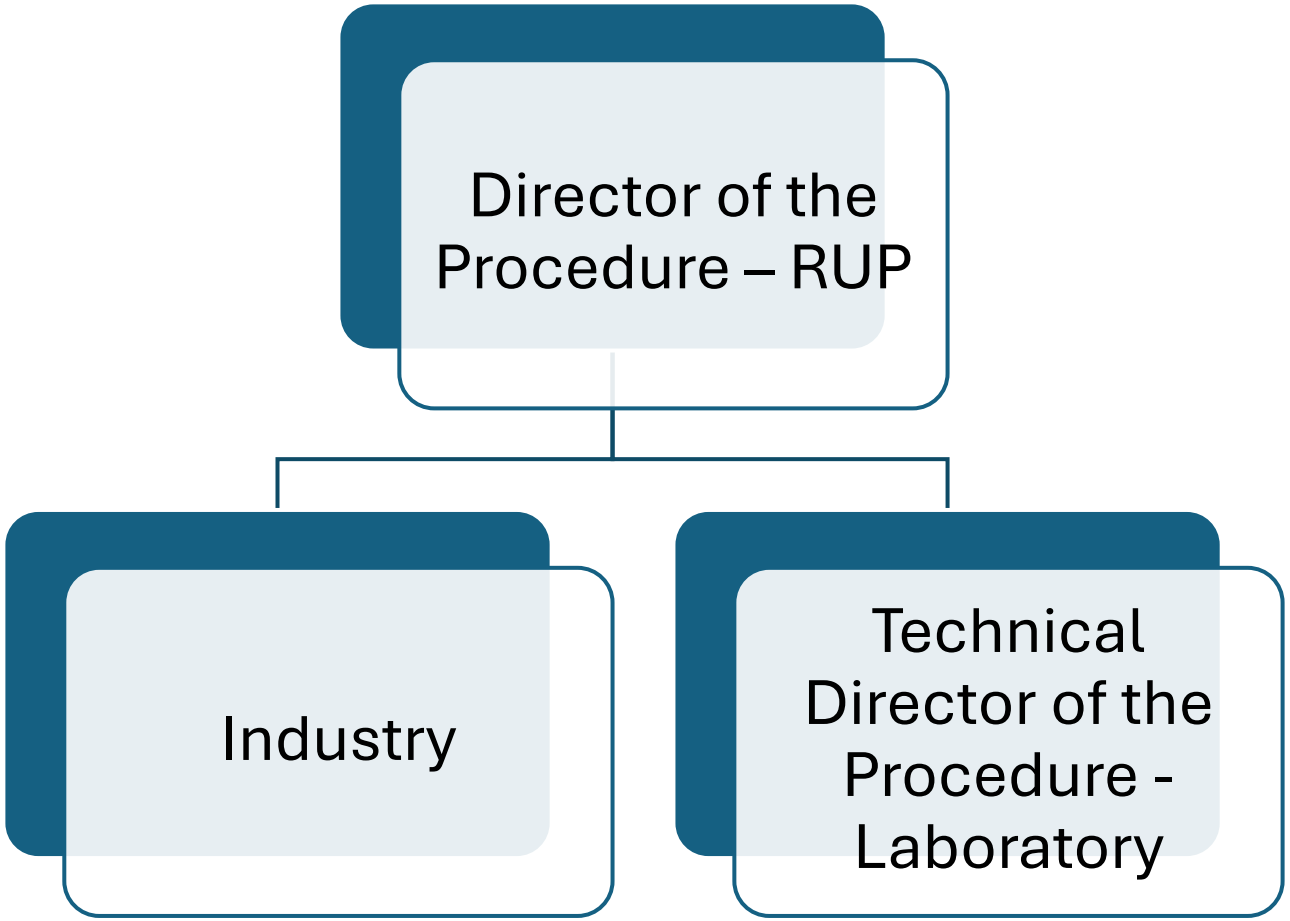
THE RESPONSABILITY OF THE LABORATORY

- **Management and review of the project**

  - **Select devices**
  - **Training staff**
  - **Quality assurance**

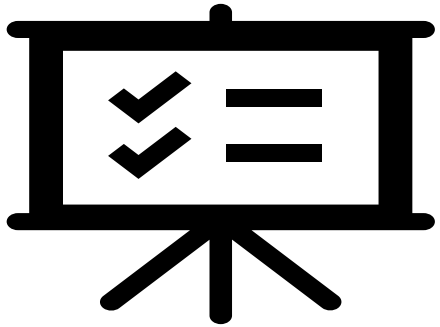
- National and Local health Authority
- ISO 15189 – annex A
- National and International Scientific Societies (SIPMEL, SIBIOC, IFCC, CLIA)

National Regulation



THE RESPONSABILITY OF THE TECHNICAL DIRECTOR

- Planning
- Implementation
- Maintenance

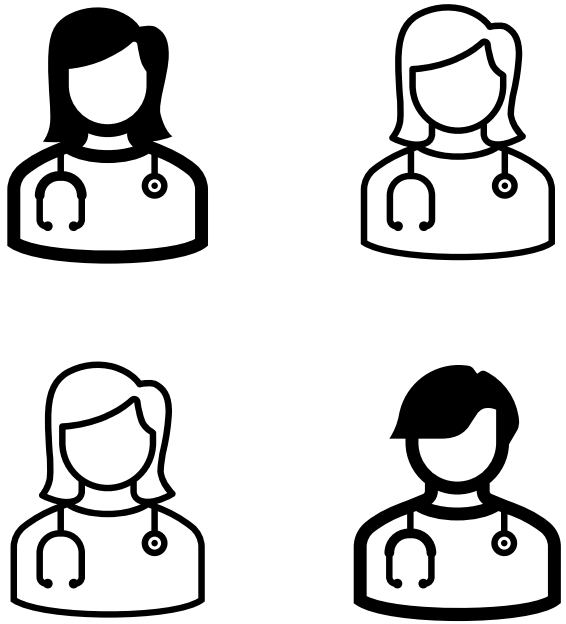


Of all technical processes of the procedure

The Sparring Partners

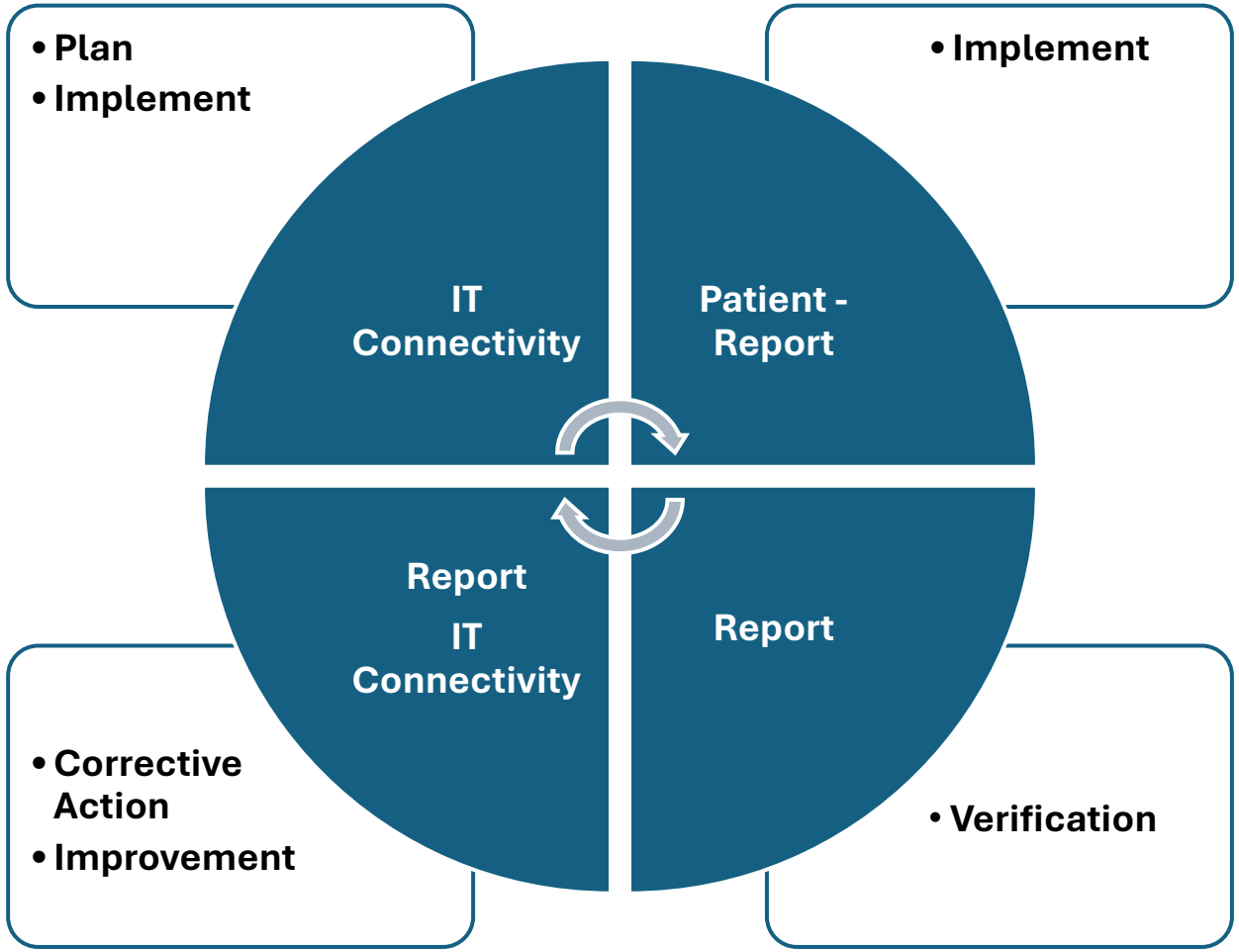
ASDAALAB Interlaboratory Management Committee	Interlaboratory LIS Team	Interlaboratory POCT Management Team
• Multidisciplinary committee with members of all laboratories • Monthly Meetings	• Group laboratory IT specialists • Monthly Meetings	• Multidisciplinary group with 8 members from all laboratories • Meetings if necessary

ASDAALAB Sub Committee 4 Directors of the Laboratories



- Connection to Health Service Management
- Control of the budget
- Connection to the Hospital Units
- Selection of devices and tests
- Report Layout
- Definition of reference intervals
- Risk and opportunity management

Interlaboratory LIS Team



Interlaboratory POCT Management Team – „the real heroes“

- Management of supply: equipment and reagents
- Method verification
- Human resources management
- Quality assurance
- Connection to POCT Manager of the Hospital Units

SOME EXSAMPLES

FEED BACK FROM THE HOSPITAL UNITS

KEEP IT SIMPLE

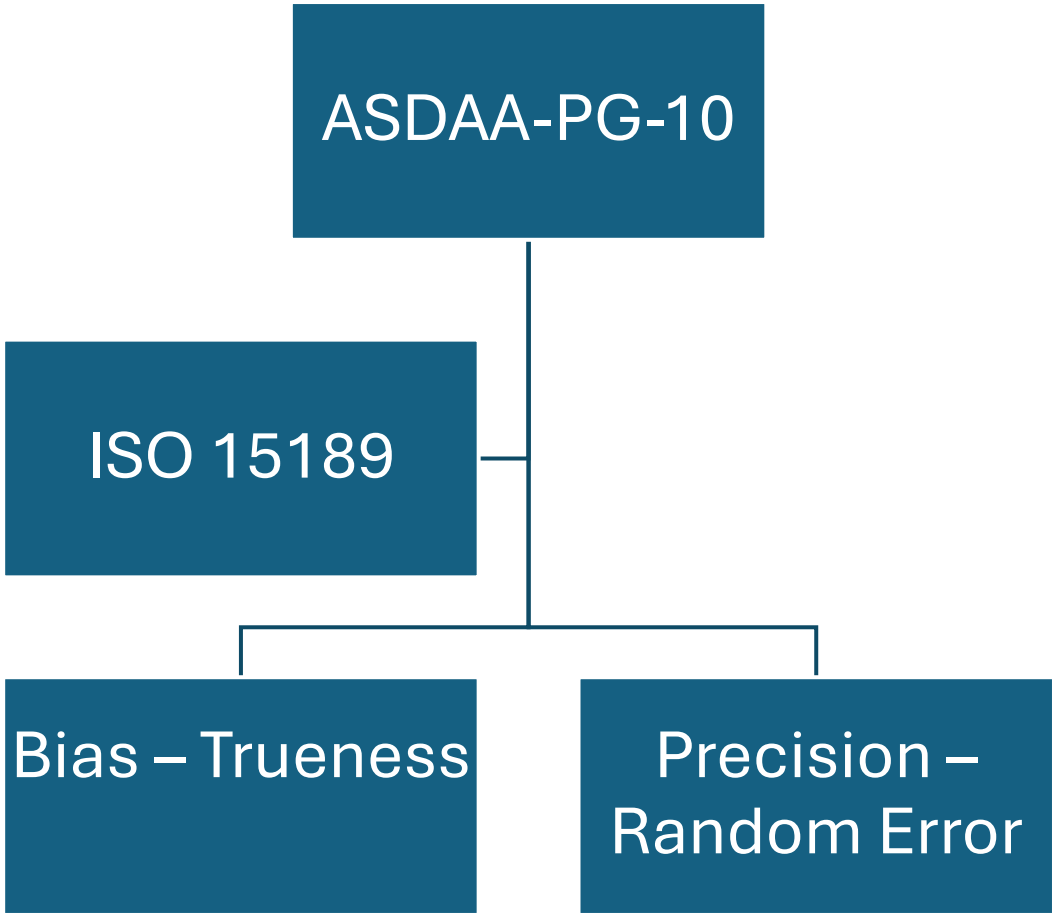
- All units shall get the same type of instrument
- All instruments have to be connected to one middleware
- All instruments have to be connected to the LIS
- All units have to participate at proficiency testing
- Lab-POCT – Manager as key figure

DEVICE AND TESTS SELECTION

USER FRIENDLY – 24/7

- Multiparameter and multi-test Cartridge System
- Full automated internal quality checks
- Full automated documentation of every event
- Low maintenance
- Remote maintenance from the main laboratories and from the supplier company

METHOD VERIFICATION



BIAS STUDY
in the main Laboratories

	Linear correlation – correlation coefficient new versus old	Specification supplier company
pH	0.9881	0.996
pCO_2	0.9786	0.994
pO_2	0.9912	0.998
Sodium	0.9998	0.996
Potassium	0.9998	0.999
Chloride	0.9998	0.996
Glucose	0.9989	0.997
Lactate	0.9982	0.996
Haemoglobin	1.0000	0.998
Calcium	0.9983	0.998

OPERATORE TRAINING and COMPETENCY ASSESMENT

FIRST STEP

Online training with online competency assessment before installation - **didatic material from the supplier company**

SECOND STEP

On-side training during device installation from the supplier company with on-side competency assessment
trained staff acts as multiplicator – «train-the-trainer»

THIRD STEP

Classroom education from the supplier company

FORTH STEP

Evaluation and retraining (**to do**!)

→ werfen academy

1000 staff members trained by now

PROFICIENCY TESTING

International Provider CSCQ – Quality Control Center Switzerland

4 Samples / Year

All devices are tested

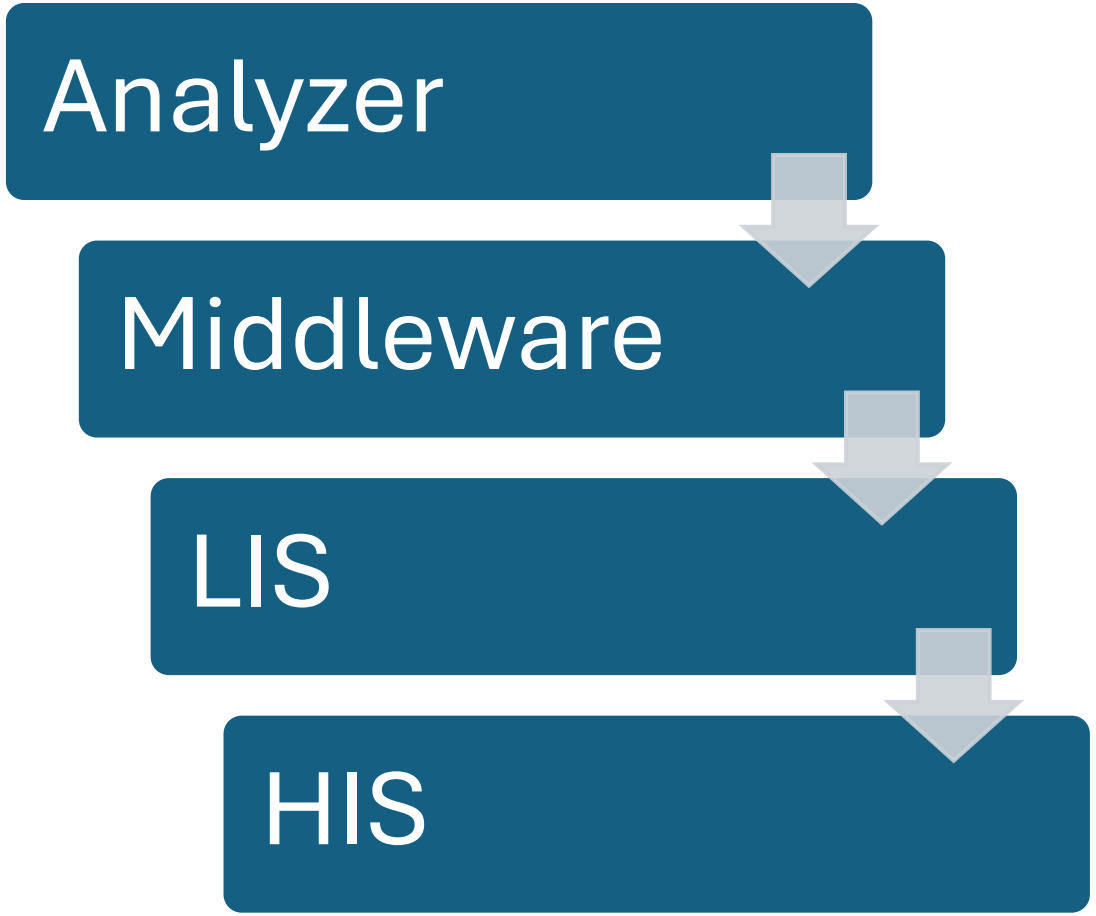
Supervisor is the local Laboratory

CONNECTIVITY

Connectivity is the cornerstone of POCT development

"CLSI Point of Care Connectivity – approved standard, 2nd ed. CLSI document POCT01-A2 2006"

GEMweb Plus500
CUSTOM CONNECTIVITY



„The Paperless Laboratory „

Connectivity plays a central role in POCT - governance

(SIBioc 2021 “Principi per l’implementazione e la gestione del Point-Of-Care-Testing (POCT): indicazioni essenziali”

15-10-2025

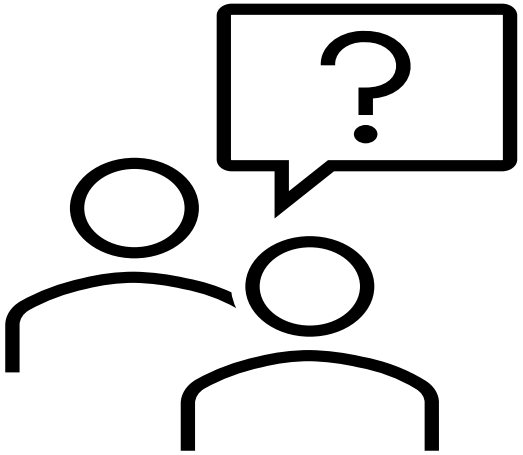
SIBIOC (2021) national scientific society	Middleware
Remote Control of all analysers – blocking if necessary	applies
Traceability of the results	applies
Traceability of the operator	applies
Multi Level -Operator - password	applies
CQI Validation	applies
CQI Governance	applies
Statistical Data from analysers, hospital units, operators and patient	applies
Automatic order entry from HIS and LIS	applies
Automatic data transfer to LIS	applies
Data storage	applies

Other tools
Web based access
Works in conformity to EU-GDPR, 2016/679
Operator certification werfen academy
Integration of other POCT platforms

GEMweb® Plus 500

CUSTOM CONNECTIVITY

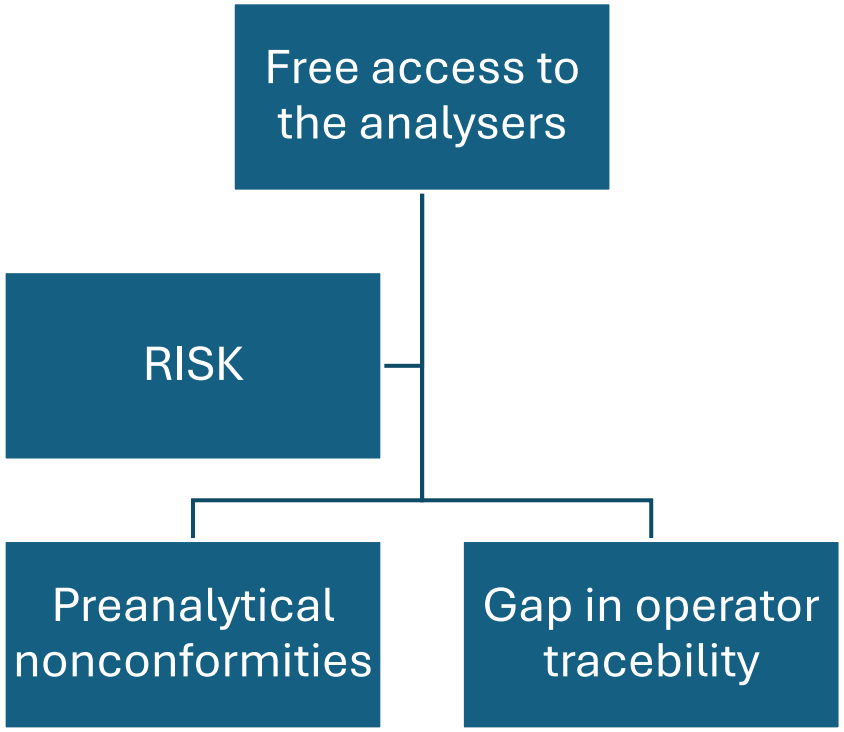
CHALLENGES?
OPPORTUNITIES?



KEEP MOVING

Opportunity operator identification

First



After

All staff members must conclude a 2-step training

After the training they receive access to the analysers with their personal password

Indicator

Hospital Unit	Access with personal ID (%)	Target: > 90%
1	81	Attention
2	87	Attention
3	91	Passed
4	88	Attention
5	81	Attention
6	95	Passed
7	90	Passed
8	53	Corrective Action
9	100	Passed

Opportunity Patient Report

First

4 different Patient Report Layout with different tests

4 different reference intervals

RISK of misinterpretation in case of transfer

After

1 Patient Report Layout

Unified reference intervals

Personaliesd Patient Report for single Unit

TRACEABILITY

Patient Report

- date/time of sample order
- date/time of sample arrival
- date/time of reporting
- Identification as POCT – Result
- Comments
- Critical value reporting

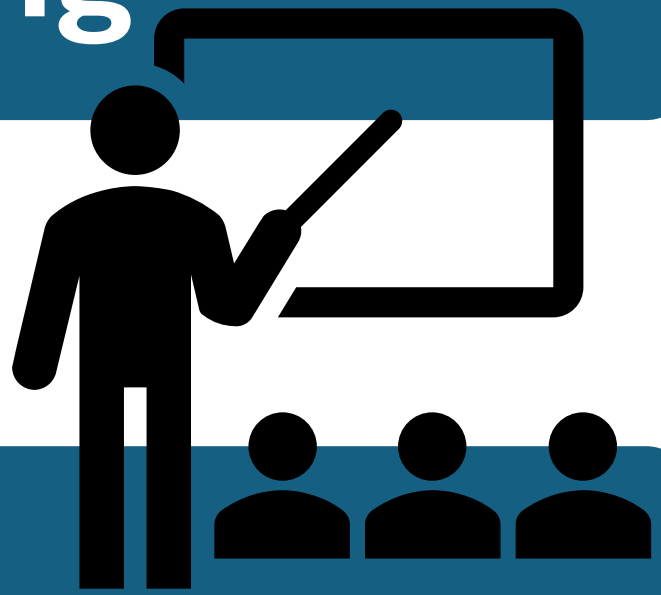
Data Management System

- Operator identification
- Nonconformities reporting
- Corrective actions reporting
- Statistic reporting

Challenge Staff Training

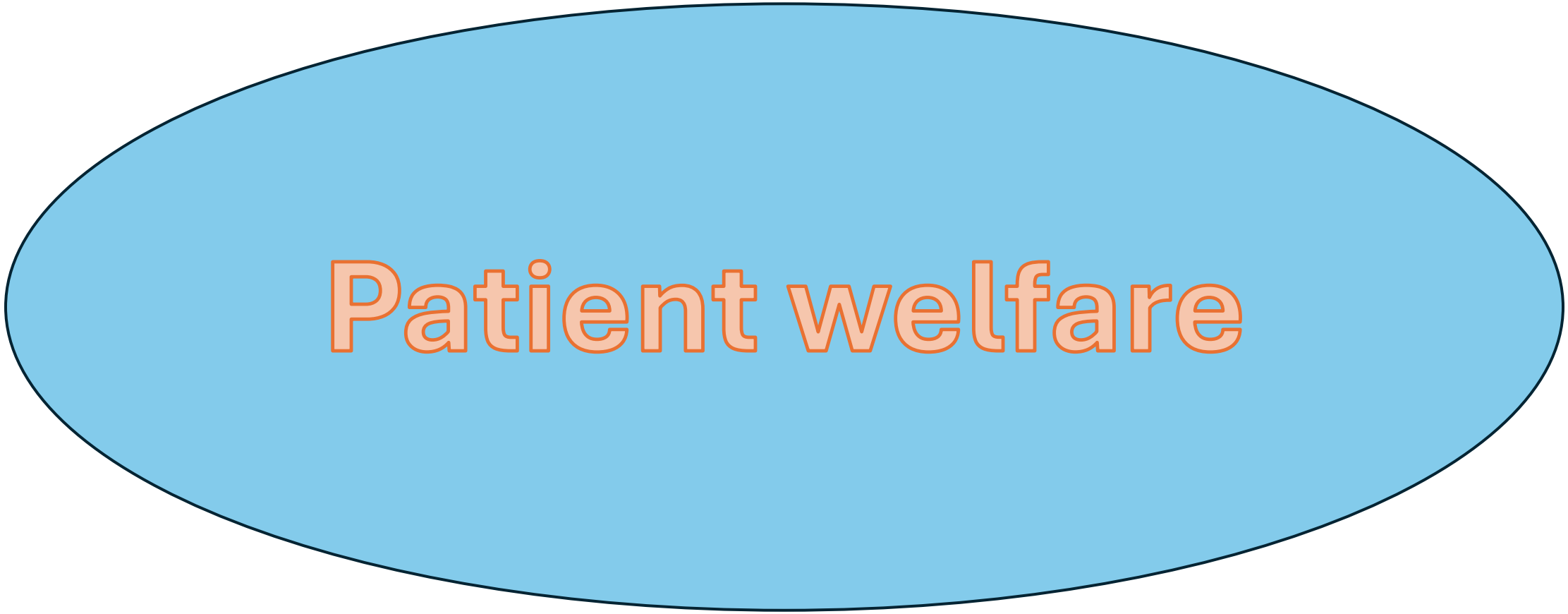
POCT Manager Training

- Basic Training
- Re Training



Evaluation

Conlusion



THANK YOU