

Translating research into clinical practice & back again: Challenges for the AoD sector

WA MHAoD Conference 2018

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Health
South Eastern Sydney
Local Health District

Why do we not always provide the interventions that are known to work?

Why do we provide interventions that are known to not work?

(How) Can we improve?

Overview

- Origins of 'decision making' in AoD treatment
- Early approaches to evidence based medicine (EBM)
- Translational Research: Evidence is not enough
- Future approaches to EBM and their application in AoD treatment

Origins of 'decision-making' in AoD treatment

- Treatment in AoD sector historically aligned to 'belief systems' re: the cause and nature of addiction ("mad, bad, dangerous")
 - Legal: incarceration
 - Moral: proliferation of faith-based / spiritual approaches
 - Sickness: psychological and medical responses
- Combination of all three
- Not just historical: 'political imperatives' still apply today

Treatment of Alcoholic Intoxication and the Withdrawal Syndrome

*A Critical Analysis of the Use of Drugs
and Other Forms of Therapy*

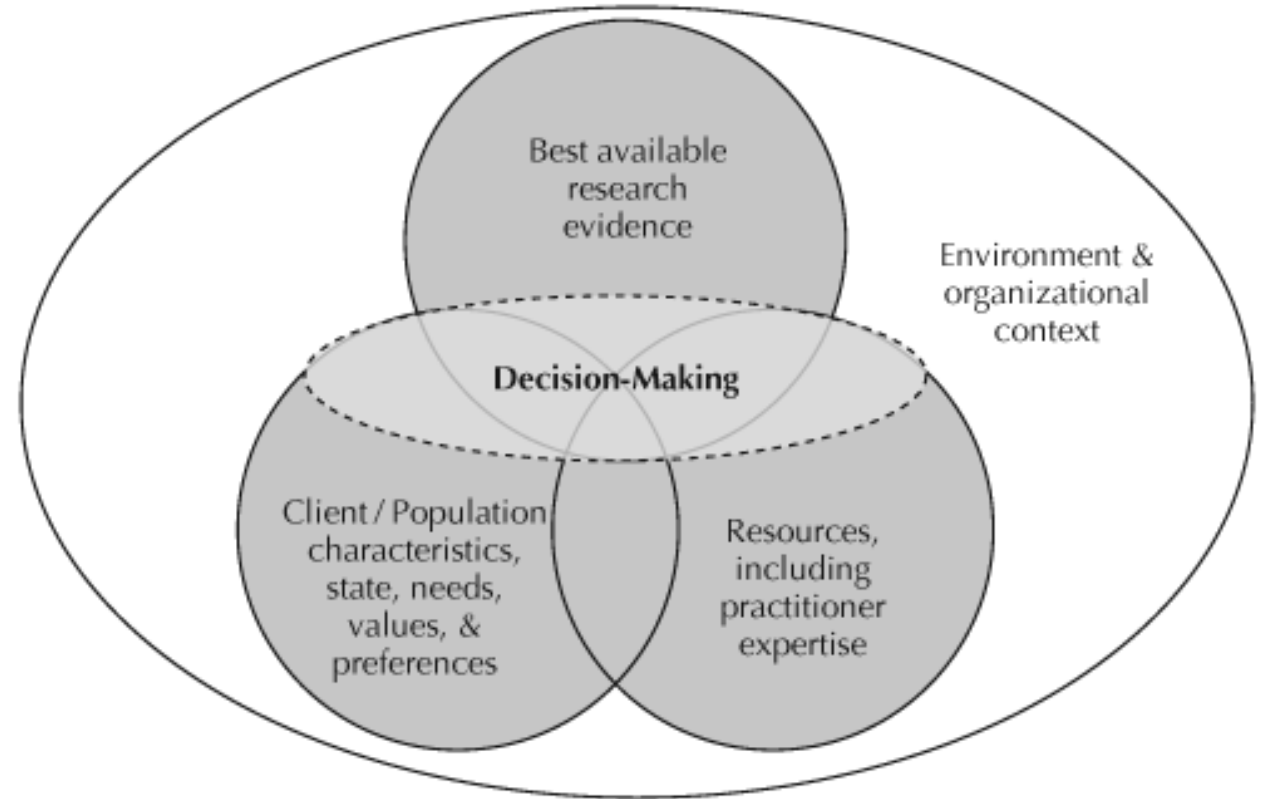
MAURICE VICTOR, M.D.

The purpose of this communication is to evaluate critically some of the current ideas about the treatment of alcohol intoxication and the withdrawal syndrome. This literature with relatively few exceptions, is characterised not only by its immense bulk, but also by its inordinately uncritical quality. Some of the shortcomings are perfectly evident and require little comment. Reference is made here to the innumerable claims for the therapeutic value of a particular drug or some other method of treatment unsupported by any meaningful data. Some of these claims are so illogical and extravagant that one wonders how they have ever found a place in what is euphemistically termed scientific literature.

(1966)

The emergence of evidence based medicine (EBM)

Originated in UK in 1990's amongst a group of cardiologists who were no longer content providing care based on "established wisdom"



What is the evidence – and how is this constructed



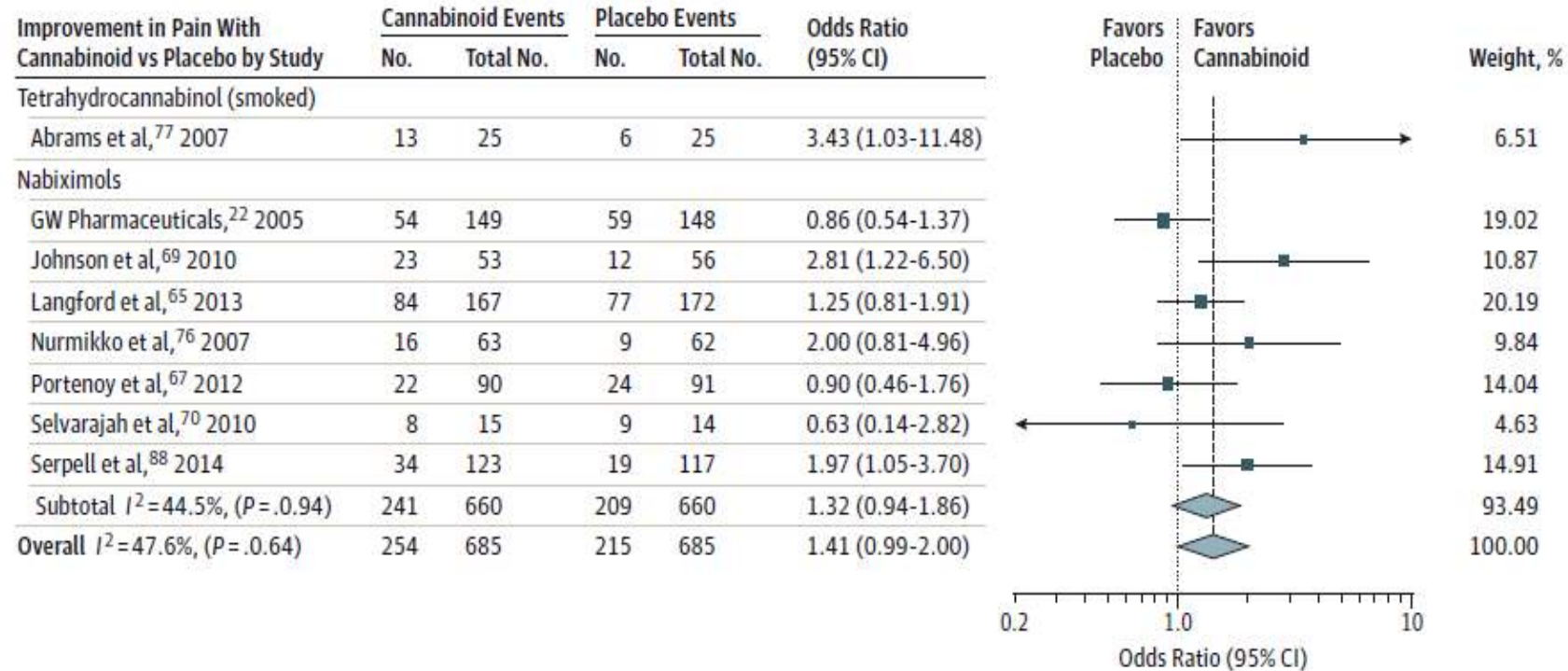
Table 1: Designations of levels of evidence [1]

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials
II	Evidence obtained from at least one properly-designed randomised controlled trial
III-1	Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group
IV	Evidence obtained from case series, either post-test or pre-test/post-test

Cannabinoids in chronic pain

Systematic review: Whiting et al JAMA June 2015

Figure 2. Improvement in Pain



Odds indicate 30% or greater improvement in pain with cannabinoid compared with placebo, stratified according to cannabinoid. The square data markers indicate odds ratios (ORs) from primary studies, with sizes reflecting the statistical weight of the study using random-effects meta-analysis. The

horizontal lines indicate 95% CIs. The blue diamond data markers represent the subtotal and overall OR and 95% CI. The vertical dashed line shows the summary effect estimate, the dotted shows the line of no effect (OR = 1).

Assessing / ranking the evidence

	Effectiveness	Appropriateness	Feasibility
Excellent	<ul style="list-style-type: none">• Systematic review• Multi-centre studies	<ul style="list-style-type: none">• Systematic review• Multi-centre studies	<ul style="list-style-type: none">• Systematic review• Multi-centre studies
Good	<ul style="list-style-type: none">• RCT• Observational studies	<ul style="list-style-type: none">• RCT• Observational studies• Interpretive studies	<ul style="list-style-type: none">• RCT• Observational studies• Interpretive studies
Fair	<ul style="list-style-type: none">• Uncontrolled trials with dramatic results• Before and after studies• Non-randomized controlled trials	<ul style="list-style-type: none">• Descriptive studies• Focus groups	<ul style="list-style-type: none">• Descriptive studies• Action research• Before and after studies• Focus groups
Poor	<ul style="list-style-type: none">• Descriptive studies• Case studies• Expert opinion• Studies of poor methodological quality	<ul style="list-style-type: none">• Expert opinion• Case studies• Studies of poor methodological quality	<ul style="list-style-type: none">• Expert opinion• Case studies• Studies of poor methodological quality

Figure 1 Hierarchy of evidence: ranking of research evidence evaluating health care interventions.

Our health care system today

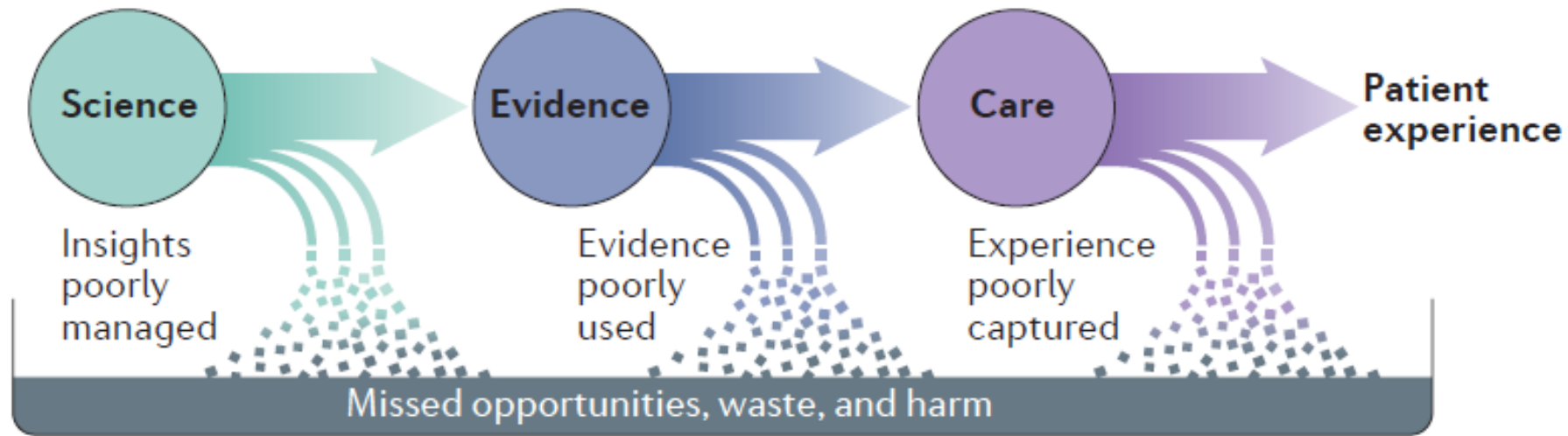
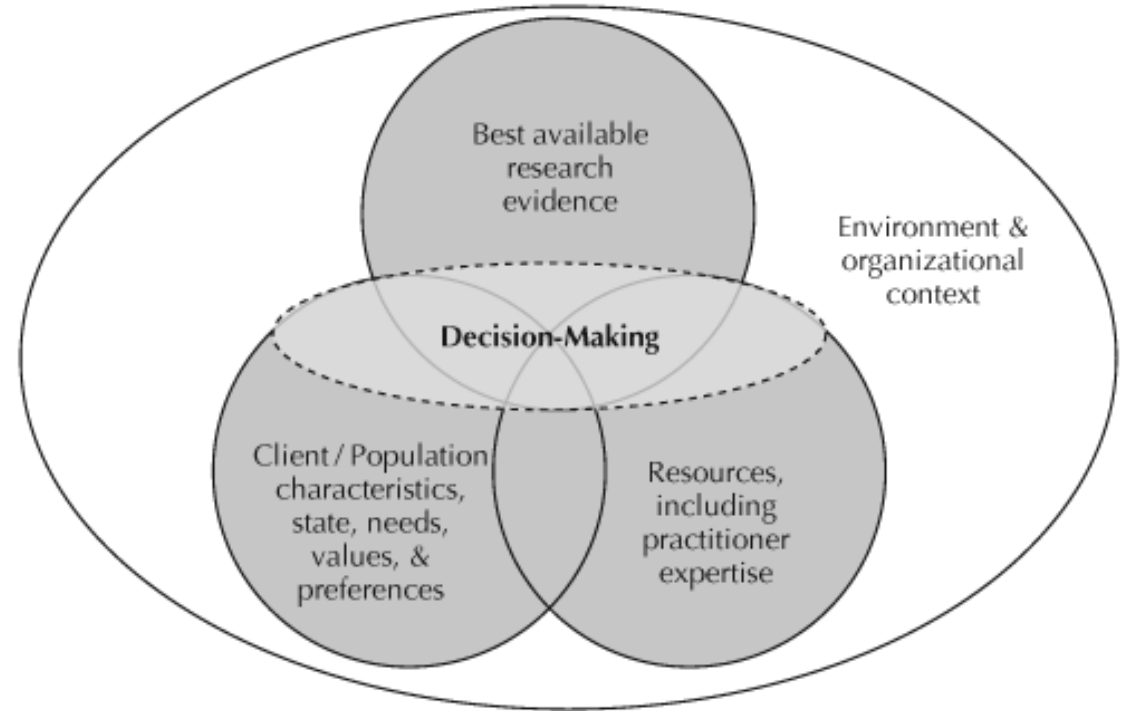


Figure 1 | **Health-care system today.** The current health-care system has important shortcomings and inefficiencies. Insights from research are poorly managed, the available evidence is poorly used, and the care experience is poorly captured, resulting in missed opportunities, wasted resources, and potential harm to patients. Reprinted with permission from *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America* (2013) by the National Academy of Sciences, courtesy of the National Academies Press, Washington, D.C.

Examples of EBM 'gone wrong' in AoD sector

- The 'opioid wars'
- Baclofen for alcohol dependence
- Take home naloxone
- Medical cannabis



The 'opioid wars': Antagonists (rapid detox, implants & depot NTX)

- Rapid detox:
 - Promoted as major advance in treating 'addicts'
 - Evidence: safety & cost concerns with no better outcomes
- Long-acting NTX products:
 - Evidence re: safety and effectiveness still emerging
 - No licensed products in Australia
 - In USA: poor uptake of Vivitrol (depot injection): expensive and 'not that popular'



Naltrexone Implant Therapy
The Best Long-Term
Anti-Addiction Treatment?



The 'opioid wars': heroin assisted treatment

- Evidence from RCTs suggests some role as second line treatment for those not responding to conventional treatment approaches
- Expensive to provide
- 'Not that popular'
- No licensed products in most parts of the world.



Some crucial elements



Needle and syringe programs (NSP)



Consumption rooms



Heroin assisted treatment (HAT)

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Alcoholism



Jessica Reed

🐦 @GuardianJessica

Fri 16 Sep 2016 20.00 AEST



🔗
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332

Baclofen: the controversial pill that could 'cure' alcoholism



Baclofen for alcohol dependence

- Baclofen: a GABA-B agonist used to treat MS spasticity
- Popularised by French doctor's own personal experience (Dr Olivier Ameisen "The Last Glass")
- Widespread uptake across France, and promoted in parts of Australia despite
 - (a) limited and conflicting evidence,
 - (b) serious concerns re: safety;
 - (c) no licensed indication or recommending guidance by authoritative bodies
- Meanwhile disulfiram, the medication shown to be most effective in treating alcohol dependence is largely ignored in Australian clinical practice.

Take home naloxone for at-risk opioid users

- Conventional evidence of safety / efficacy difficult to establish
- Consensus approach to evidence as a public health measure
- Barriers to uptake in Australia
 - Attitudes of health workers and opioid users
 - Regulatory & funding models for medication & service providers
 - A 'prevention' not a 'treatment' intervention: changing paradigms
- Yet to see the 'enablers of practice change' routinely seen in clinical change management (e.g. professional guidance, training, industry support)

Medical cannabis: a contemporary challenge to 'EBM'

- Historical evidence of cannabis use as a medicine
- Preclinical evidence supportive of cannabinoids for many conditions
- High levels of positive patient reported experiences and outcomes
- Clinical trials: hampered by quality concerns
- Poor consensus on what the evidence is telling us
 - support in some quarters (community, politicians, industry, some clinicians)
 - resistance in others (medical establishment)

Australian Faculty Pain Medicine

Statement on “Medical Cannabis” (2015)

“FPM does not recognise a need for greater availability of medicines in general and in particular **does not endorse the use of cannabinoids in chronic non-cancer pain until such time as a clear therapeutic role for them is identified in the scientific literature.**”

“With the possible exception of pain and spasticity in multiple sclerosis, there is **little evidence for the effectiveness of cannabinoids in chronic non-cancer pain situations**, whether or not the pain attracts the descriptor “neuropathic”.”

Ware & Desroches (2014). *What does the practicing pain clinician need to know?*

“... the response ... that there is ‘not enough information’ is disingenuous at best, and at worst, an abnegation of clinical responsibility.”

“Careful consideration of cannabis use in pain medicine provides an opportunity to deepen and refine our pain-management toolbox, understand our patients’ needs and wishes, strengthen our relationships, and improve the quality of our care, while we wait for more long-term RCTs to provide more definitive evidence.”

Medical cannabis and the addictions

Could medical cannabis have a role in addiction treatment?

- Arguments against ...
 - Cannabis is an addictive harmful drug causing mental health, cognitive, physical and social harms
 - Prohibition must be upheld ... now is not the time to “go soft on the war on drugs”
- Arguments for
 - Research increasingly highlighting that many people use cannabis as a means of substitution from more harmful substances (e.g. heroin, alcohol, BZDs)
 - Many people with SUDs have a range of comorbidities for which cannabis may have potential benefits (e.g. chronic pain, sleep disorders, PTSD)
 - Medical cannabis is the ‘backdoor approach’ to drug law reform

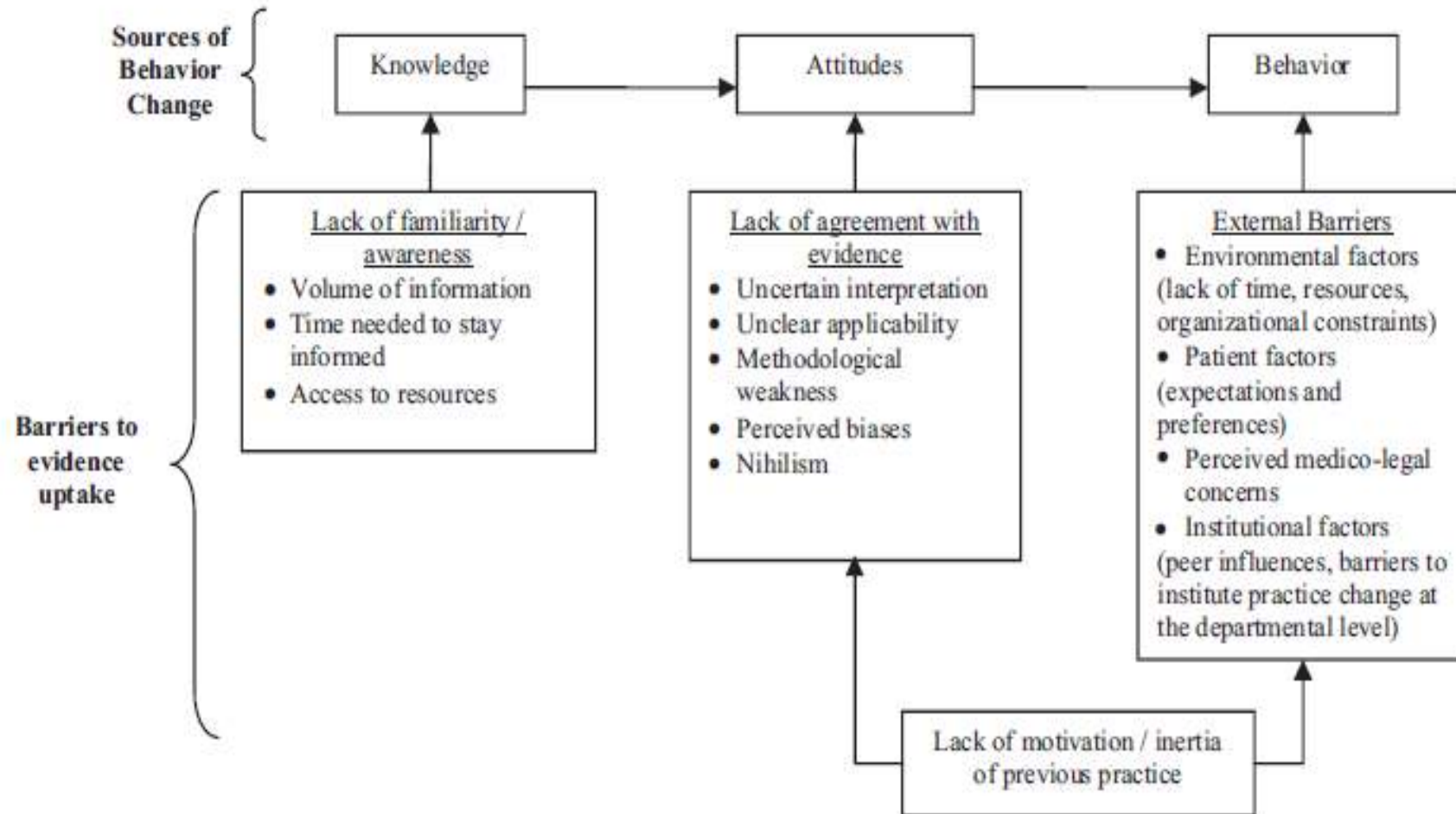


Figure 2. Barriers to evidence uptake. Innovation and change in clinical practice at the individual, departmental, and institutional levels are contingent on 3 key sources of behavior change: knowledge, attitudes, and behavior. However, a series of complex barriers exists for each of these dimensions, some of which are illustrated here. Adapted from Cabana et al.³³

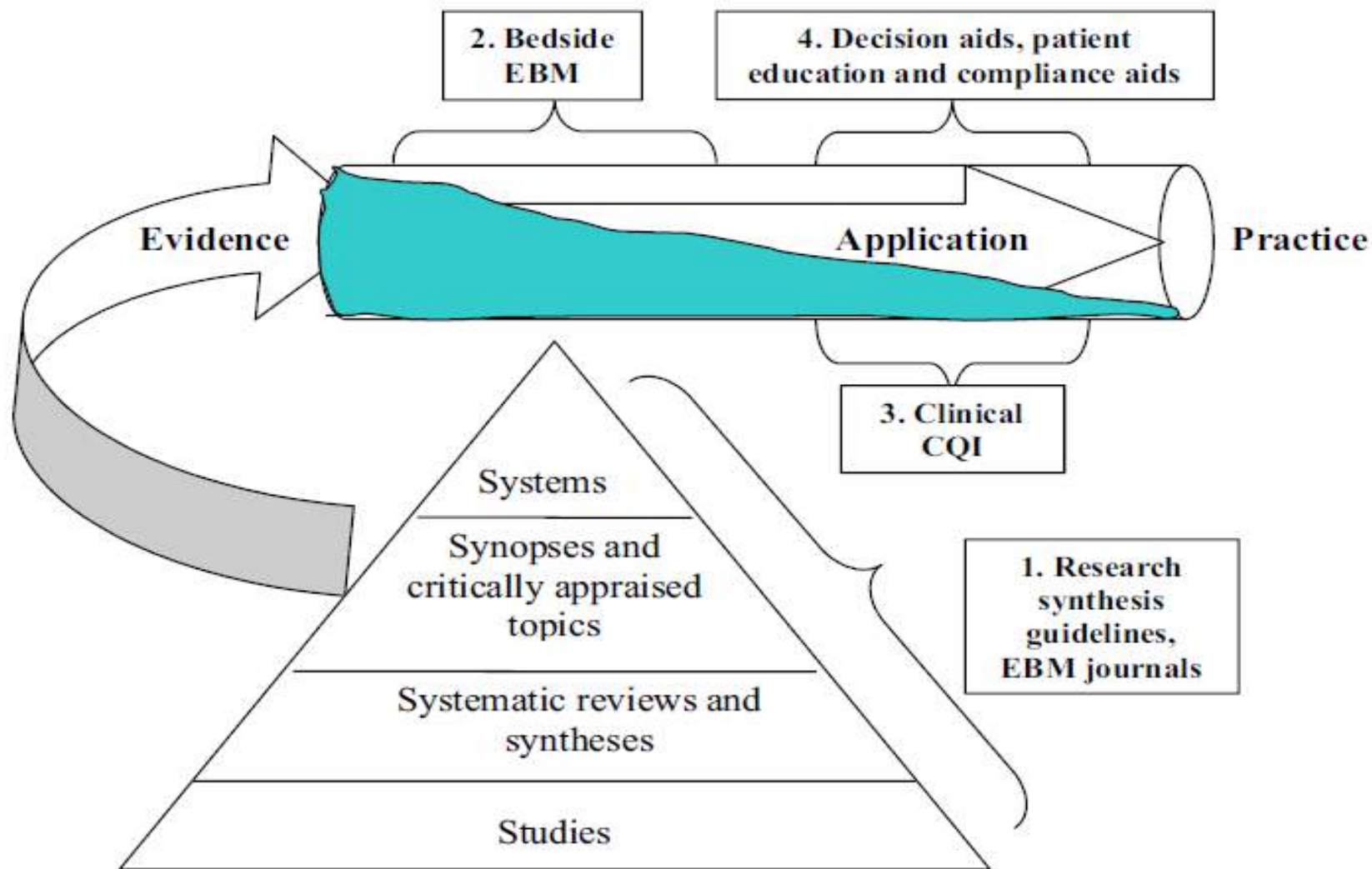
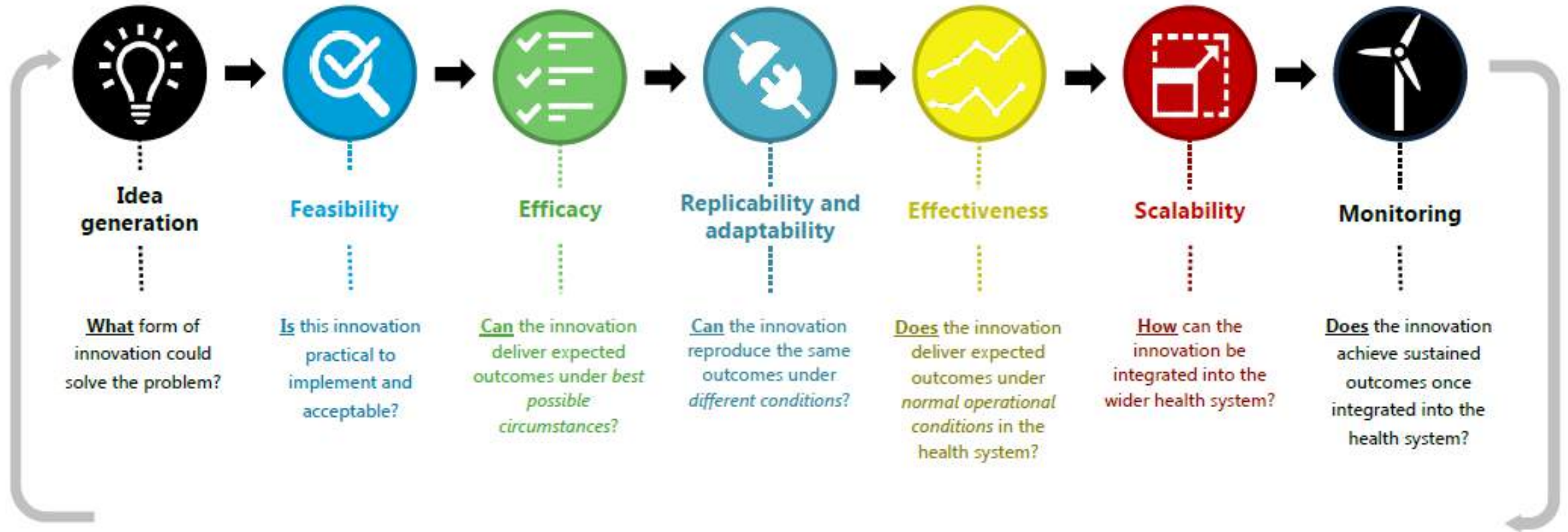


Figure 1. A model for closing the evidence-to-practice gap. This schematic demonstrates 4 stages of moving from research to practice-altering outcomes. The first stage involves getting the evidence straight, illustrated by increasingly more applicable forms of information drawn from valid and important clinical research and represented in the 4S pyramid. The evidence-to-practice pipeline, also shown, reveals the dissipation of useful conclusions from clinical research, thus failing to make it into practice. The 3 remaining disciplines of knowledge translation can facilitate evidence uptake and help close the gap between research and practice. Adapted from Glasziou and Haynes.¹⁶ *EBM*, Evidence-based medicine; *CQI*, continuous quality improvement.

The goals of translation research

1. Changing practitioner behaviour in the direction of applying evidence-based interventions and strategies to patient care
2. Demonstrating improved patient outcomes

Translational research framework



The Sax Institute. *Translational Research Framework* 2016

Enhancing Translational research and EBM in Australian AoD sector

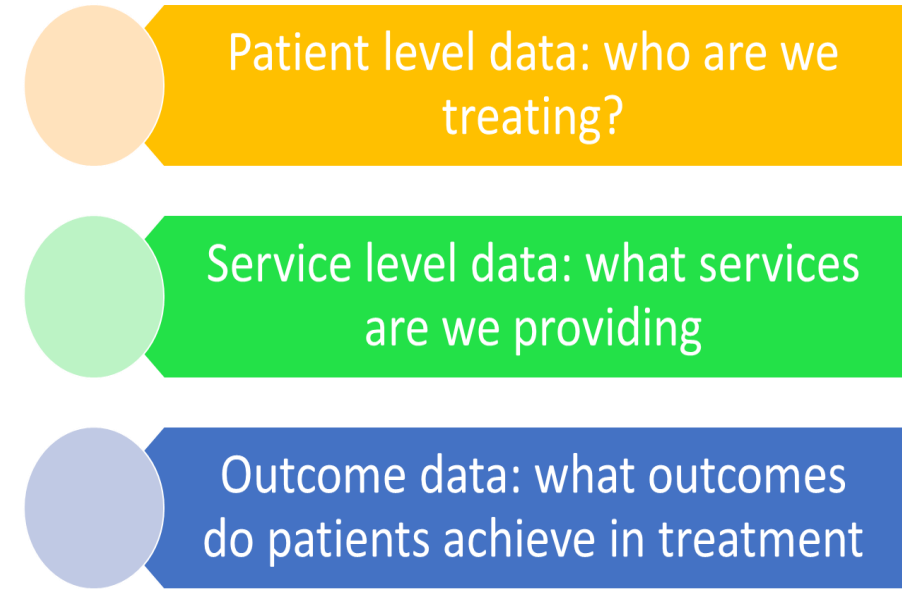
- Increasing our ability to conduct translational clinical research:
Establishing a national clinical research network in AoD
- Developing the next generation of clinical information systems that enables data informed services and continuous improvement

Towards a national clinical research network in AoD

- To develop & conduct research that is informed by, and in turn impacts upon, clinical practice
- Research done 'with' - not 'to' patients and clinicians
- Identify relevant clinical research questions, research projects and have the network that allows multisite studies to occur
- Bring together relevant stakeholders:
 - Clinical services with research capacity
 - Consumers
 - Academics
 - Governments & other 'purchasers' of services
- Has the time come for a National Clinical Research Network?
- NSW D&A Clinical Research & Improvement Network established 2018

Clinical information systems: 'data driven' services

- Building systems that enable 'real world' and 'real time' data from clinical services
- Developments with electronic clinical information systems, computer power & data linkage is transforming service delivery in many sectors of health care
- Triangulation of patient, service and outcome level data.



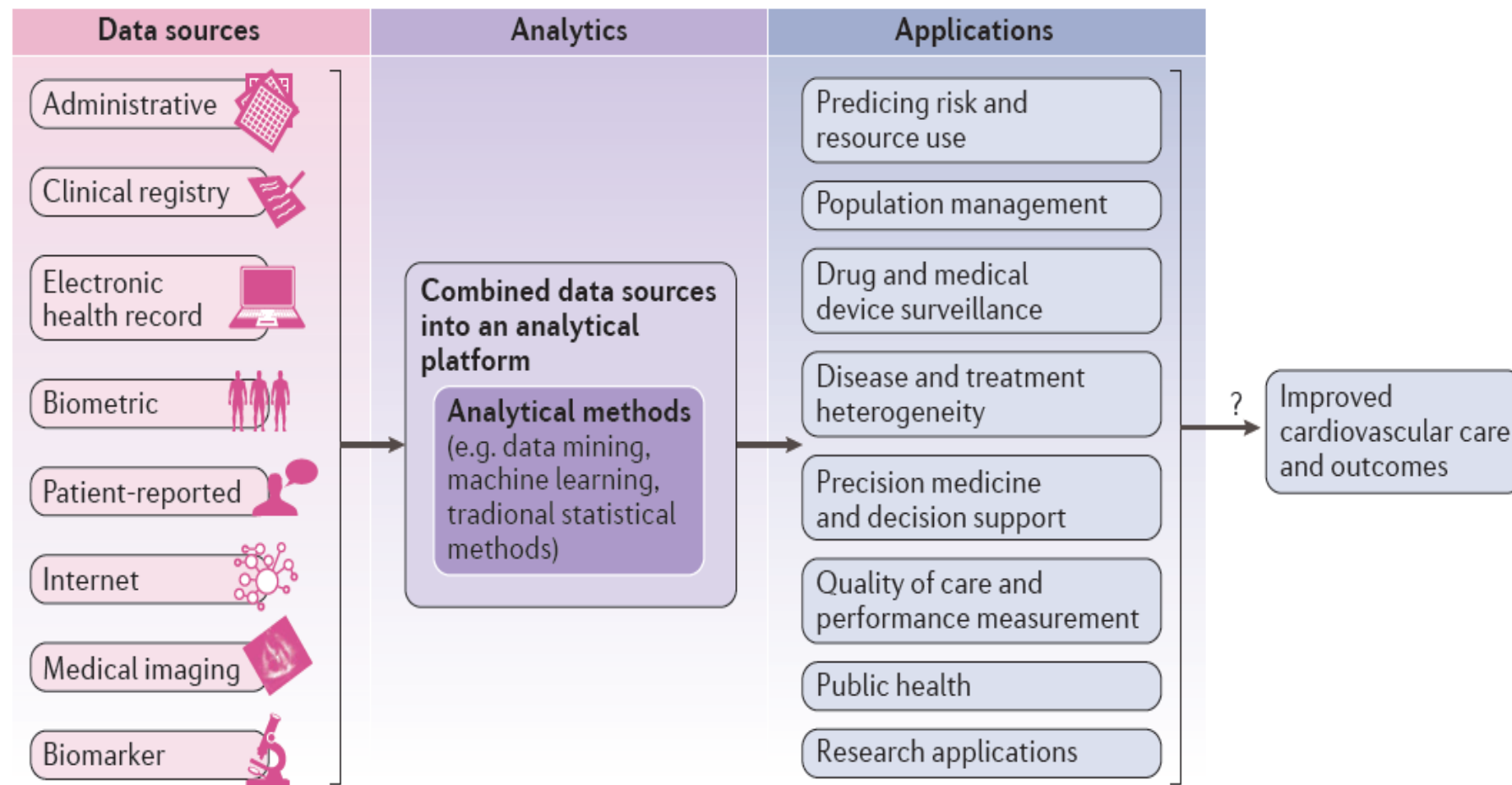


Figure 2 | **Overview of big data analytics and applications.** Examples of the inputs (data sources) and outputs (analytical methods and applications) of big data analytics that can potentially improve cardiovascular quality and outcomes of care.

NSW Health AoD Clinical Outcomes & Quality Indicator (COQI) Project

- Opportunity of introduction of electronic clinical information system (eMR) across NSW Health AoD treatment services
- Identify and build 'data items' that are embedded in 'routine care' & enable outcomes and quality indicators to be examined
- Aims to address 2 key questions:
 - “Do patients get better” (Clinical outcomes)
 - “Did we deliver treatment well?” (Quality indicators)

Measuring Outcomes

- Combination of
 - Process measures (treatment completion, safety measures)
 - Patient and clinician reported outcomes
 - Change in substance use
 - Physical health, psychological health, quality of life
- Vary according to type of treatment service
 - Inpatient detox / counselling / resi rehab / methadone

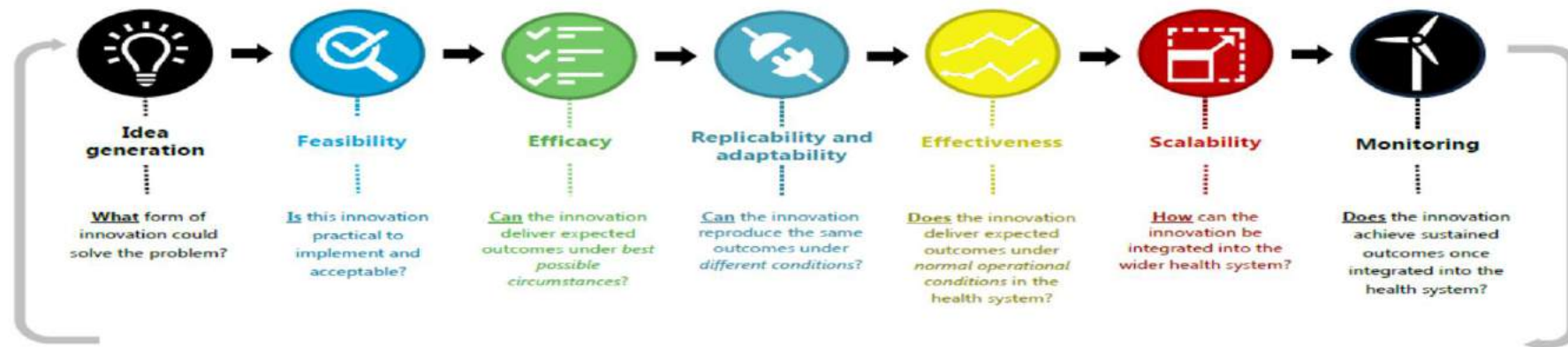
ATOP OUTCOME MODULE		Surname: _____ MRN: _____ Given Names: _____ Date of Birth: ____/____/____ Sex: _____ <i>Affix Patient Label here</i>										
ATOP DATE ____/____/____		CLINICIAN _____										
Treatment stage: <input type="checkbox"/> Start of service episode <input type="checkbox"/> Progress review <input type="checkbox"/> Discharge <input type="checkbox"/> Post Discharge												
Section 1: Substance use												
Record number of days used in each of the <u>past four weeks</u>												
	Ave qty per day	Units Std drinks	Week 4 (most recent)	Week 3	Week 2	Week 1	TOTAL					
a Alcohol	<input type="text"/>	<input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-28 <input type="text"/>					
b Cannabis	<input type="text"/>	<input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-28 <input type="text"/>					
c Amphetamine type substances (eg. ice, MDMA etc.)	<input type="text"/>	<input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-28 <input type="text"/>					
d Benzodiazepines (prescribed & illicit)	<input type="text"/>	<input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-28 <input type="text"/>					
e Heroin	<input type="text"/>	<input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-28 <input type="text"/>					
f Other opioids (not prescribed methadone/buprenorphine)	<input type="text"/>	<input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-28 <input type="text"/>					
g Cocaine	<input type="text"/>	<input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-28 <input type="text"/>					
h Other problem substance	<input type="text"/>	<input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-28 <input type="text"/>					
i Daily tobacco use?	<input type="text"/>				Yes <input type="checkbox"/> No <input type="checkbox"/>							
Record number of days client injected drugs in the <u>past four weeks</u> (if no, enter zero and go to section 2)						TOTAL						
j Injected	<input type="text"/>	<input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-28 <input type="text"/>					
k Inject with equipment used by someone else?			Yes <input type="checkbox"/> No <input type="checkbox"/>									
Section 2: Health and Wellbeing												
Record days worked and at college, school or vocational training for the <u>past four weeks</u>												
	Week 4	Week 3	Week 2	Week 1	TOTAL							
a Days paid work (incl. all paid work; not voluntary work)	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-28 <input type="text"/>							
b Days at school, tertiary education, vocational training	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-7 <input type="text"/>	0-28 <input type="text"/>							
Record the following items for the <u>past four weeks</u>												
c Have you been homeless?					Yes <input type="checkbox"/> No <input type="checkbox"/>							
d Have you been at risk of eviction?					Yes <input type="checkbox"/> No <input type="checkbox"/>							
e Have you, at any time in the past four weeks, been a <u>primary caregiver for or living with</u> any child/children					(i) under 5yo? Yes <input type="checkbox"/> No <input type="checkbox"/>							
					(ii) 5-15yo? Yes <input type="checkbox"/> No <input type="checkbox"/>							
f Have you been arrested?					Yes <input type="checkbox"/> No <input type="checkbox"/>							
g Have you been violent (incl. domestic violence) towards someone?					Yes <input type="checkbox"/> No <input type="checkbox"/>							
h Has anyone been violent (incl. domestic violence) towards you?					Yes <input type="checkbox"/> No <input type="checkbox"/>							
i Client's rating of psychological health status (anxiety, depression and problem emotions and feelings)												
	0	1	2	3	4	5	6	7	8	9	10	
	Poor					Good						
j Client's rating of physical health status (extent of physical symptoms and bothered by illness)												
	0	1	2	3	4	5	6	7	8	9	10	
	Poor					Good						
k Client's rating of overall quality of life (e.g. able to enjoy life, gets on well with family and partner, satisfied with living conditions)												
	0	1	2	3	4	5	6	7	8	9	10	
	Poor					Good						

Quality Indicators

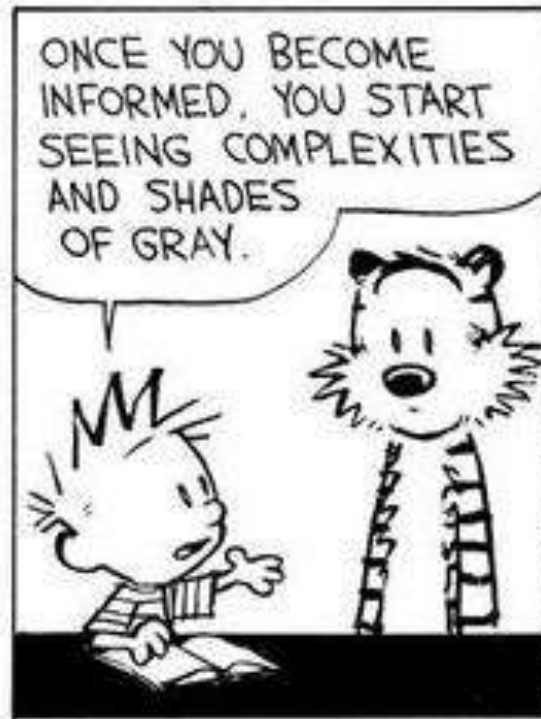
- 'Service level' indicators: accreditation, incident reporting, systems to enhance staff and consumer engagement
- 'Patient level' indicators: PREMs
- 'Episode level' indicators: Clinical care standards identified:
 - Intake
 - Assessment
 - Global care plan
 - Managing risk (child protection, DV, homelessness, suicide, BBV
 - Monitoring treatment outcomes over time
 - Transfer of care / discharge

How will we use our own data to inform practice?

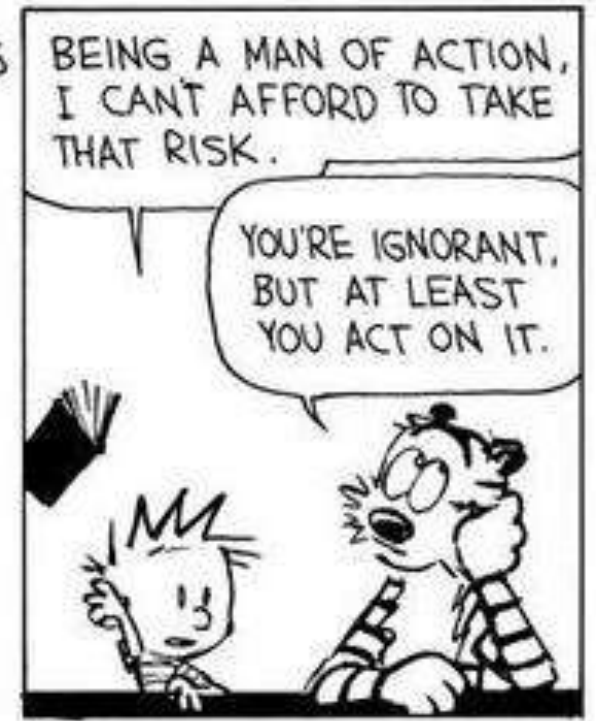
- “What services are used and what are the outcomes for homeless clients attending our services?”
- “Do older clients have different health problems or treatment outcomes than younger clients?”
- “Who was treated with baclofen, naltrexone or disulfiram, and did it make any difference?”
- “How did the group of clients recruited to the RCT compare with clients in our service?”



The opportunity to become data informed services



YOU REALIZE THAT NOTHING IS AS CLEAR AND SIMPLE AS IT FIRST APPEARS. ULTIMATELY, KNOWLEDGE IS PARALYZING.



Conclusions

- Services for clients with AoD problems are subject to 'interference' from a range of political and social forces, both patients and services must negotiate discrimination and stigma, and there is considerable nihilism in the community and amongst health providers regarding the role of AoD treatment
- We must get better at demonstrating our services provide EB interventions and result in positive client outcomes
- Translational research approaches require a shift in the relationship between clients, services and researchers
- The promise of a national clinical research network & 'smart' clinical information systems