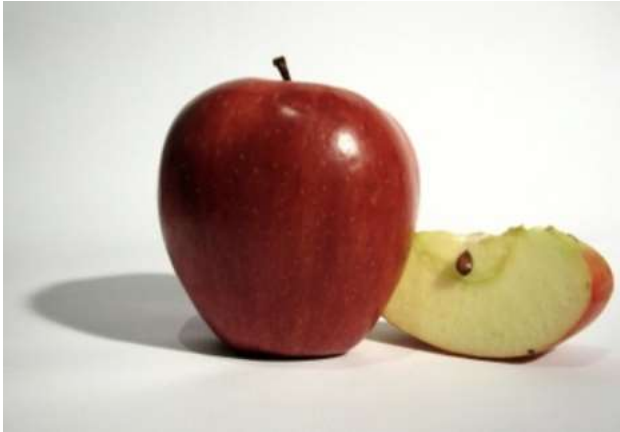# Safety at the Core

Digital Clinical Safety

...at the core

What, How, Why?

Right technology in the right place at the right time, used….

Right data in the right place at the right time, used….
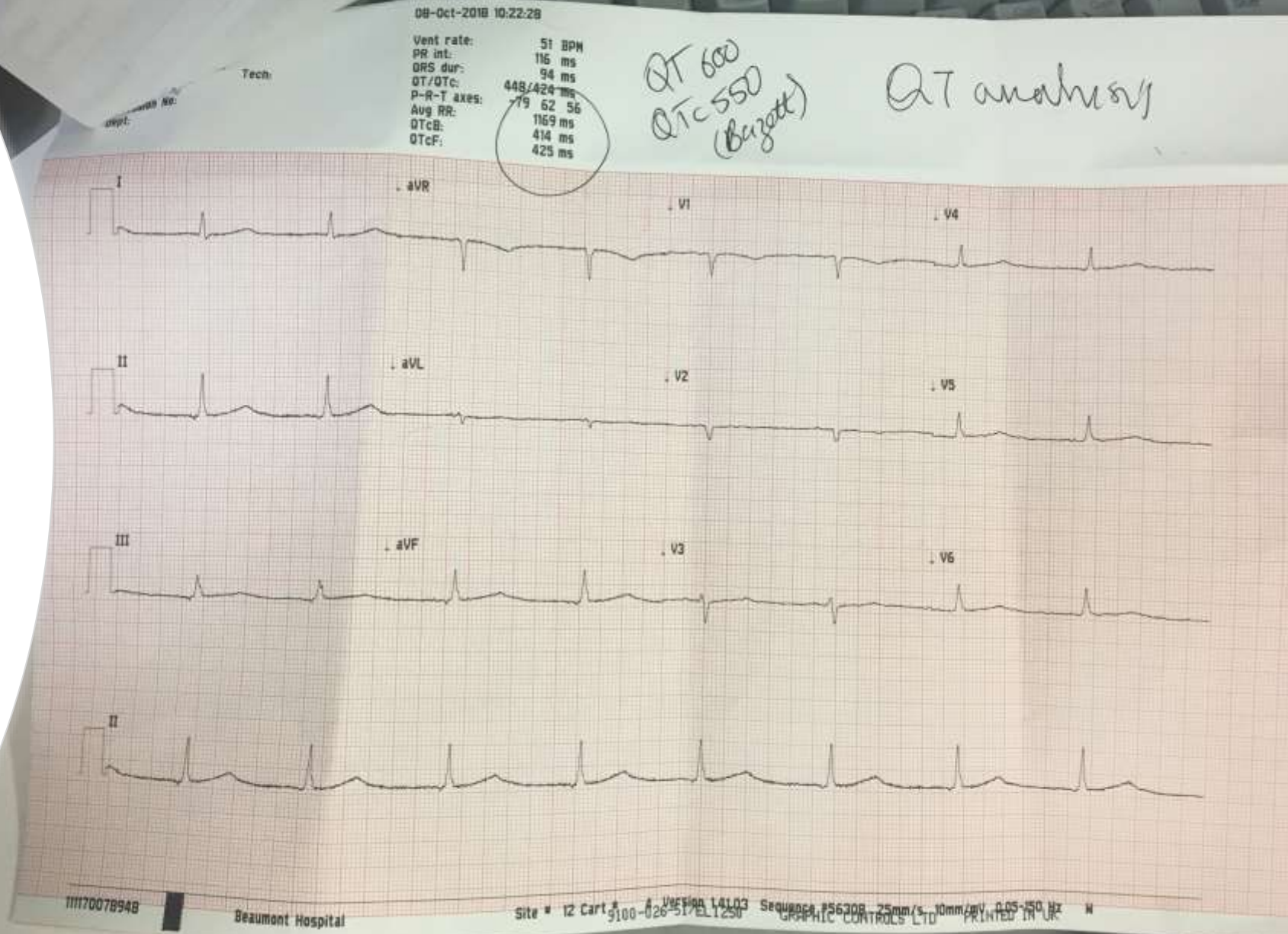
Used in accordance with Instructions for Use

Standards

- Solutions which are not based on **standards** but solve today's problems today are great today….

- They might half work in a year's time….

- You'll abandon them in 2-3 years.

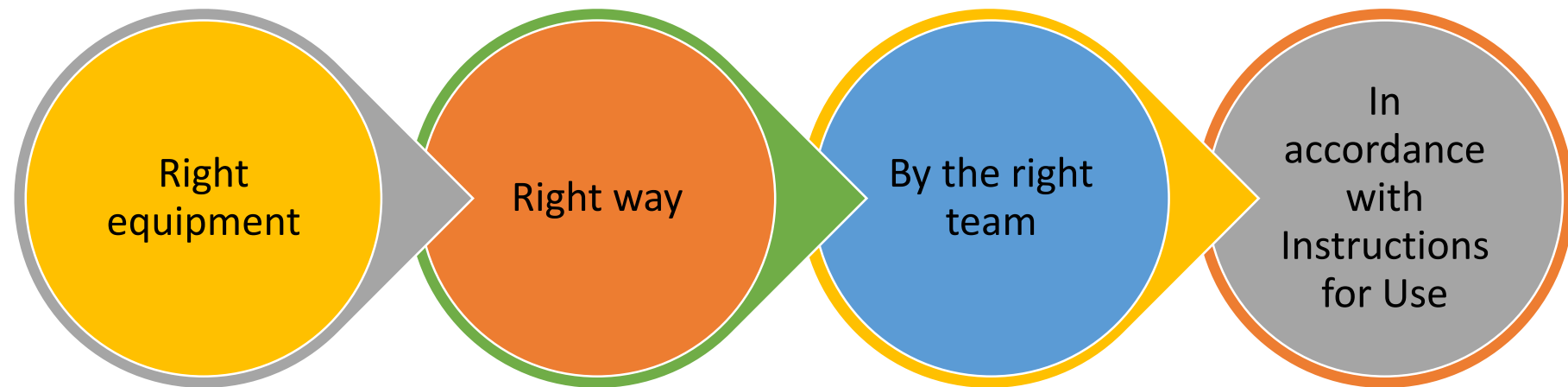# Always challenge – even the obvious

- Machine calculated QTc: 414ms
- Measured QTc: 550ms

No Guarantees – Assume nothing

Right equipment → Right way → By the right team → In accordance with Instructions for Use

Where does that leave us with AI?

What about the data?

- Name
  - Meabh, Maeve, Medbh, Méabh;
  - Smith, Smyth
  - First name, second name: 8, 16 if I don't define the order.
- Units
  - Peak flow: L/min, L/sec?
  - Glucose:Milligrams per Deciliter (mg/dL); Millimoles per Liter (mmol/L)

Data Governance

- Policies and Procedures
- Data Classification and Categorization
- Data Stewardship
- Data Ownership
- Data Retention and Deletion:
- Data Security and Access Controls
- Records Management
- Data Quality and Integrity
- Change Management

How can we know that we have the right app for the right patient, doing the right thing?

Digital Clinical Safety

There are structural changes which need to happen and they are coming;

There are standards we can use;

We must always question;

We must embrace new technology, new processes;

But there must be structure, documentation, governance;

Our workforce must be enabled.

What am I doing about it?

- Figuring it out;

- Developing "A Framework for Digital Clinical Safety" (Min requirements & Guidance);

- Supporting Digital Health Learning from our Implementations;

- Supporting the Telehealth Roadmap;

- Learning, Listening and Lobbying.

More in 2024

- 20 Seedling Projects
- Blueprints
- Training
- App Assessment Processes

AMBULATORY CARDIAC MONITORING –
DIGITAL HEALTH BLUEPRINT

PROJECT SUMMARY

A concern for patients who have been admitted to the stroke unit, is that they will have undiagnosed Afib. This means that patients may wait for telemetry while an inpatient, may go on a waiting list for a holter monitor or a waiting list for a Loop recorder. These are all scarce resources.

A proof of concept for discharge of some patients with ambulatory cardiac monitoring was proposed. Clinical and Administrative Pathways were agreed and Standard Operating Procedures were drafted.

A full business case was submitted and the service introduced fully.

The Challenge

When patients were medically ready for discharge from the stroke unit, discharge was sometimes delayed where there was suspected Afib, waiting for diagnostics, or patients were added to waiting lists for holter or loop recorders potentially resulting in delayed diagnosis.

In addition, there are several unfilled Cardiac Physiologist posts, resulting in significant pressure on that team.

The Solution

A CE-Marked ambulatory cardiac monitor with published literature evidencing its efficacy in identification of Afib, and which had referees at a number of sites in other jurisdictions was identified. ECGs are reviewed by Cardiac Physiologists employed by the service provider. Results are on a dashboard and an agreed process for management of reports of concern was developed.

The Clinical Leads in Stroke and Cardiology fully supported the proof of concept. Pathways were developed based on the proof of concept.

A successful business case lead to the routine use of the ambulatory cardiac monitor. Access to raw ECG record possible.

Commercial Images

The Smarter CardioSTAT Service

CardioSTAT ECG Clinical Report
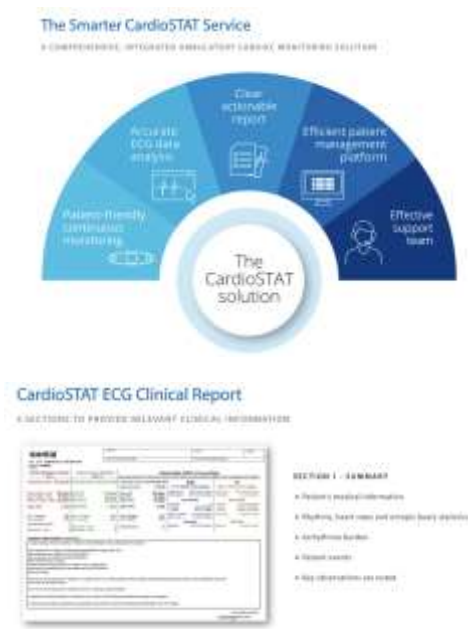
Costs and Resources

Set-up costs:
No set-up fee. Dashboard access included as part of service. IT department must agree access to URL. Patient documentation and videos available.

Devices:
Monthly order. Cost of device depends on duration of monitoring. All consumables supplied with the devices.

Workforce:
Consultant identifies patients and reviews reports. Escalates to Cardiology if necessary.

CNS/ANP manages and oversees patients and devices. Escalates clinical, technical, and admin concerns.

Admin: ensures pdf reports are saved to clinical documentation in patient record.

Benefits

- Reduced LOS
- Improved care for patients
- Reduction Loop recorders
- Reduced pressure on Cardiac Physiologists

Further Information

For further information, contact:

Current verdict: September 2023   *Positive*

Vision for Digital Health Clinical Safety

1. **People-Centred Digital Health**

2. **Interoperability and Integration:** communication and data sharing leading to a more comprehensive and holistic patient view.

3. **Clinical Safety Framework:** risk management, safety monitoring, and continuous improvement processes to support technology adoption in healthcare.

4. **Education and Training**

5. **Standards and Guidelines**

6. **Advocate for User-Centred Design**

7. **Data Governance and Privacy**

8. **Continuous Evaluation and Improvement**

9. **Encourage & Support Research and Innovation**

10. **Collaboration and Stakeholder Engagement**

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