Enabling the adoption of new diagnostics within the UK healthcare system:

The key role of diagnostics in the AMR challenge

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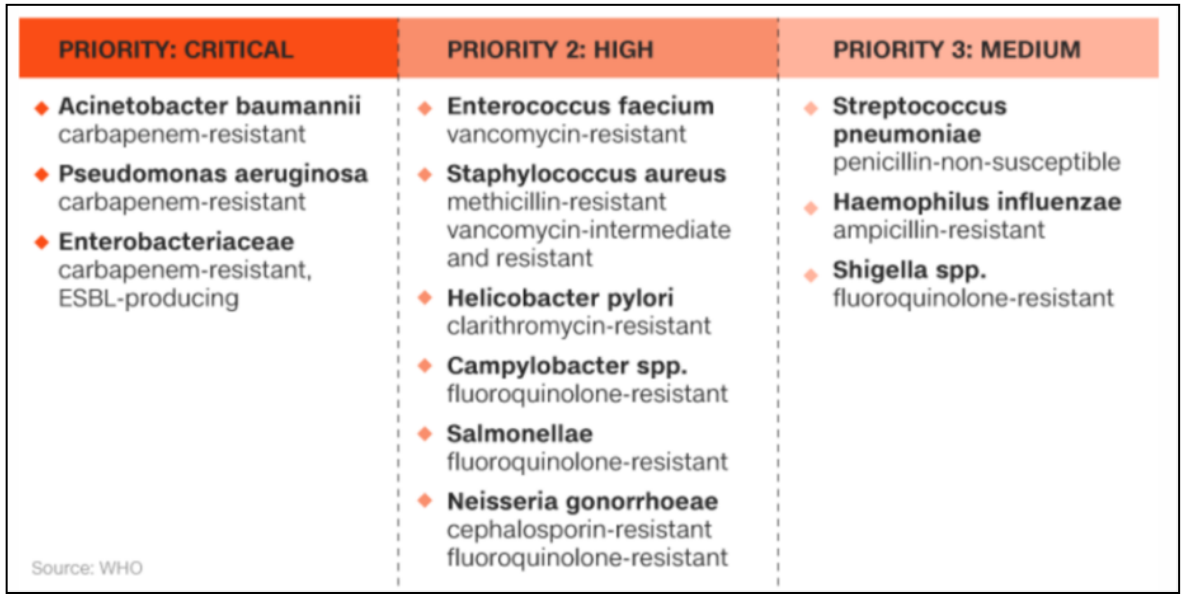
The rising tide of Antimicrobial resistance

- Infections are increasingly developing that we cannot treat with a rapid spread of multi-drug resistant (MDR) bacteria
- We may not be able to treat or prevent everyday infections or disease
  - Existing antimicrobials are becoming less effective
  - Bacteria, fungi, viruses are adapting naturally and becoming increasingly resistant
  - Inappropriate use of these medicines
  - All-time low in new antibiotics being developed

Recognising this is a '**one health**' agenda

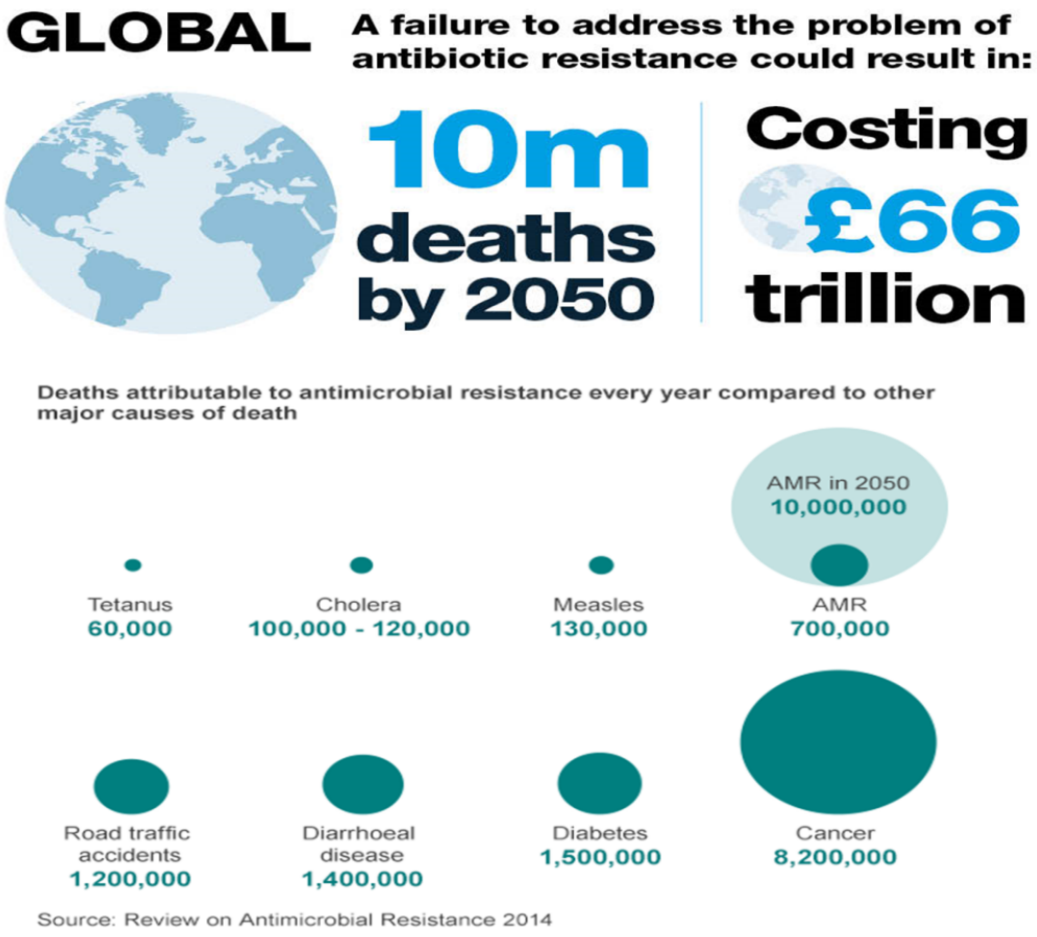


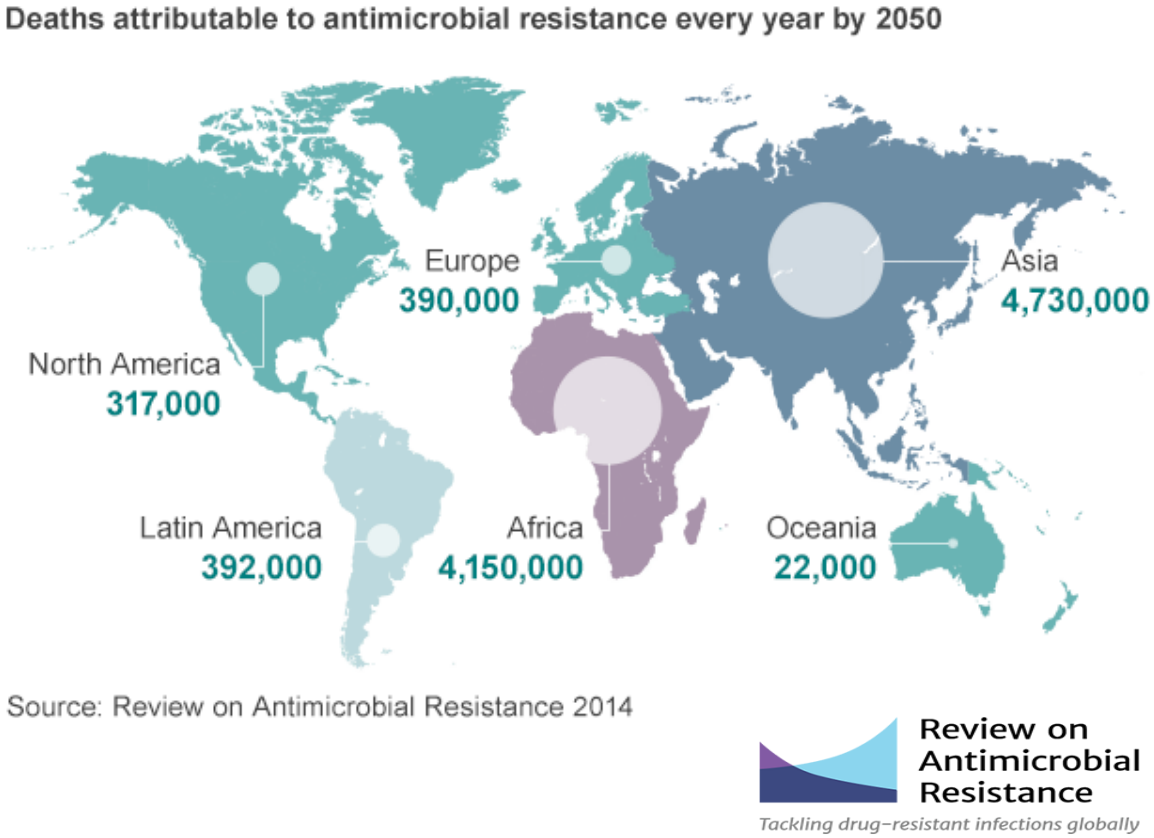
PRIORITY: CRITICAL	PRIORITY 2: HIGH	PRIORITY 3: MEDIUM
Acinetobacter baumannii carbapenem-resistant	**Enterococcus faecium** vancomycin-resistant	**Streptococcus pneumoniae** penicillin-non-susceptible
Pseudomonas aeruginosa carbapenem-resistant	**Staphylococcus aureus** methicillin-resistant vancomycin-intermediate and resistant	**Haemophilus influenzae** ampicillin-resistant
Enterobacteriaceae carbapenem-resistant, ESBL-producing	**Helicobacter pylori** clarithromycin-resistant	**Shigella spp.** fluoroquinolone-resistant
	Campylobacter spp. fluoroquinolone-resistant	
	Salmonellae fluoroquinolone-resistant	
	Neisseria gonorrhoeae cephalosporin-resistant fluoroquinolone-resistant	

Source: WHO

WHO priority list of 12 resistant bacteria that pose the greatest threat to human health ***www.who.int***

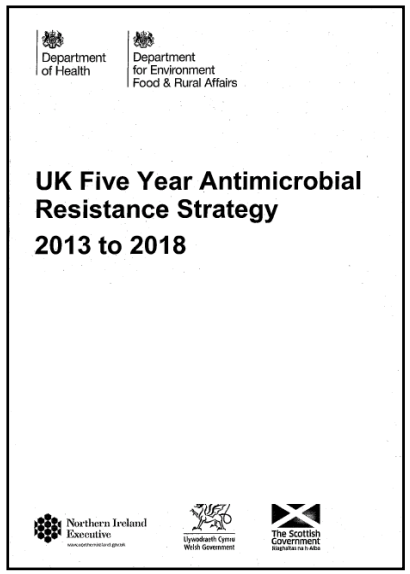
The future if we do not act now



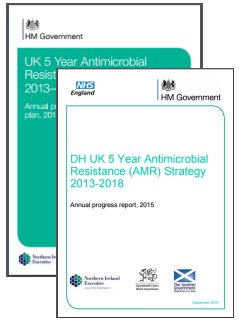


By 2050: more deaths from resistant infections than cancer

UK response to this challenge



- Improving infection protection and control
- Developing new drugs, treatments and diagnostics
- Optimising prescribing practice
- Better access to and use of surveillance data
- Strengthened international collaboration
- Improving professional education, training & public engagement
- Better identification and prioritisation



Progress against the strategy is reported on an annual basis

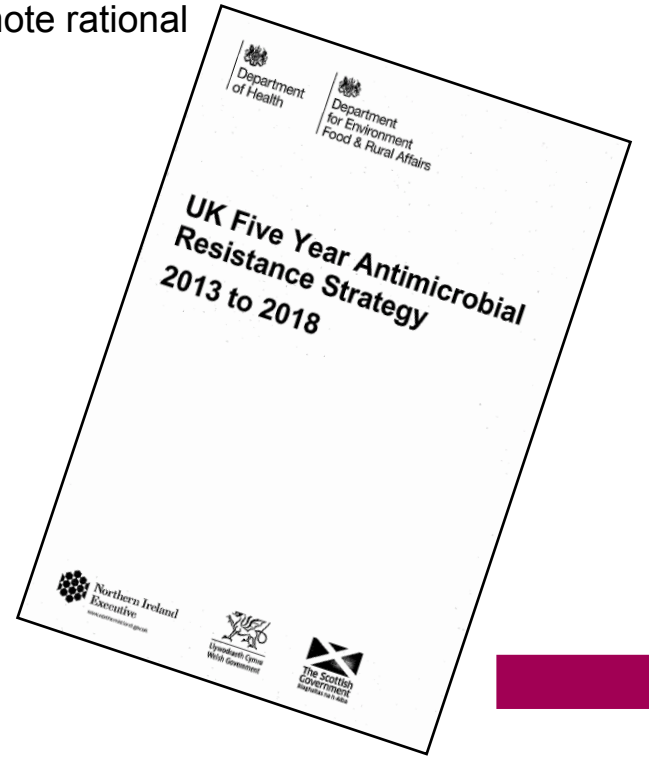
The UK AMR Strategy: a tripartite approach

A One Health approach

- **PREVENT** infection prevention and control
- **PRESERVE** existing antibiotics through stewardship programmes that promote rational prescribing and **better use of existing and new rapid diagnostics**
- **PROMOTE** the development of new antimicrobials, new approaches and better **diagnostics**.

Underpinned by:

- Surveillance
- Research and Development
- Education, training and awareness
- International collaboration



The role of diagnostics in AMR

Independent review of Antimicrobial Resistance - Jim O'Neill

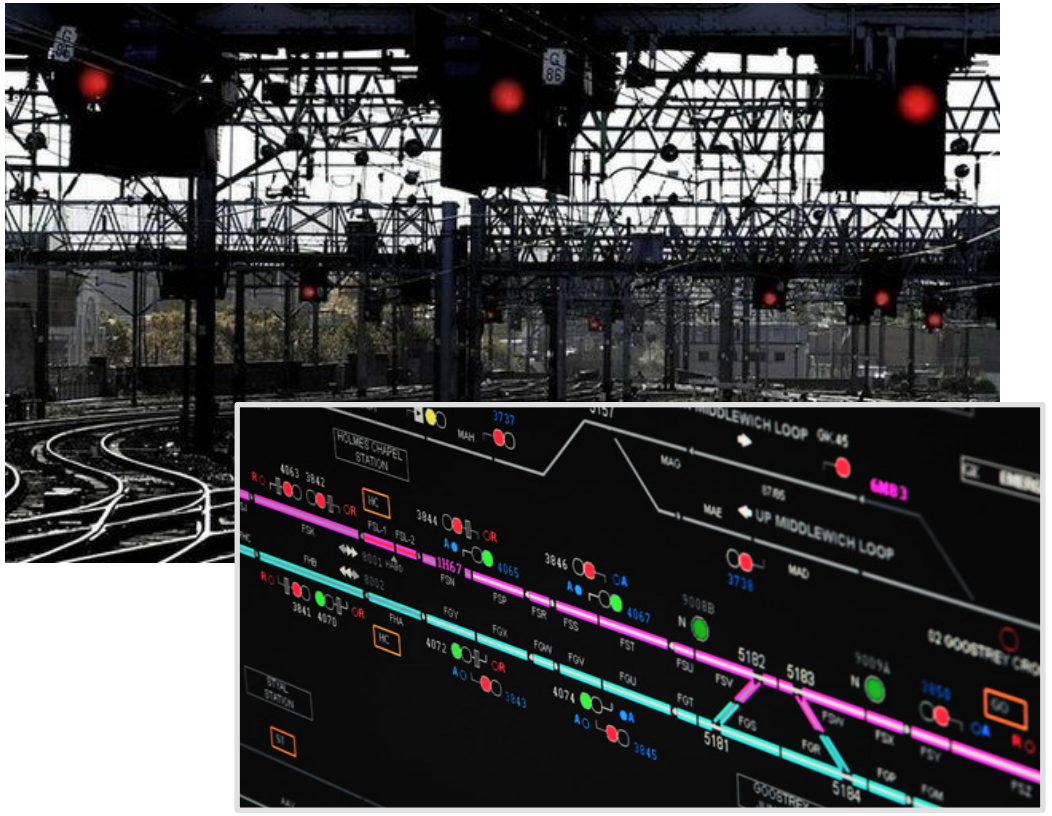
- Diagnostics are critical to the appropriate use of antimicrobials
- Step change in the way technology is incorporated into the decision making process
- Currently many decisions are based on an empirical diagnosis
- Rapid point of care diagnostics enabling a precise, timely diagnosis
- Decision support approach to drive change in prescribing

"I call on Governments to ensure that, by 2020, all antibiotic prescriptions will need to be informed by …. a rapid diagnostic test wherever one exists" Jim O'Neill

"Having rapid, low-cost, and readily available diagnostics is an essential part of the solution to this urgent problem." Dr Margaret Chan, DG, World Health Organisation

Diagnostics – the signalling system for the NHS

- Direct patients and patient flows so that **the right people get to the right place at the right time**
- Ensure treatment and management is efficient, effective and coordinated
- Have a critical role in prioritising activity so that services are resilient and sustainable
- Fundamentally shape the health economics of particular patient pathways



Which diagnostics could be used in AMR?

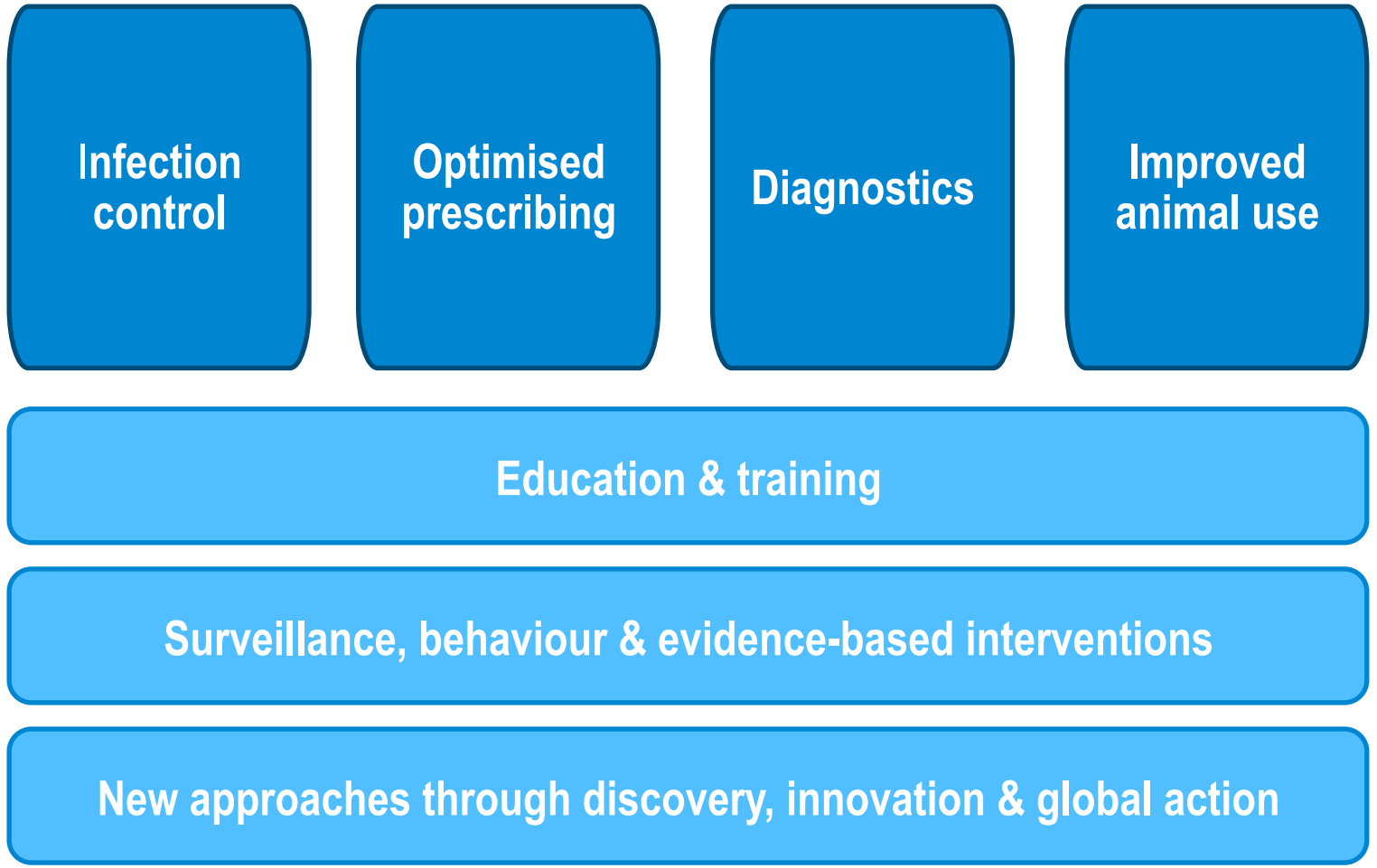
- **Bacterial or viral**
- **Bacterial type**
- **Resistance** (*which antibiotics **must I not** use?)*
- **Susceptibility** (*which antibiotics **can I** use?)*

Recognising there is also a role for host response biomarkers

From O'Neill http://amr-review.org/

National ambitions

1. Halve gram –ve HCAI blood infections by 50% by 2020
2. Halve inappropriate prescribing in humans by 2020
3. Reduce animal antibiotic use to 50mg/kg by 2018
4. Work internationally to bring new products to market



UK AMR Diagnostics - Vision

…..“This strategy will tackle the issues around AMR through patient-centred, cost effective diagnostics by ensuring that the right test is available at the right place at the right time.

“It will maximise the use of available technologies in human & animal health sectors in the most appropriate settings.”

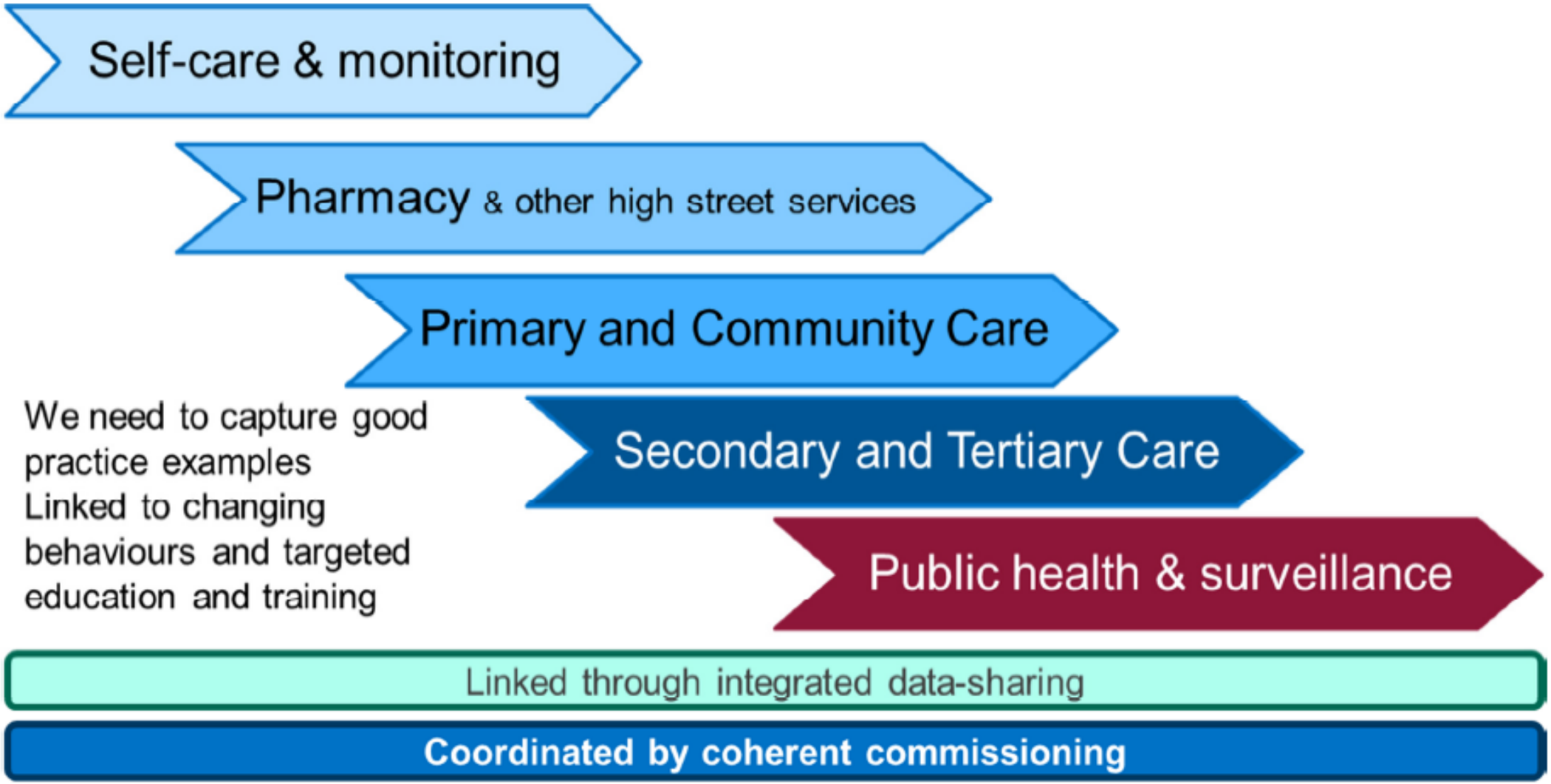
The vision will be delivered through a coordinated & consistent national approach to standards & practice

- In every part of the country, in every healthcare setting, **the same level of access to rapid diagnostic technology & digital antimicrobial guidance tools are available**
- **The technology meets nationally set standards of quality & response times**
- There is recognition that different settings might need different technical solutions
- Services are flexible & responsive to the adoption of new technologies that will provide continuous improvement

UK AMR Diagnostics – Strategy

NHS England

Ensuring that the **right test** is available at the **right place** at the **right time.**



Diagnostic challenges – current landscape

- Lack of clinical trial data and cost effectiveness assessments.
- The need to avoid the inappropriate use of tests. There are many clinical scoring tools based on symptoms and signs that can be used to rule in or rule out infection.
- Collecting the outcome of tests to inform national and local data collections
- If tests do not have cost benefit or adequate performance characteristics in the patient population under investigation they have potential to do harm.
- Rapid adoption of new technology - change behaviours around the use of tests.

How do we value diagnostic tests in the context of their contribution to the prevention of the growth of resistance?

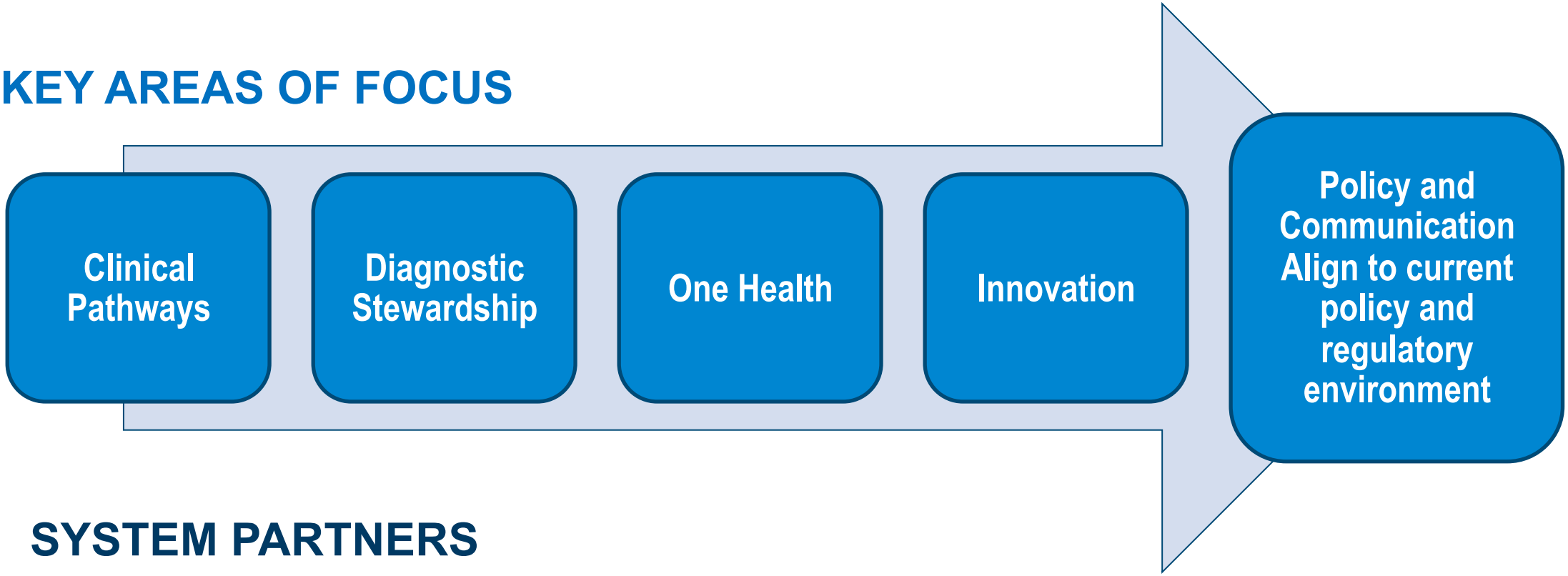
Diagnostic challenges – specific tests

- The right setting – *different settings might need different technological solutions*
- Meeting quality standards - *including response time*
- Personal to the needs of the patient - *their symptoms, healthcare system, behaviours and social setting, supporting shared decision making*
- Place in the care pathway – *diagnostic strategies*
- Clinical judgement – *supporting, not replacing*

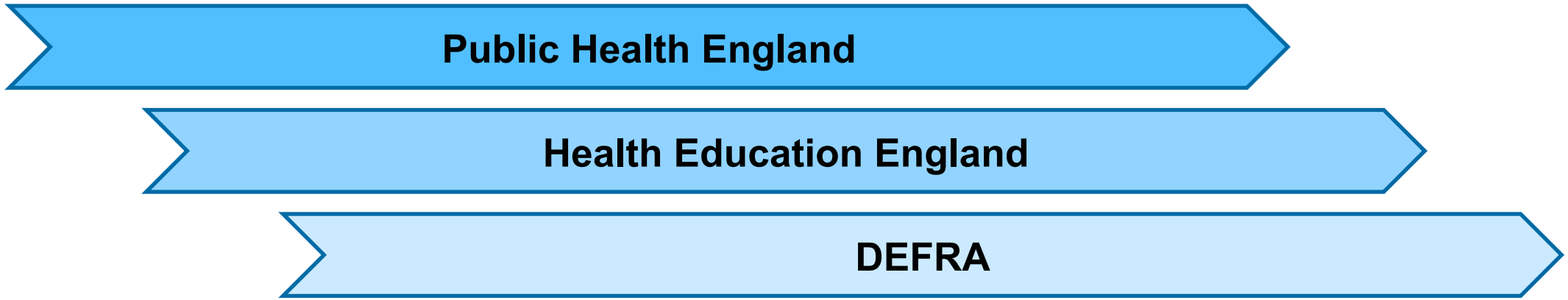
UK AMR Diagnostic Collaborative Programme

NHS England

KEY AREAS OF FOCUS

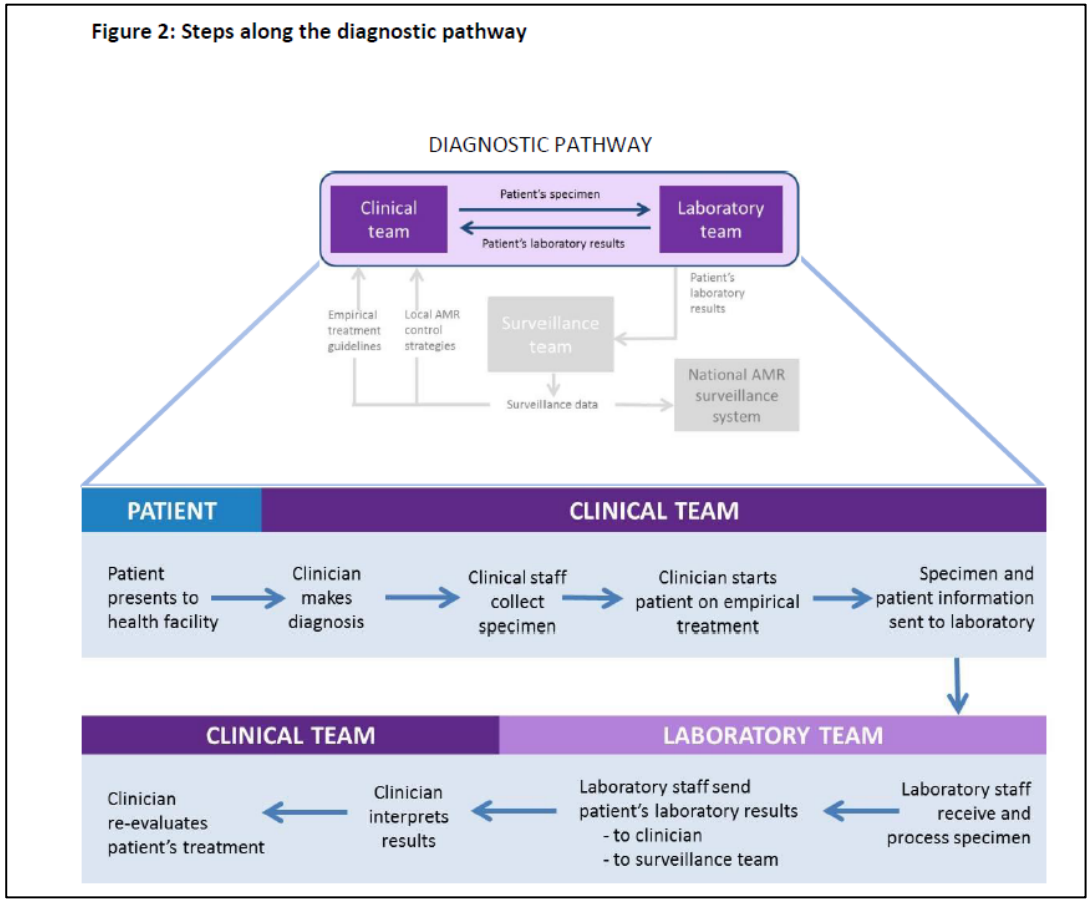


SYSTEM PARTNERS



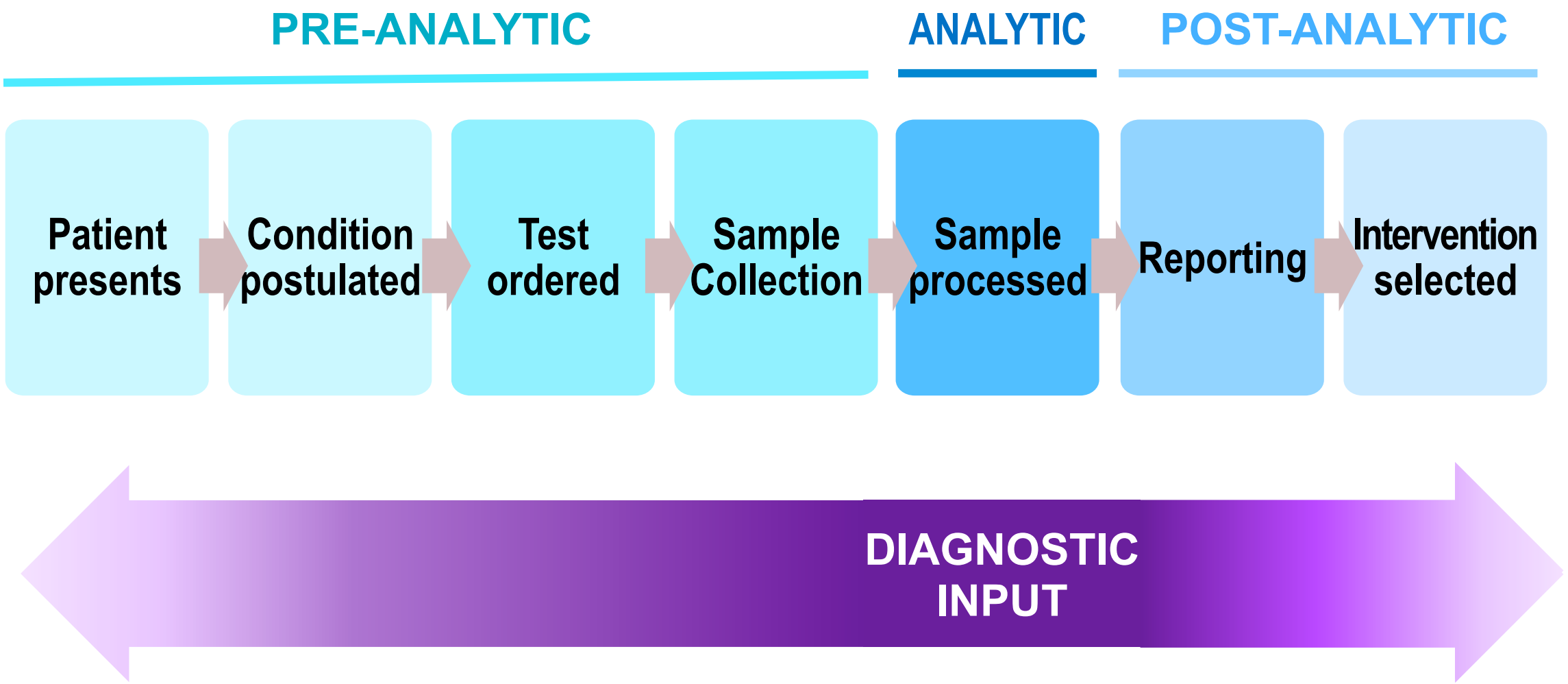
Diagnostic stewardship- definition

- **Co-ordinated professional guidance and interventions** to improve patient care and management through the appropriate use of clinical scoring algorithms, biomarker tests and/or microbiological diagnostics to guide therapeutic decisions.
- It should **promote appropriate, timely diagnostic testing**, including specimen collection, and pathogen identification and accurate, timely reporting of results to guide the treatment of suitable patients.
- It should **discourage unnecessary diagnostic testing** and the use of tests that yield misleading results.
- It should **generate microbiological data**, including accurate and representative AMR surveillance data to inform treatment guidelines, and AMR control strategies, and should be an **integral component** of measures to improve antimicrobial stewardship and infection prevention and control.



WHO 2016: **Diagnostic stewardship**
A guide to implementation in antimicrobial resistance surveillance sites

Laboratory as part of the multi-professional approach

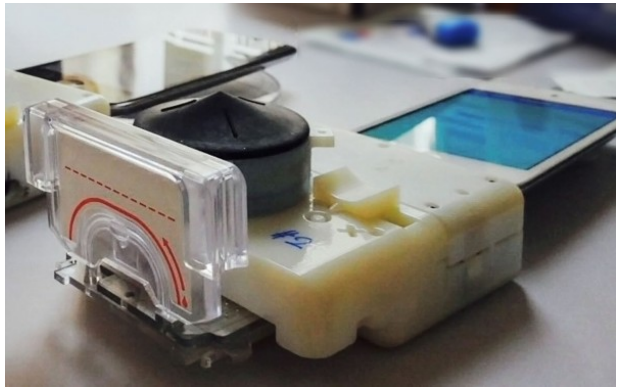


UK AMR DC 18/19 areas of focus -Diagnostic Stewardship

- Use of biomarkers eg CRP/Procalcitonin in acute settings or as POCT in the community
- Quality improvement approach to diagnostics within the sepsis pathway enabling timely review of antibiotic therapy
- Tackling inappropriate use of urinary diagnostics particularly in the frail elderly population #ToDipOrNotToDip

UK wide building on good practise, driving quality improvement and addressing variation

Innovation - opportunities through new diagnostics



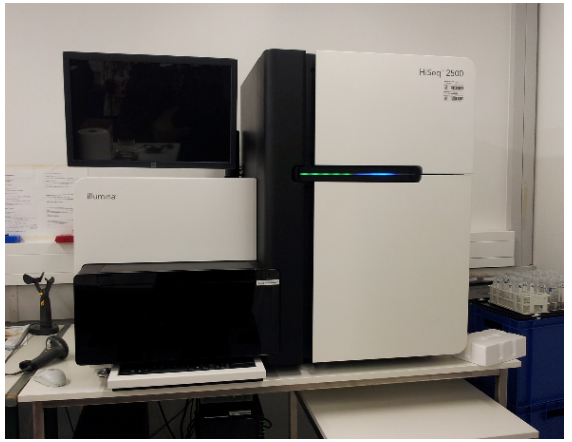
Handheld ‘lab on a chip’

Coupling smartphones with ‘lab on a chip’ technology for tests egg gene arrays
Still at research stage but show great potential

Point of care testing

Well established for indirect technologies such as CRP testing.

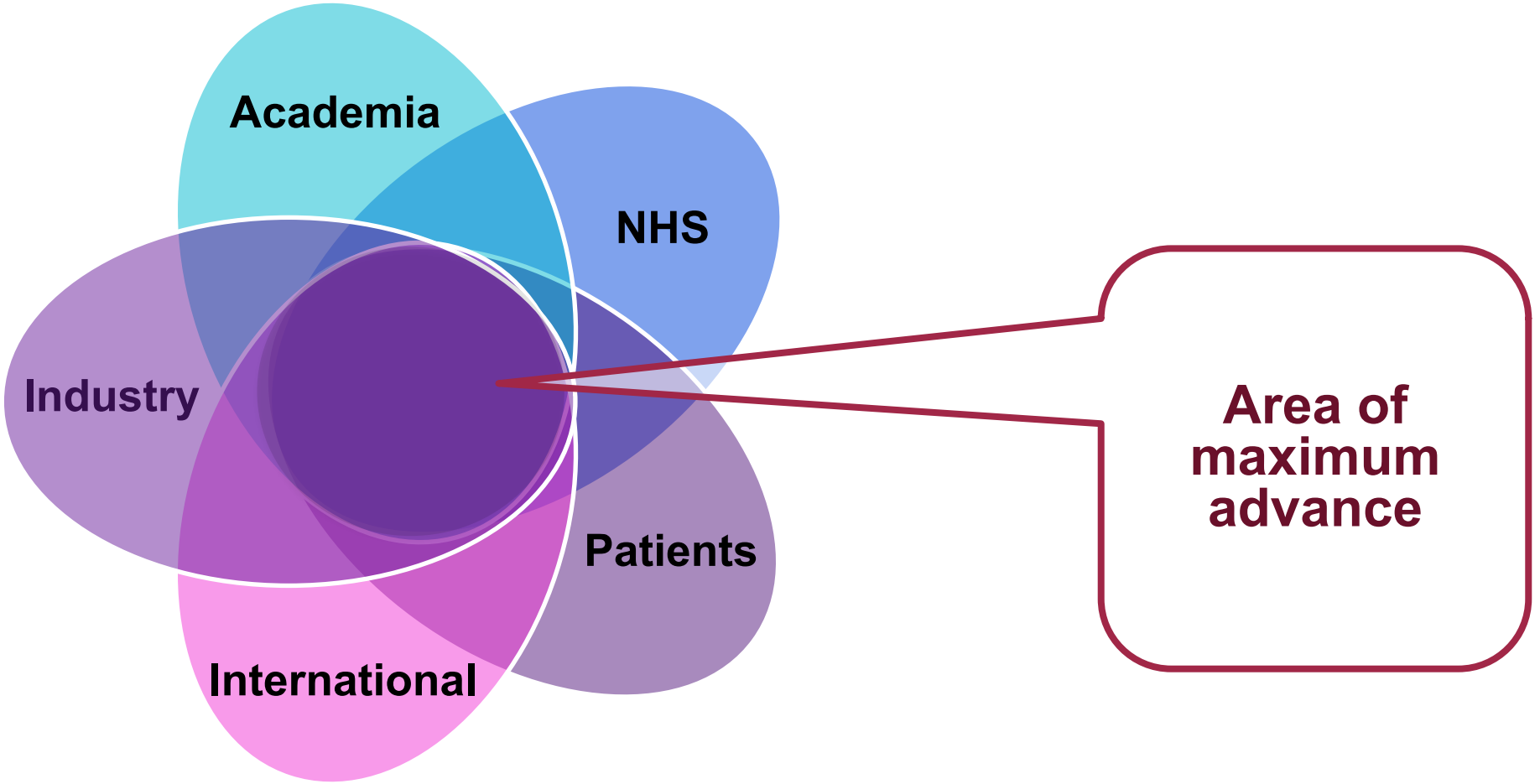
Developments in microarrays offer increased potential for direct testing



High throughput genomic technologies

Delivers rich direct testing, allowing detailed identification & surveillance
Seeing advances in speed of test and reduction in cost

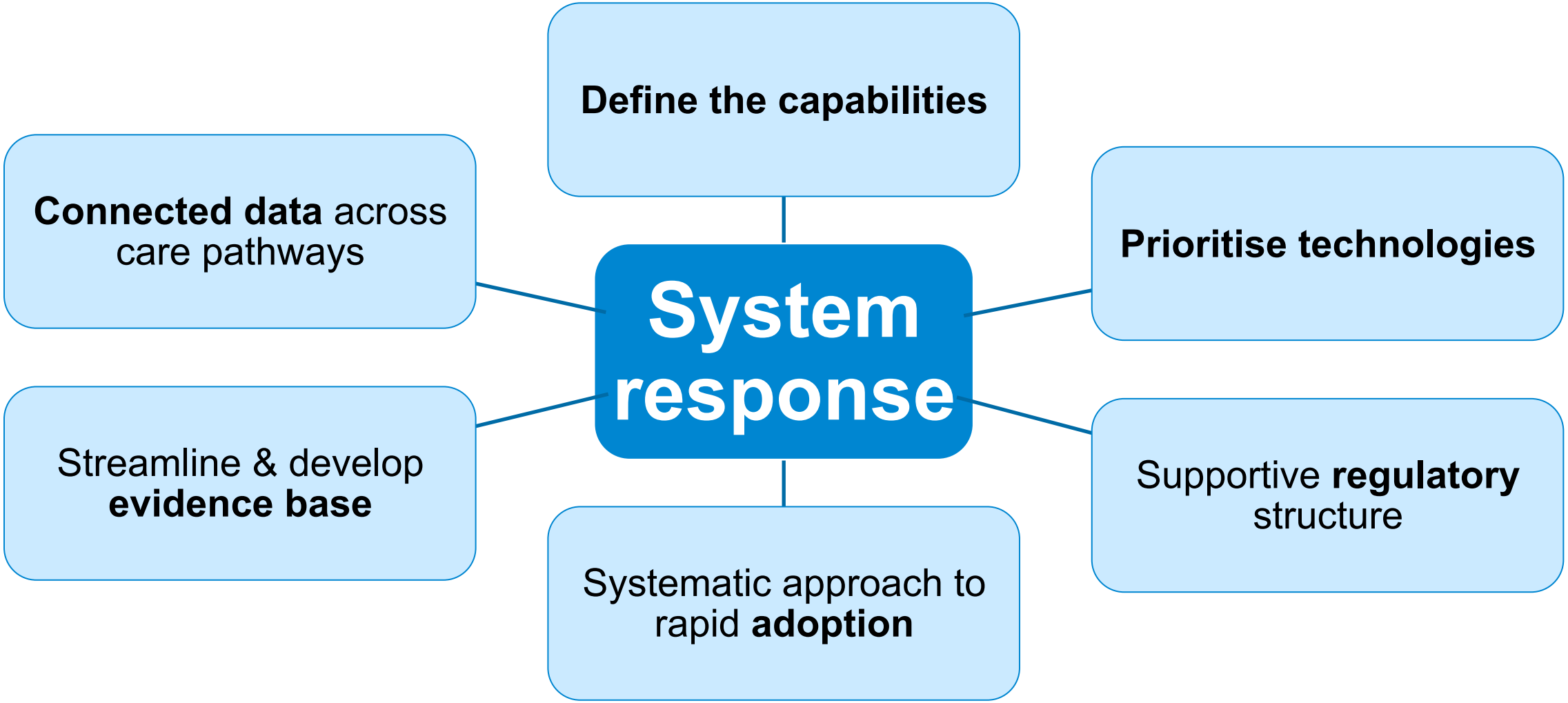
Integration and collaboration is everything



INVENTION → EVALUATION → ADOPTION → DIFFUSION

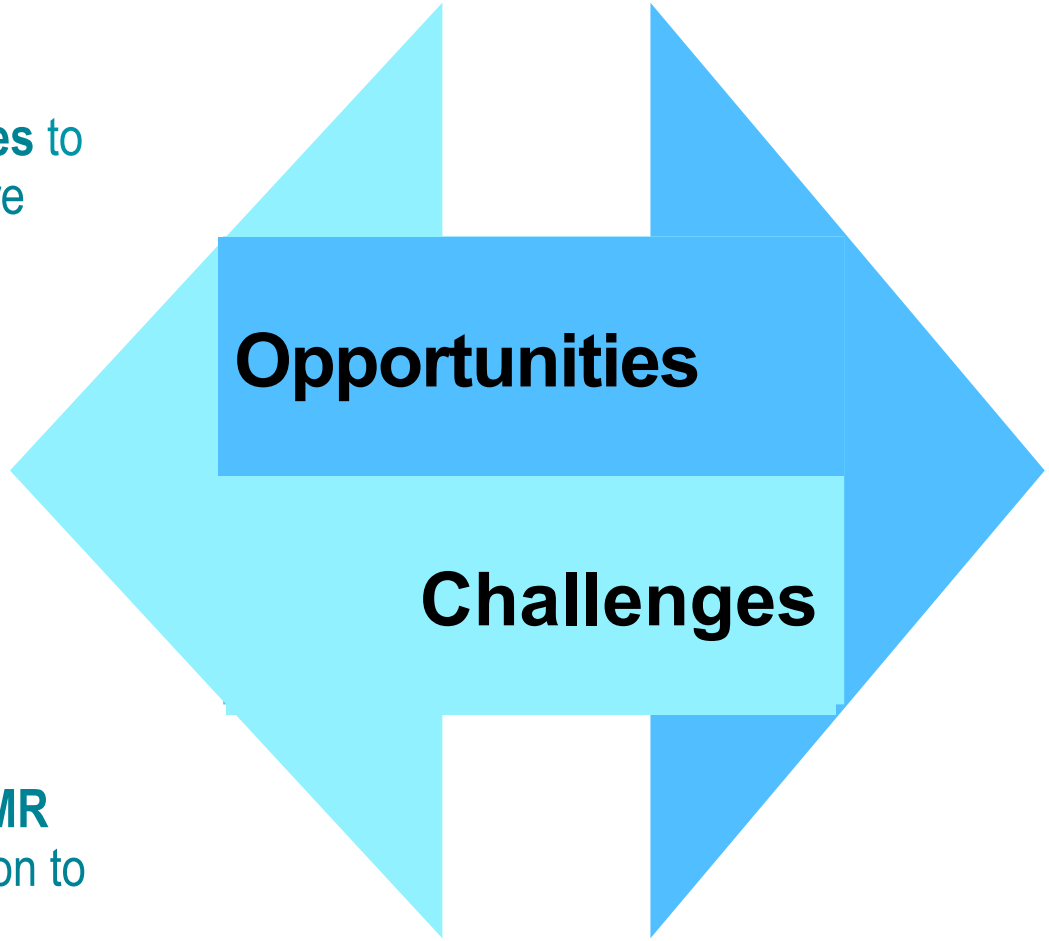
The system must be responsive

The work of the UK AMR diagnostic collaborative is crucial in ensuring that all the right groups and agencies are working together to address these challenges.



The power of diagnostics in AMR: opportunities and challenges

- **Transforming existing pathways and approaches** to support new models of care
- **Unpicking commissioning of diagnostics** to focus incentives
- **Quality of data available** about current use of diagnostics and outcomes
- **Constant evolution of AMR** requiring ongoing innovation to keep up



- **Next-gen diagnostics offer a precise, timely diagnosis** – allowing the use of the right drug in the right place at the right time
- **New settings for diagnostics** utilising point of care testing and multi-professional teams
- **Commissioning levers** such as CQUIN, to drive uptake of new approaches