



**ResistancePlus MG Flexible
for the GeneXpert enables
near patient testing of
Mycoplasma genitalium
and macrolide resistance
markers**

Corey Oostendorp

Application Specialist, SpeedX

Disclosures

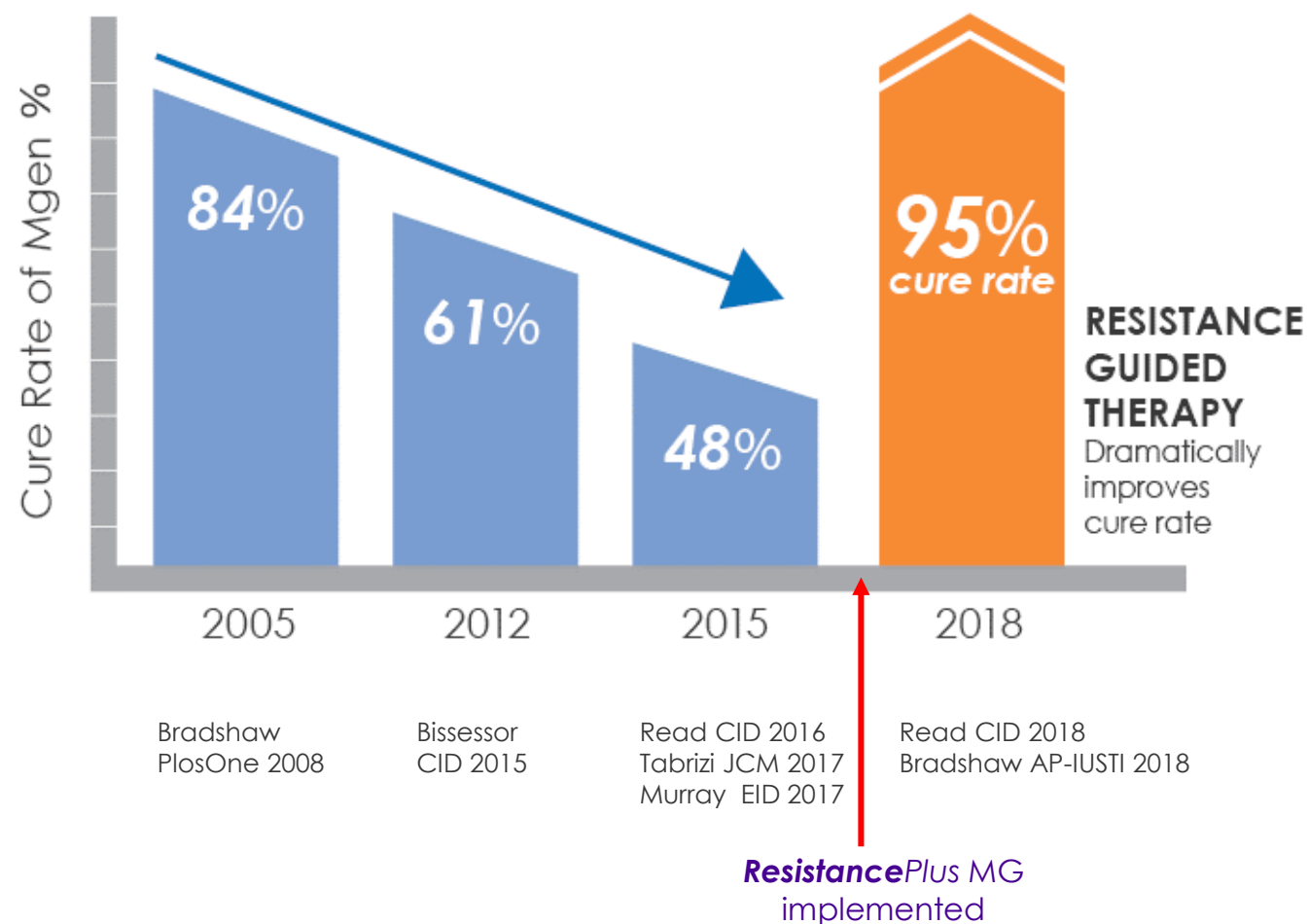
- ▶ Study funded by SpeedX

Background of *Mycoplasma genitalium* (Mgen)

- ▶ Known cause urethritis in men, cervicitis and PID in women
- ▶ Very difficult to culture
- ▶ Increasing resistance to frontline treatment (azithromycin) due to single point mutations on the 23S rRNA gene.
- ▶ A need for resistance-guided therapy over empirical treatment.
- ▶ *ResistancePlus*® MG detects presence of Mgen and also the markers of macrolide resistance.

ResistancePlus® MG - Clinical advantage

Management of Mgen at Melbourne Sexual Health Centre (MSHC), Australia



Current *ResistancePlus*® MG test format

- ▶ Requires sample processing and testing equipment
- ▶ Multiple operator steps
- ▶ Skilled operator needed
- ▶ Sample batching - problematic for low volume labs
- ▶ Samples may need to be sent to centralised labs for external testing
- ▶ Clinics in rural and remote settings can experience delayed results



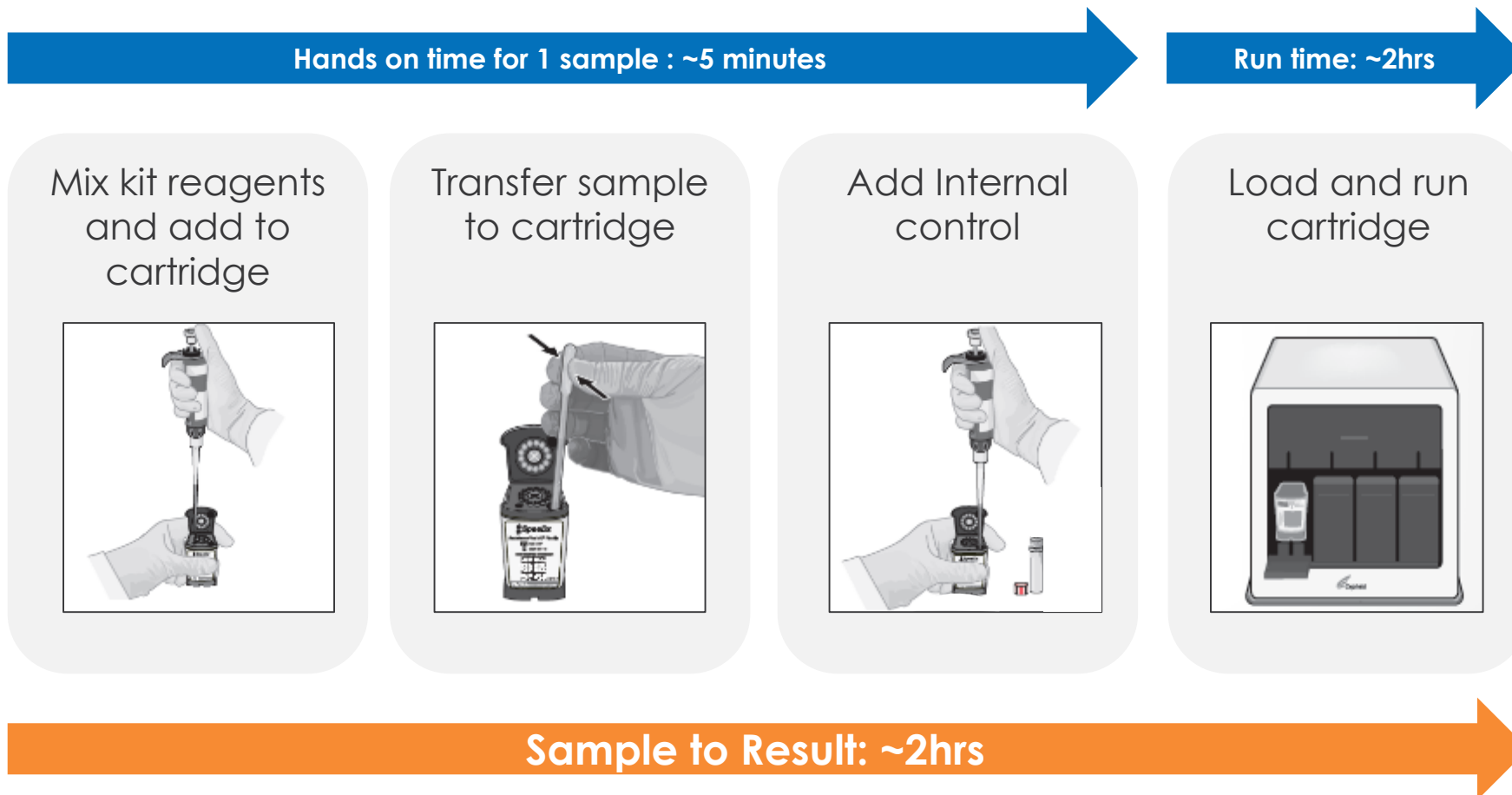
ResistancePlus MG Flexible* test format

- ▶ Sample to answer instrument, only GeneXpert required
- ▶ Minimal operator steps
- ▶ Suitable for less skilled operators
- ▶ Opens up testing to a broader ranges of facilities, from central labs to sexual health clinics



Increased access to Resistance Guided Therapy >
Improved Patient Outcomes

ResistancePlus MG Flexible work flow



ResistancePlus MG Flexible:

Validated sample types and collection devices

▶ Sample types:

- Urine
- Urethral swab
- Vaginal swab
- Cervical swab
- Rectal swab

▶ Validated Collection devices:

- Xpert® Vaginal/Endocervical Specimen Collection kit (Cepheid)
- Xpert® Urine Specimen Collection Kit (Cepheid)
- Regular FLOQSwab™ in 3 ml of UTM™ media (Copan)
- Neat urine
- cobas PCR media

Mgen diagnostics: Translational research to guided therapy

A/Prof. S. Tabrizi
 Approached SpeedX
 to design IVD for
 Mgen + resistance



Europe
 Resistance testing
 recommended -
 if available



UK
 Recommends Resistance
 Guided Therapy
 (based on Australia)



TGA & CE
ResistancePlus MG
 Flexible



Licensing technology
 Licensing and
 designing highly
 multiplex SNP
 assays for our
 partners

IVD manufacturer
 Switch to
 producing
 SpeedX
 products



TGA & CE
ResistancePlus MG
 launched



Australia
 Resistance Guided
 Therapy:
 Treat based on
 resistance result



France
 Recommends
 Resistance
 Guided
 Therapy



THE UNIVERSITY
OF QUEENSLAND
AUSTRALIA

CREATE CHANGE

Evaluation of the *ResistancePlus* MG FleXible for the GeneXpert

Dr Emma Sweeney

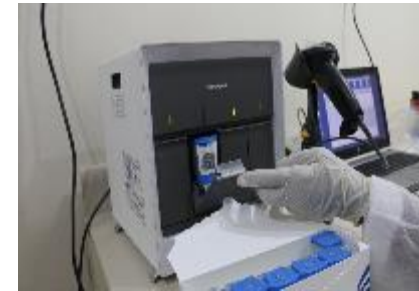
Postdoctoral Researcher

The University of Queensland Centre for Clinical Research

About the test set-up

- Three simple steps to generate results:
 - Prepare PCR master mix in a clean environment
 - Add 1 mL of sample (urine or swab in cobas PCR media), PCR master mix and internal control to the cartridge
 - Add cartridge to GeneXpert → begin reaction

Turnaround time: approx. 2 hours from adding the sample, to generation of report: hands-off workflow



Evaluation of *ResistancePlus* MG Flexible

Evaluation performed at UQ-CCR, Brisbane using a bank of 181 clinical samples

63 *M. genitalium* positive samples

119 *M. genitalium* negative samples

Samples chosen based on availability of both original patient sample and nucleic acid extract from the sample

All samples tested using:

- In-house PCR assay to detect *MgPa* gene of *M. genitalium* (performed by local pathology provider)
- Speedx **ResistancePlus MG** (TGA-approved PCR assay detecting *M. genitalium* and macrolide resistance mutations)
- Speedx **ResistancePlus MG Flexible** (near point of care test on GeneXpert)

Evaluation of *ResistancePlus* MG FleXible

Results summary:

No. of samples	Gender (M/F)	Sample type (number)	In-house <i>MgPa</i> PCR	<i>ResistancePlus</i> MG	<i>ResistancePlus</i> MG FleXible
7	F	Cervical (3), Vaginal (1), Urine (3)	DETECTED	MG DETECTED. 23S rRNA mutations DETECTED.	MG DETECTED. 23S rRNA mutations DETECTED.
36	M	Urine (31), Rectal (3), Urethral (2)	DETECTED	MG DETECTED. 23S rRNA mutations DETECTED.	MG DETECTED. 23S rRNA mutations DETECTED.
5	F	Cervical (2), Vaginal (2), Urine (1)	DETECTED	MG DETECTED. 23S rRNA mutations not detected.	MG DETECTED. 23S rRNA mutations not detected.
13	M	Urine (11), Rectal Swab (2)	DETECTED	MG DETECTED. 23S rRNA mutations not detected.	MG DETECTED. 23S rRNA mutations not detected.
2	M	Urine (1), Rectal Swab (1)	DETECTED	MG DETECTED. 23S rRNA mutations not detected.	Mg not detected. 23S rRNA mutations not detected.
92	M	Urine (85), Rectal Swab (6) Genital Swab (1)	nd	Mg not detected. 23S rRNA mutations not detected.	Mg not detected. 23S rRNA mutations not detected.
24	F	Cervical (4), Vaginal (2), Urine (16), Rectal (2)	nd	Mg not detected. 23S rRNA mutations not detected.	Mg not detected. 23S rRNA mutations not detected.
2	M	Rectal Swab (1), Urine (1)	nd	Mg not detected 23S rRNA mutations not detected.	Invalid

nd = not detected

- 61/63 *M. genitalium* positive samples were correctly characterised in all assays
 - Sensitivity = 96.8%
- All *M. genitalium* negative samples were correctly characterised in all assays
 - Specificity = 100.0%

Evaluation of *ResistancePlus* MG Flexible

Results summary:

No. of samples	Gender (M/F)	Sample type (number)	In-house <i>MgPa</i> PCR	<i>ResistancePlus</i> MG	<i>ResistancePlus</i> MG Flexible
7	F	Cervical (3), Vaginal (1), Urine (3)	DETECTED	MG DETECTED. 23S rRNA mutations DETECTED.	MG DETECTED. 23S rRNA mutations DETECTED.
36	M	Urine (31), Rectal (3), Urethral (2)	DETECTED	MG DETECTED. 23S rRNA mutations DETECTED.	MG DETECTED. 23S rRNA mutations DETECTED.
5	F	Cervical (2), Vaginal (2), Urine (1)	DETECTED	MG DETECTED. 23S rRNA mutations not detected.	MG DETECTED. 23S rRNA mutations not detected.
13	M	Urine (11), Rectal Swab (2)	DETECTED	MG DETECTED. 23S rRNA mutations not detected.	MG DETECTED. 23S rRNA mutations not detected.
2	M	Urine (1), Rectal Swab (1)	DETECTED	MG DETECTED. 23S rRNA mutations not detected.	Mg not detected. 23S rRNA mutations not detected.
92	M	Urine (85), Rectal Swab (6) Genital Swab (1)	nd	Mg not detected. 23S rRNA mutations not detected.	Mg not detected. 23S rRNA mutations not detected.
24	F	Cervical (4), Vaginal (2), Urine (16), Rectal (2)	nd	Mg not detected. 23S rRNA mutations not detected.	Mg not detected. 23S rRNA mutations not detected.
2	M	Rectal Swab (1), Urine (1)	nd	Mg not detected 23S rRNA mutations not detected.	Invalid

nd = not detected

Two samples had discrepant results:

Urine sample & rectal samples. Both had low *M. genitalium* loads, as evidenced by amplification values in *ResistancePlus* MG PCR assay

Rectal sample had < 1 mL starting volume, likely contributing to the discrepancy

Evaluation of *ResistancePlus* MG Flexible

Assessment of Limit of Detection of both *ResistancePlus* MG and *ResistancePlus* MG Flexible

A known *M. genitalium* positive sample (with macrolide resistance mutations) with defined, high, amplification values was chosen

Serial 10-fold dilutions of sample performed in known *M. genitalium* negative urine

Samples tested on *ResistancePlus* MG and *ResistancePlus* MG Flexible

***ResistancePlus* MG Flexible** was able to reliably detect an additional dilution over the *ResistancePlus* MG PCR assay

Conclusion

The ***ResistancePlus MG Flexible*** cartridge was highly sensitive and specific for the detection of *M. genitalium* and macrolide resistance mutations

Moving diagnostic testing closer to the point of care will empower clinicians to make rapid, informed decisions regarding diagnosis and treatment of *M. genitalium* infections, which will enhance antimicrobial stewardship

Acknowledgements

Supervisor: A/Prof David Whiley

- Microbial diagnostics and characterisation group
 - Lebo Mhango

@MicroDx_UQ 

Pathology Queensland

- Prof Graeme Nimmo
- Dr Cheryl Bletchly
- Fleur Francis

SpeedX

Funding of consumables and reagents

- Dr Tina Lonergan
- Rachel Wee
- Akanksha Arvind
- Dr Litty Tan

