Melbourne Genomics
Health Alliance

Genomics and Your Hospital: a toolkit

Prof Clara Gaff and A/Prof Cate Kelly

November 2024

Alliance members

The Royal Melbourne Hospital
The Royal Children's Hospital Melbourne
The University of Melbourne
WEHI brighter together
murdoch children's research institute
CSIRO
agrf
Peter Mac Peter MacCallum Cancer Centre Victoria Australia
Austin Health
Monash Health

Supported by

Victoria State Government

Acknowledgement of Country

We acknowledge the Traditional Custodians of the unceded land on which BCEC stands.

And we acknowledge the Wurundjeri people of the Kulin Nation, on whose lands we work and live. We pay respect to Elders past and present.

And we acknowledge First Nations health professionals, researchers and leaders who are leading, contributing to and shaping the future of health care.

What we'll cover

About us

01

02

Our landscape

Our co-design process

Learnings and development

03

04

Introducing the near-final toolkit

Next steps

Broader reflections

05

Please note publication pending so please avoid widely disseminating. Thank you!

Melbourne Genomics Health Alliance 2013-25

Vision
Equitable, evidence-based use of genomics in the Victorian healthcare system.

Unincorporated Joint Venture

The Royal Melbourne Hospital
The Royal Children's Hospital Melbourne
The University of Melbourne
WEHI brighter together
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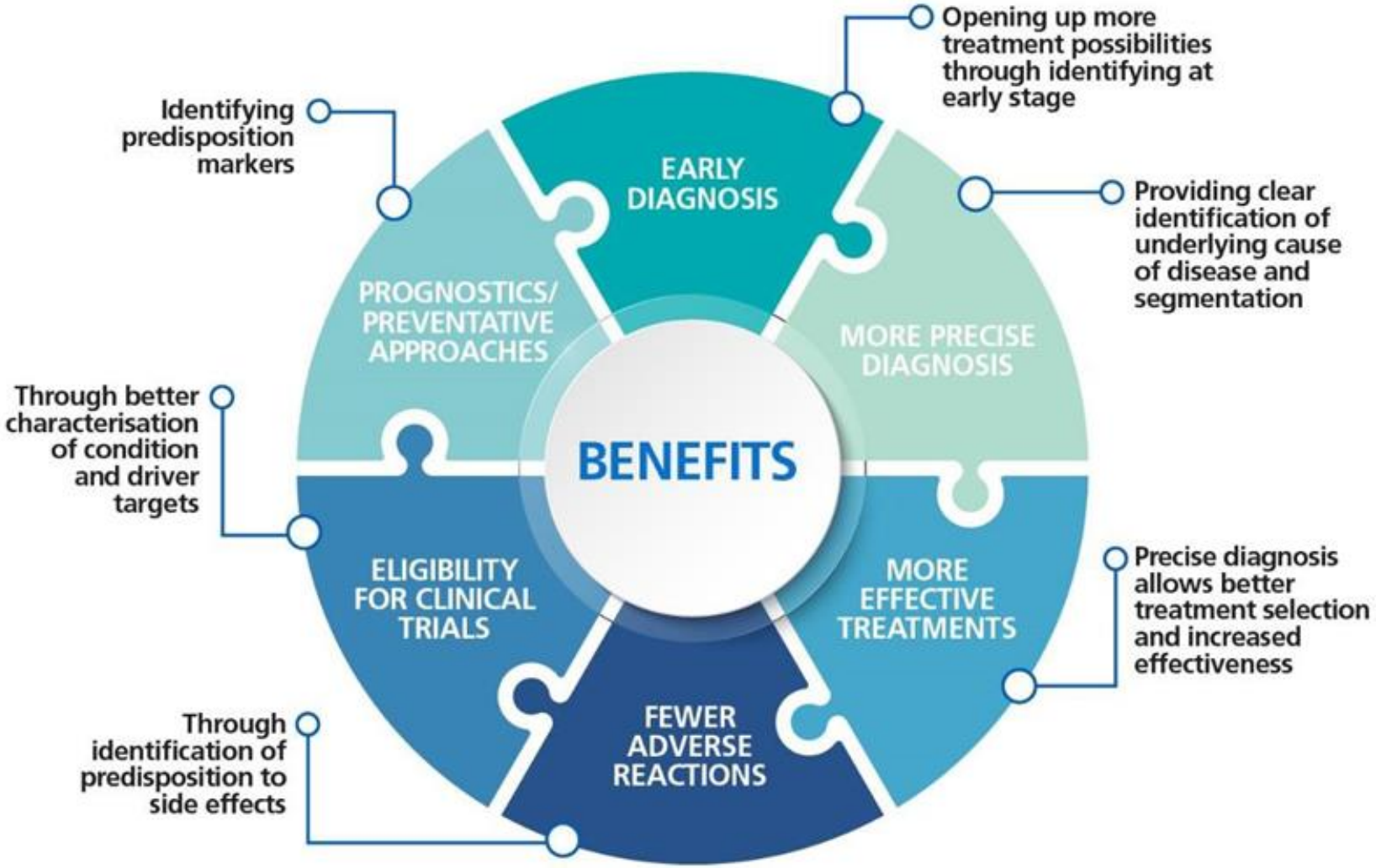
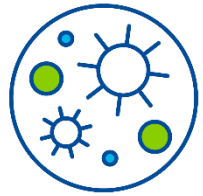
What is genomic medicine?



Rare genetic and complex diseases

Cancer



Microbial

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NHS England » Genomics strategy Genomics and Medicine (genome.gov)
NHS England » Accelerating genomic medicine in the NHS

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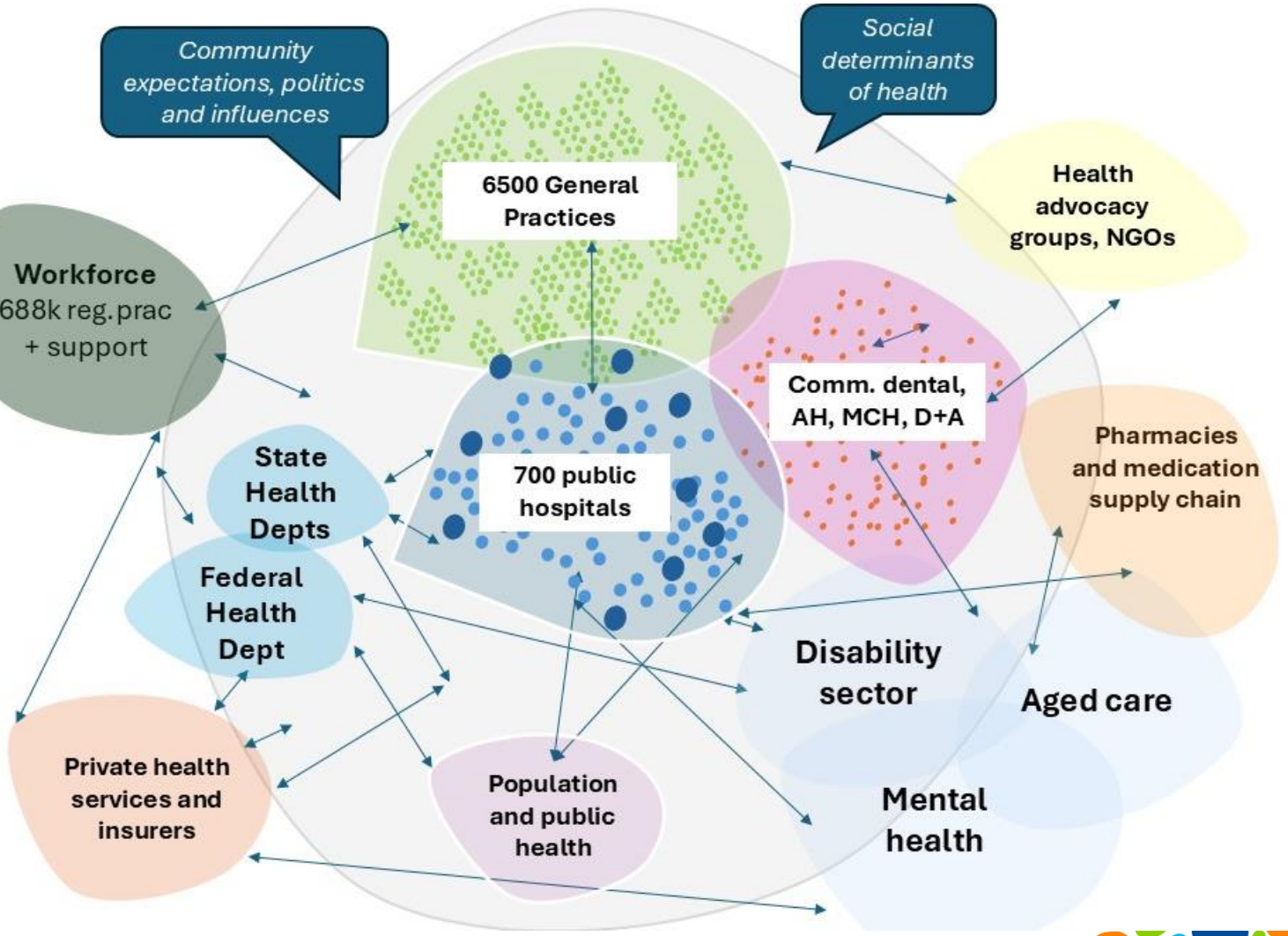
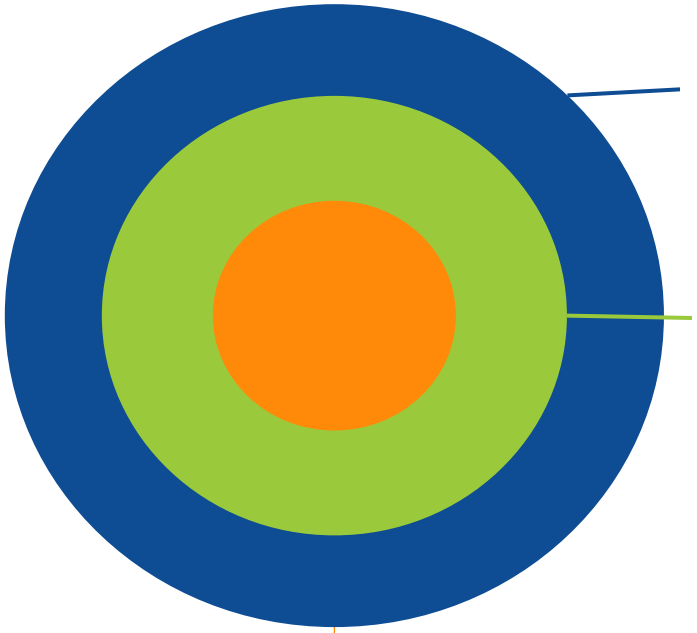
Our landscape

We want to achieve change in a *complex adaptive system*



AND…there are different LEVELS in a system



MACRO → Society as a whole (e.g., political, economic, social factors)

MESO → Parts of the society e.g. orgs, groups, communities

MICRO → Actions of individuals

Javaid A, Javed A, Kohda Y. Exploring the role of boundary spanning towards service ecosystem expansion: A case of Careem in Pakistan. Sustainability. 2019;11(15):3996. https://www.cambridge.org/core/elements/governance-and-leadership/9FBFA3C48A57CCB5B97F5899895D011D

What does this look like in healthcare?

- Layers intersect and intertwined
- Understanding the interactions critical

https://www.cambridge.org/core/elements/governance-and-leadership/9FBFA3C48A57CCB5B97F5899895D011D

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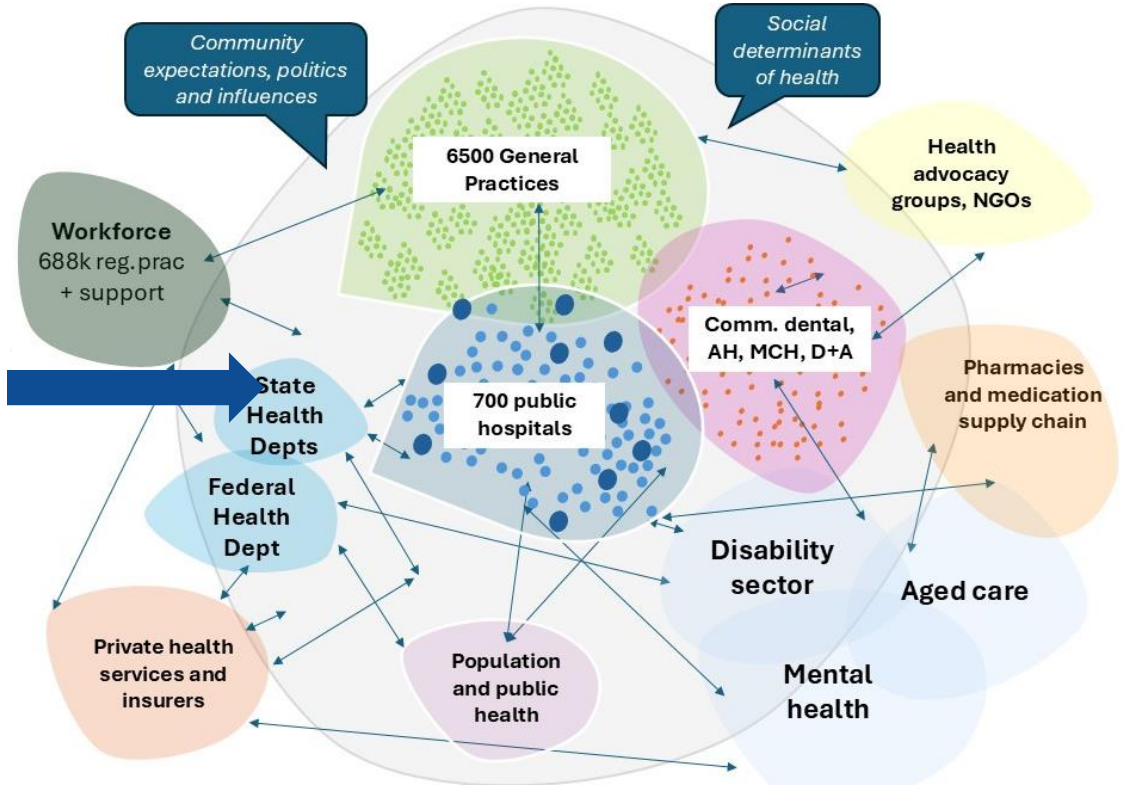
So where does genomic medicine fit in there?

Macro
- Fed DOH
- Australian Genomics

Meso
- State DOH
- Health services & hospitals

Micro
- Clinical genetics services
- Individual clinicians

?



Genomic medicine overall in Australia:
- Good evidence base for a range of tests with an expected ↑ in use
- Excellent national and international policy environment, research
- Ltd evidence of meso needs , barriers and enablers

Gap at meso level, supporting health services operationalise policy and research translation.

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The potential gap / need

- How can we support the meso level, particularly hospitals, to safely, appropriately and effectively implement genomics?

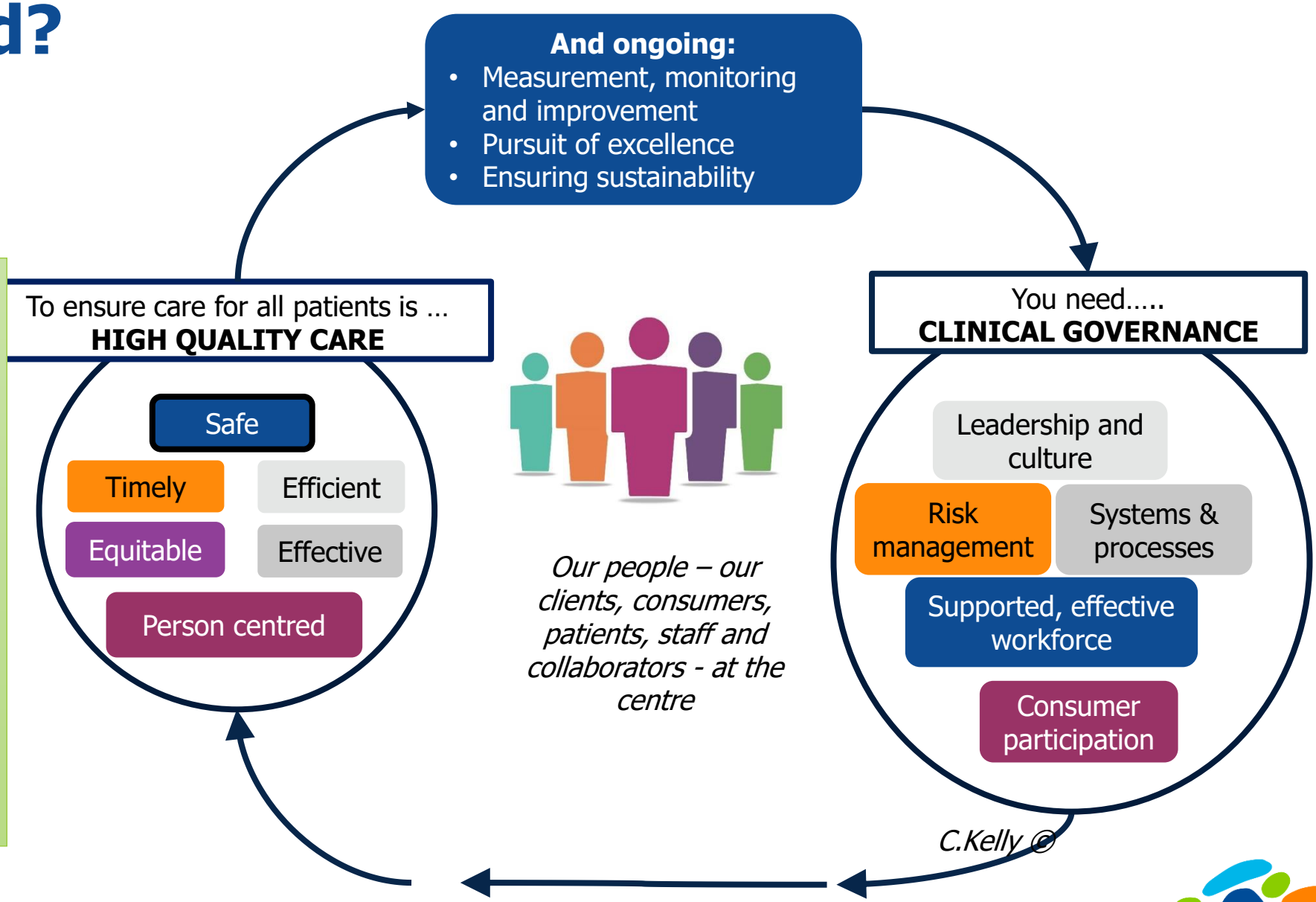
- **Our goal:**
  - Every Victorian health service has systems in place to support their patients to get high-quality genomic care – either onsite or via the right referral pathways.

- **Our concept:**
  - Create resources to support Victorian health services to govern a implement genomic care so that the care is safe, effective and value-based.

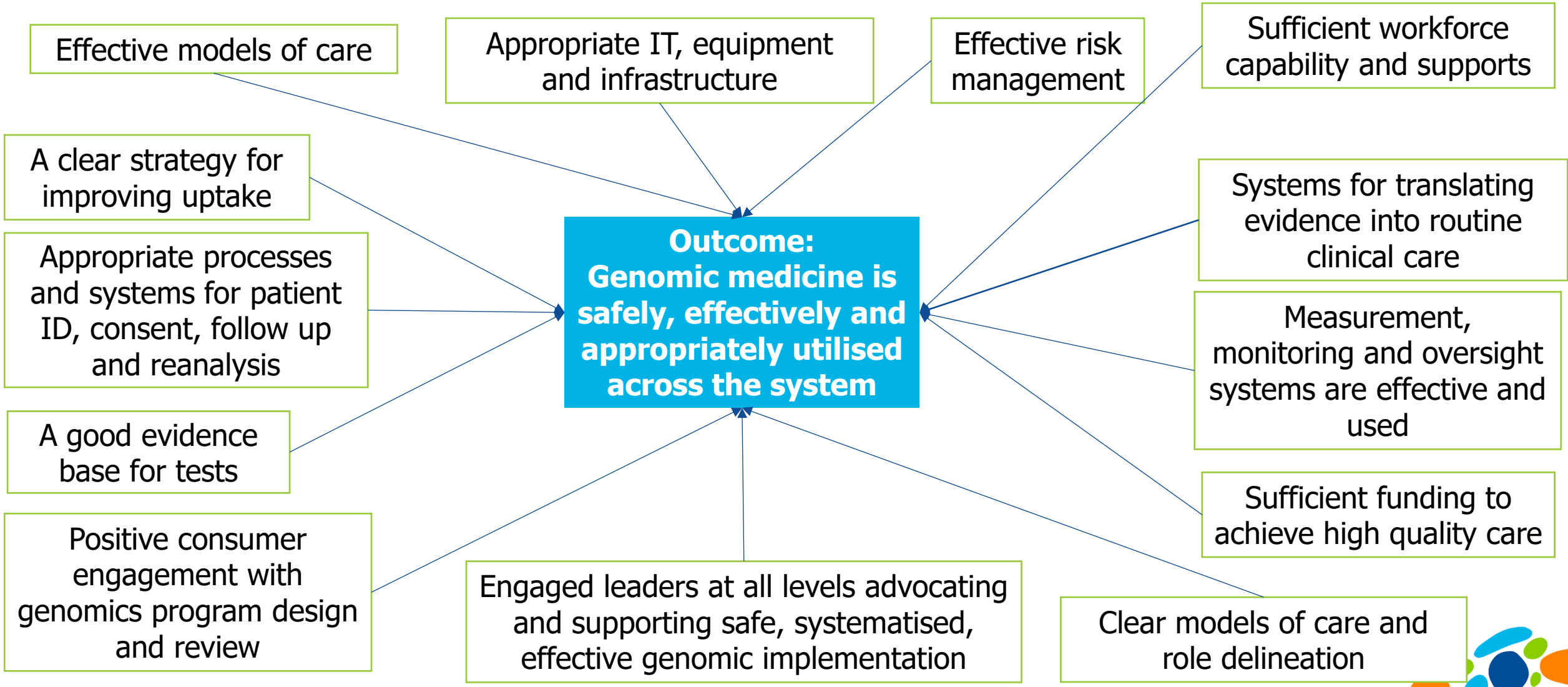
What is required? What already exists?

Our initial challenge:
- How can we support hospitals to safely and effectively implement genomics?

Our planned approach:
- Use Clinical Governance to address the complex MF requirements in a structured, holistic way to ensure genomic care is safely, effectively and appropriately utilised across the system.



To implement high quality genomic care, multifaceted, integrated change is needed across the system.



Using clinical governance to achieve safe and effective implementation of genomic medicine

Leadership and culture:

- Organisational commitment to genomic medicine including strategy/ implementation plan and resourcing
- Organisational coordination of the different components
- Visible leadership of genomic medicine
- Communication to staff about importance and focus

Systems and processes

- An understanding of the end-to-end processes, who is responsible and the escalation path at each step
- Clear SOPs (including training in these and assessment of effectiveness)

Continuous measurement monitoring and improvement

- A system for measuring and monitoring achievement of activities and impact
- High quality data and analytics that are used to inform decision making

Consumer participation

- A culture of deep patient engagement in genomic medicine
- Adequate resources to support active participation in a consumers care
- Systems to hear feedback from consumers about genomic medicine related issues

Supported, effective workforce

- Trained staff
- Sufficient staffing to be able to compete the tasks
- Role clarity and clear accountabilities for each role

Risk management

- A risk register and system for responding to adverse events
- An understanding of risks at each step and our proposed mitigation steps

Genomics doesn’t quite fit the CG / "New tech" model

- Rapidly updating and emerging evidence, often small cohorts
- Multiple specialties delivering care, and new, evolving workforce skill requirements
- ‘Patients’ can include families
- Large, complex, sensitive datasets in context of community concern about use of genomic data
- Potential for future reanalysis of genomic data

And through our work over last 10y we have also found some additional "System in practice" challenges

Healthcare leaders

Lack of bandwidth for non-urgent activity

Funding challenges

Perceptions that its:

- too technical
- too niche
- Belongs in research

Clinicians

We are already doing it, our care is great, we know what we are doing, there's no need to change / add anything.

It's not relevant to my clinical care

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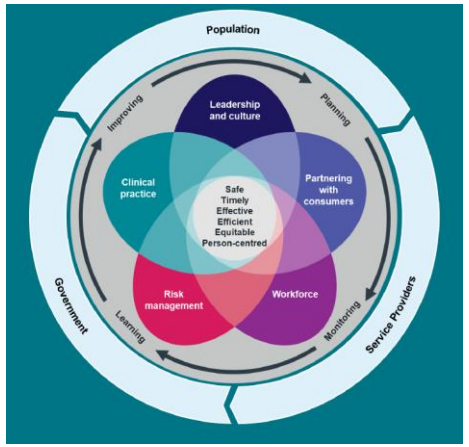
Our co-design process

Co-designing a solution

01

Research

Scoping review for comparable frameworks.



Initial draft of CAT

02

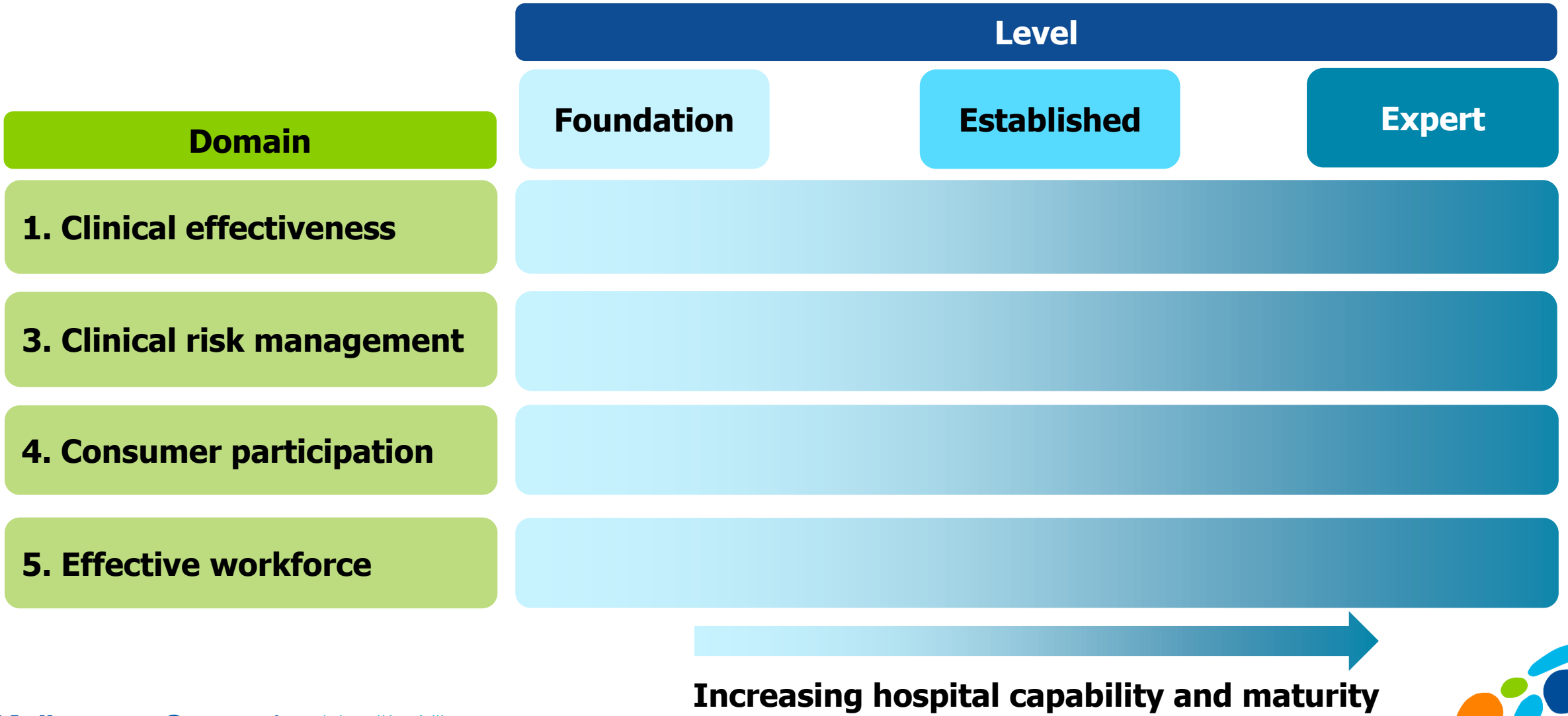
The Capability Assessment Tool (CAT)

- Review of CGF to consider and agree what is <u>specifically relevant to genomic medicine</u>
- Development of a series of self- assessment points based on those genomics specific elements

Ongoing updates and feedback from member hospitals staff (HIRG and other)

https://www.safercare.vic.gov.au/sites/default/files/2024-08/Victorian%20Clinical%20Governance%20Framework.pdf

The Capability Assessment Tool (CAT)



Domains of the capability assessment tool

Clinical effectiveness

- Benchmarking and monitoring processes
- Effective service model
- Evidence for effectiveness in patient population
- Initial determination and ongoing review of local appropriateness
- Innovation and improvement processes

Clinical risk management

- Clinical process review agreement and monitoring
- Data governance
- Monitoring and managing outcomes
- Organisational assessment of risk

Effective workforce

- Availability of appropriate expertise
- Clear accountabilities
- Workforce aligned to clinical service needs
- Leadership and culture

Consumer participation

- Consumer input into program design
- Consumer input into reviewing A/E
- Patient resources

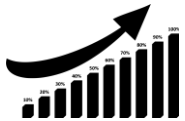
Clinical effectiveness e.g.

- Effective service model
  - Does your hospital have guidance outlining the local model of care e.g.: triaging, consent, results return, long term follow up of results (e.g., in the face of later emerging evidence), family discussion management and referral decision points and processes

Principles of the CAT

Supportive guidance for interested health services to achieve outcomes. Processes can and should be specific to each hospital.

Balances innovation, safety and effectiveness



Dynamic resources that will change and evolve with use and as the field develops

User friendly and makes the right thing to do the easiest

Aligns with broader clinical governance principles and does not replicate existing frameworks/resources

Co-designing a solution

01

Research

Lit review for comparable frameworks.

Initial draft of CAT

02

03

Second iteration

Self-assessment tool for hospitals mapped to clinical governance domains.

04

Codesign touchpoint (1)

- Concept testing of a genomics specific CG framework.
- Workshop with healthcare leaders and consumer advocates.

Codesign touchpoint (2)

- Two expert working groups convened to develop specific detailed content.
- Community Advisory Group took carriage of consumer resource.

Codesign touchpoint (3) Useability testing

- Five hospitals tested the tool. Identified key benefits and aspects to improve.

Ongoing updates and feedback from member hospitals staff (HIRG and other)

Second iteration

- Refined content based on workshop feedback
- Worked to improve readability and useability
- Initiated working groups
- Determined approach to useability testing
- Engagement with Health Ec
- CAG oversight of consumer components

The working groups

Measuring Quality

- How will we know our genomic medicine care is **safe, effective and value-based**? (What can we measure?)

Professional Governance

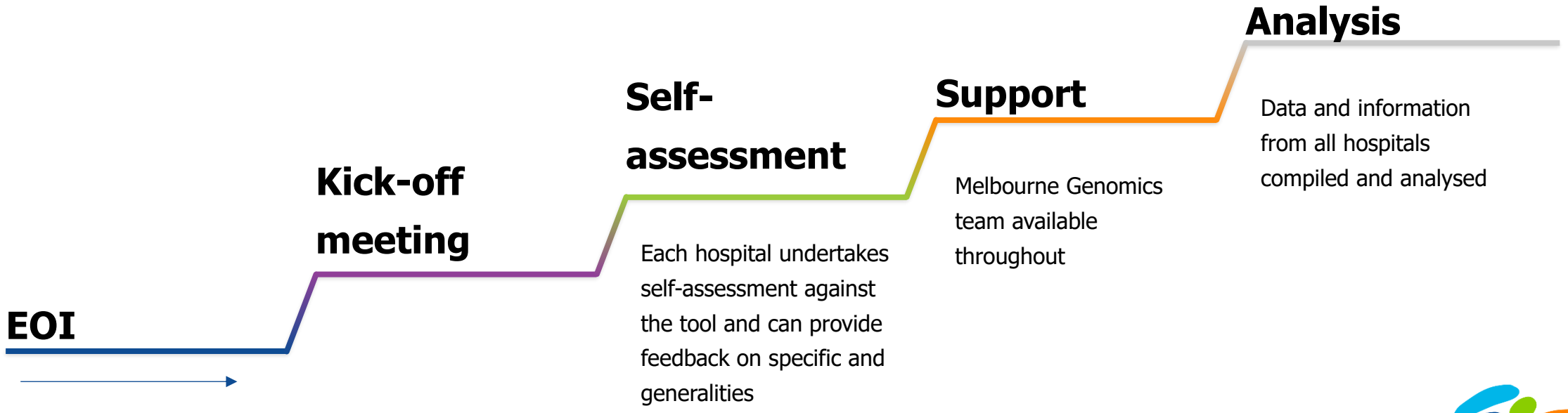
- What controls might health services need to support clinicians to practice safely and within their scope of experience, knowledge and skills.

Useability testing

Purpose:

- How useful is the tool currently to hospitals?
- How can we make the tool most valuable and useful to hospitals?

Approach:



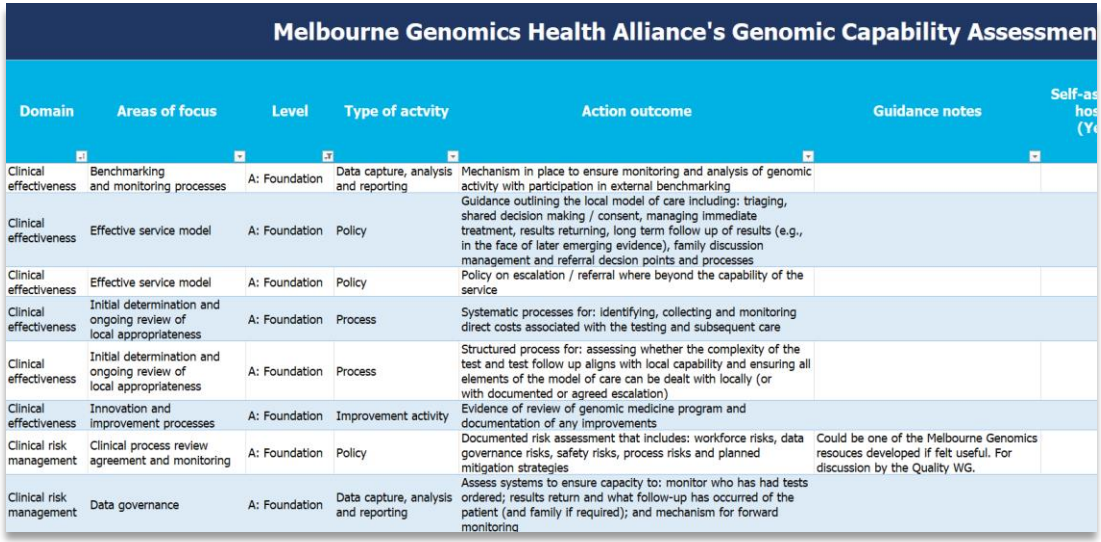
Useability testing findings

5 Hospitals participated:

- 3 metro, 1 rural and 1 regional

Feedback from participants:

- Content was relevant and important
- Difficult to perform hospital-wide assessment due to variability and lack of existing collective approaches
- Tool at times too detailed and repetitive
- It wasn't always clear where hospital should prioritise efforts
- Getting clinicians and hospital leaders together to talk genomics was a highly valued outcome that required shared space, time and language



Melbourne Genomics Health Alliance's Genomic Capability Assessmen

Domain	Areas of focus	Level	Type of actvity	Action outcome	Guidance notes	Self-as hos (Y
Clinical effectiveness	Benchmarking and monitoring processes	A: Foundation	Data capture, analysis and reporting	Mechanism in place to ensure monitoring and analysis of genomic activity with participation in external benchmarking		
Clinical effectiveness	Effective service model	A: Foundation	Policy	Guidance outlining the local model of care including: triaging, shared decision making / consent, managing immediate treatment, results returning, long term follow up of results (e.g., in the face of later emerging evidence), family discussion management and referral decision points and processes		
Clinical effectiveness	Effective service model	A: Foundation	Policy	Policy on escalation / referral where beyond the capability of the service		
Clinical effectiveness	Initial determination and ongoing review of local appropriateness	A: Foundation	Process	Systematic processes for: identifying, collecting and monitoring direct costs associated with the testing and subsequent care		
Clinical effectiveness	Initial determination and ongoing review of local appropriateness	A: Foundation	Process	Structured process for: assessing whether the complexity of the test and test follow up aligns with local capability and ensuring all elements of the model of care can be dealt with locally (or with documented or agreed escalation)		
Clinical effectiveness	Innovation and improvement processes	A: Foundation	Improvement activity	Evidence of review of genomic medicine program and documentation of any improvements		
Clinical risk management	Clinical process review agreement and monitoring	A: Foundation	Policy	Documented risk assessment that includes: workforce risks, data governance risks, safety risks, process risks and planned mitigation strategies	Could be one of the Melbourne Genomics resouces developed if felt useful. For discussion by the Quality WG.	
Clinical risk management	Data governance	A: Foundation	Data capture, analysis and reporting	Assess systems to ensure capacity to: monitor who has had tests ordered; results return and what follow-up has occurred of the patient (and family if required); and mechanism for forward monitoring		

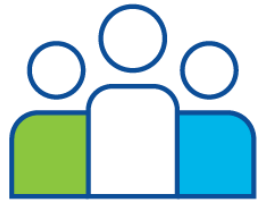
Our observations…

Useability testing findings (addit)

In all health services, including those where individual clinicians and departments were substantially advanced in their genomics journey:

There was a lack of organisational coordination, planning and monitoring of genomic care.

There was a mismatch of understanding around topics such as clinical risk



The breadth of participants in the kick off meetings had not had the chance to come together with a focused, shared agenda on genomic care.

Our response…

Our response:

Updated resources need to:

- Continue to provide support for strengthening genomics CG systems
- Provide more specific guidance about actions for organisations to take
- Be more streamlined to improve useability
- Facilitate clinical and organisational leaders to come together about genomic care implementation and monitoring

Our response:
From capability assessment to toolkit

Use the feedback to determine priority actions that all hospitals should consider and begin with

- Use this as a basis of a toolkit
- Create practical guides and tools to support those actions
- With detailed CAT continuing to be available as a resource if required

Genomics and Your Hospital

A toolkit to support high-quality genomic care

Seven key actions that give **any** hospital a strong foundation in genomics.

Key actions with tools to help.

Form a genomics leadership group

Tool

- Model Terms of Reference with suggested activities

Determine models of care

Tools

- Resources to support defining and documenting your genomics model of care
- Demand modelling framework

Understand and mitigate risks

Tools

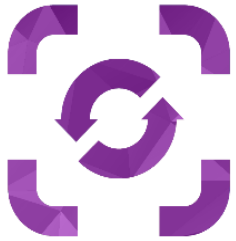
- A guide to genomics-specific risks
- A template genomic risk register

Check workforce skills and support

Tool

- Principles and recommended activities for effective workforce credentialling and support

Key actions with tools to help.



Support and monitor quality and value

Tool

- Using clinical governance to guide decision making and approach
- List of suggested metrics to support safe, high quality genomic care

Review new genomic practice

Tool

- Screening tool for reviewing new genomic practice for safety, effectiveness and value

Involve consumers in genomic medicine services

Tool

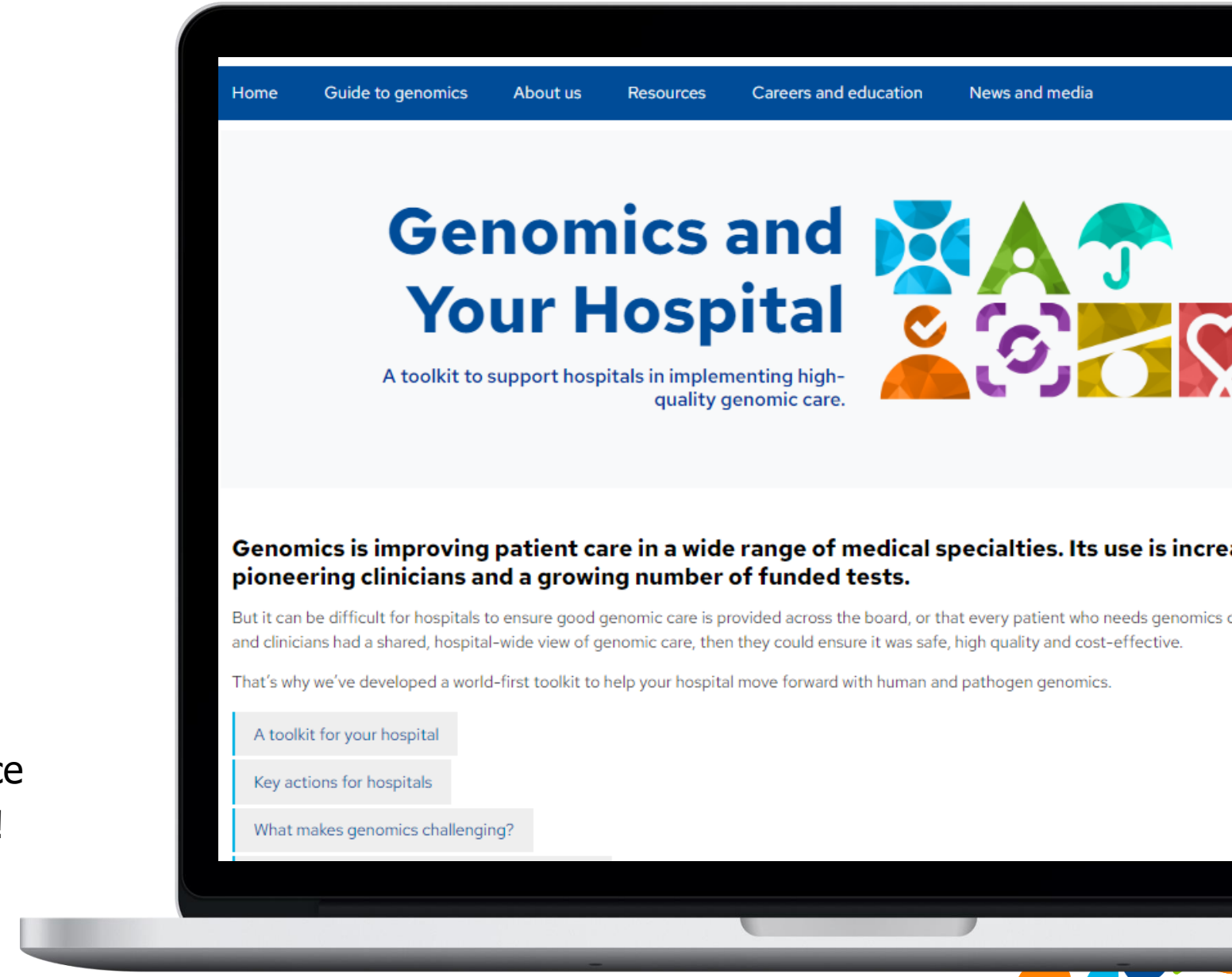
- Recommendations for consumer engagement in genomic implementation

Our next steps

- Publish website
- In situ Ax
- Health service roadshow
- Disseminate

GenomicsToolkit**.org.au**

Follow Melbourne Genomics Health Alliance on LinkedIn to find out when it goes live!



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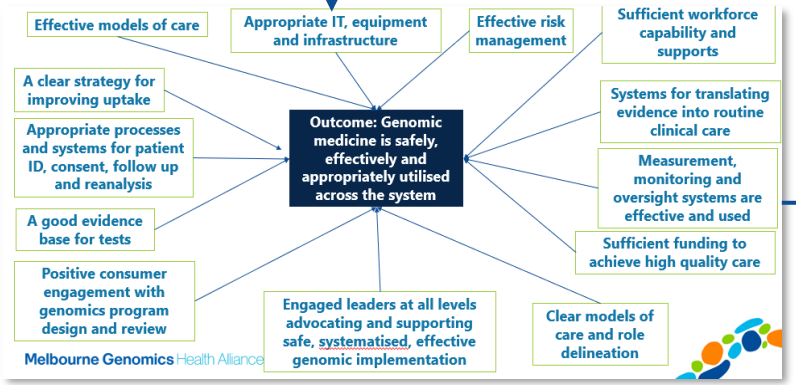
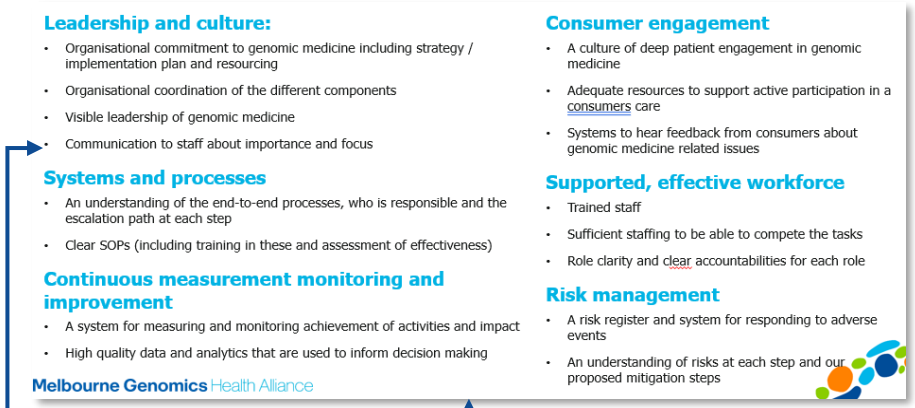
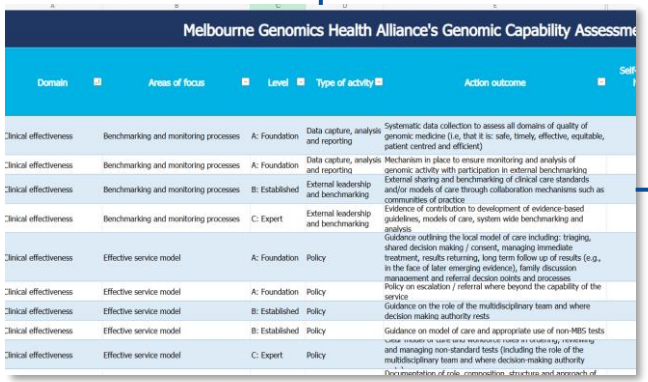
Summary







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Significant co-design throughout

Genomics and Your Hospital

A toolkit to support high-quality genomic care

Shared language, space and relationships critical

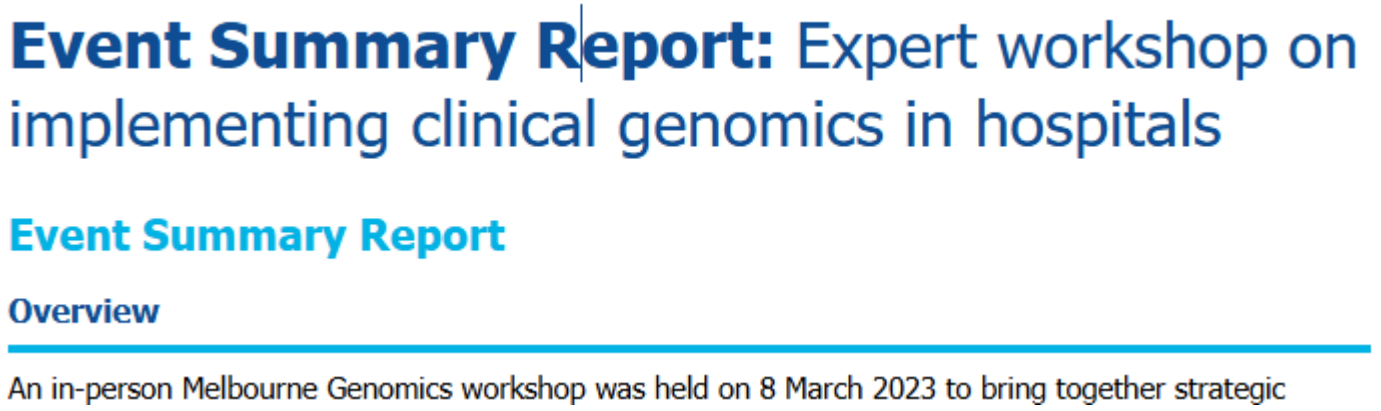
Melbourne Genomics Health Alliance

- **Acknowledgements:**
  - MGHA Hospital Implementation Program Team members (and their wealth of experience in genomics, impln science, evaluation, and science communication)
  - HIRG members
  - CAG
  - MGHA stakeholders (>80 stakeholders provided feedback on 1 or more tools / elements)

- **Thankyou!**

- **Questions?**

The workshop



Event Summary Report: Expert workshop on implementing clinical genomics in hospitals

Event Summary Report

Overview

An in-person Melbourne Genomics workshop was held on 8 March 2023 to bring together strategic

- 29 attendees – including Board chairs, health leaders, clinical leaders, geneticists and GCs
- Feedback:
  - approach and the "straw man" of content broadly supported
  - ongoing communication and collaboration critical
  - Participants greatly valued the range of diverse attendees and perspectives
  - The active, in-person format worked well to discuss complexity