GOVERNMENT OF WESTERN AUSTRALIA

PathWest
LABORATORY MEDICINE WA

THE UNIVERSITY OF WESTERN AUSTRALIA

In-house deployable tests

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Why point-of-care tests?

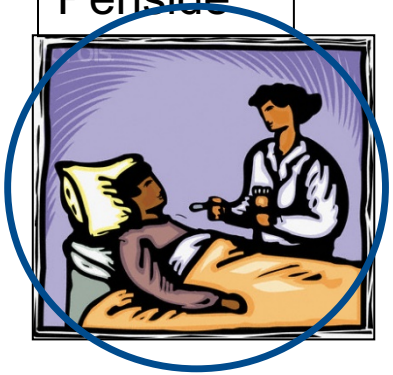
- Advantages
  - Greater accessibility, especially in resource poor and/or remote settings
  - Quicker results – assists with outbreak investigation, early management, isolation/cohorting of patients, avoidance of unnecessary investigations and antibiotic use
  - Possibly reduced test costs
- Disadvantages
  - Test performance - most not good as tests available within laboratories
  - Limited range of tests and inflexibility in test development and modification
  - Lower operator training, skill and depth of knowledge
  - May not have adequate infrastructure support, specimen handling, storage, QA, data accumulation and reporting, scientific expertise
  - Potentially increased test costs – high unit cost, labour intensive, inefficient for high throughput, performed “as well as” rather than “instead of”

Near patient testing for outbreaks of emerging, exotic and rare pathogens

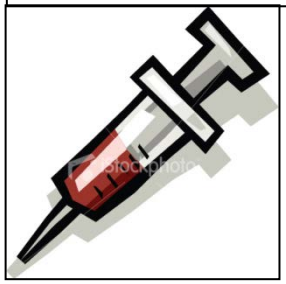
- Early phase of the response require the ability to develop, evaluate and modify tests, i.e. requires in house test development with high levels of expertise
- Once performance requirements are defined, and tests are developed and reliable, then the response is better served by transfer to more user-friendly, lower cost POCTs

Point of Care: At what point do we care?

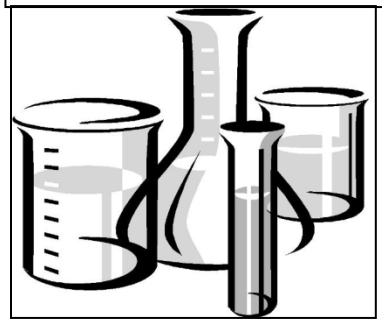
Bedside/
Penside



Collection Centre



Local Laboratory



Reference Laboratory

Complexity

Speed

Adaptability

POC test in the epidemic/pandemic context

- Needed early to allow large volume testing, and to make it accessible to the whole population
- Must be maximally sensitive and as specific as possible
- Early – unlikely to be any existing suitable assays, and preferred targets for assays unlikely to be determined
- Later – transition to test platforms that can be used in a wider range of settings

Deployable Laboratory Response to Influenza Pandemic; PCR Assay Field Trials and Comparison with Reference Methods

Inglis TJJ, Merritt AJ, Levy A, Vietheer P, Bradbury R, et al. (2011) Deployable Laboratory Response to Influenza Pandemic; PCR Assay Field Trials and Comparison with Reference Methods. PLOS ONE 6(10): e25526. https://doi.org/10.1371/journal.pone.0025526

	PoCT	MagMAX-24 extraction StepOne thermal cycler Labeled probe		6-tube hand-held extraction StepOne thermal cycler Labeled probe	
	Nose	Nose	Throat	Nose	Throat
Positive	7	12	11	4	3
Negative	6	0	0	4	2
Equivocal	0	0	1	0	0
Inhibitory	0	0	0	3	5
Not Done	0	0	0	2	3

POCT = point of care test.
doi:10.1371/journal.pone.0025526.t002

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- Conclusions:
  - Rapid in-house development of a deployable epidemic influenza assay allowed a flexible laboratory response
  - It provided the public health laboratory service with a set of verification tools for resource-limited settings.
  - It has the ability to be developed and deployed rapidly

Deployable Molecular Detection of Arboviruses in the Australian Outback

Am. J. Trop. Med. Hyg., 95(3), 2016, pp. 633–638 doi:10.4269/ajtmh.15-0878

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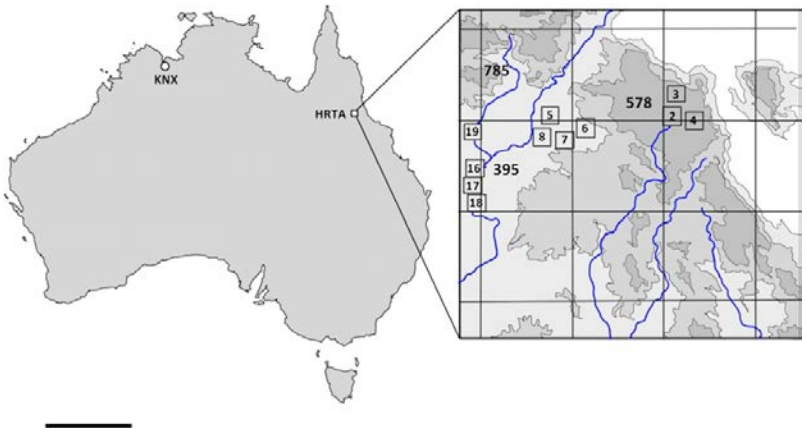

- **We were able to show that these tests can be successfully deployed to detect both alphaviruses and flaviviruses in mosquito populations**
- **Logistic challenges of these remote locations:**
  - Early depletion of critical reagents meant that we could not complete a second round of tests for all arboviruses of interest
  - Lack of a reliable cold chain on the return journey prevented us from undertaking confirmatory testing and sequencing
- **We were therefore unable to confirm the sensitivity of deployed field PCR assays on residual mosquito homogenates and recognize this as a priority for future field assay development.**

Flexibility to meet fitness for purpose