

Enhancing Australia's Clinical Research Capacity to Respond to Methamphetamine and Emerging Drugs

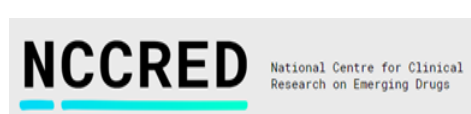
A Consultation Paper to support the Development of a
Workforce Development Strategy

Prepared for the National Centre for Clinical Research on
Emerging Drugs by the National Centre for Education and
Training on Addiction

Written submissions close Monday 15 July 2019 and can
be emailed to nceta@flinders.edu.au

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About NCETA

NCETA is based at Flinders University in South Australia and is an internationally recognised research and training centre that works as a catalyst for change in the alcohol and other drug (AOD) field. NCETA's areas of expertise include training needs analyses, the provision of training and other workforce development approaches. We have developed training curricula, programs and resources, and provided training programs, to cater for the needs of: specialist AOD workers; frontline health and welfare workers; Indigenous workers; community groups; mental health workers; police officers; and employers and employee groups. The Centre focuses on supporting evidence-based change and specialises in change management processes, setting standards for the development of training curriculum content and delivery modes, building consensus models and making complex and disparate information readily accessible to workers and organisations.

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About NCCRED

The National Centre for Clinical Research on Emerging Drugs (NCCRED), was established by the Commonwealth Government in 2018 as part of the National Ice Action Strategy, recognising the need for improved treatments for methamphetamine, as well as more prompt detection and response to emerging drug threats.

NCCRED aims to support clinicians to detect and respond to new drug health problems by developing innovative and evidence-based new treatments for drug dependence; building clinical research capacity in the Australian alcohol and other drug (AoD) workforce; and the rapid translation of research findings into clinical practice.

The Centre was formed as a consortium between St Vincent's Health Australia (SVHA); The National Centre for Education and Training on Addiction (NCETA, Flinders University); The National Drug Research Institute (NDRI, Curtin University); and The National Drug and Alcohol Research Centre (NDARC, The University of New South Wales).

Foreword

The National Centre for Clinical Research on Emerging Drugs (NCCRED) aims to enhance Australia's capacity to respond to emerging drugs.

NCCRED's objectives include:

- *Generating new evidence-based knowledge that leads to improved treatment and health outcomes*
- *Translating evidence-based research outcomes into clinical practice and clinical guidelines and guidance products*
- *Supporting and implementing health and medical research workforce development for healthcare workers in the AOD and primary healthcare sectors*
- *Facilitating collaboration within the AOD sector and across other sectors*
- *Undertaking and contributing to the evaluation of treatment models and outcomes.*

NCCRED also aims to enhance Australia's clinical research capacity by further developing current and future workforces responsible for initiating, undertaking and implementing relevant clinical research. This clinical research will address issues ranging from early intervention through to tertiary interventions focussed on problems such as withdrawal and dependence.

NCCRED engaged the National Centre for Education and Training on Addiction (NCETA) to develop a Workforce Development (WFD) strategy that addresses the needs of clinical researchers. The WFD Strategy will provide a blueprint for NCCRED to enhance WFD among the clinical research workforce. The Strategy will be aligned with the National AOD Workforce Development Strategy 2015-2018, other relevant strategies and policy initiatives, and NCCRED's overall program of work.

While the clinical researcher workforce has not been extensively examined, researchers are likely to come from diverse backgrounds. Some researchers come from a clinical background and go on to attain skills and qualifications in research. Others come from a quantitative or qualitative research background and apply these skills to the area of emerging drugs. The WFD needs of these diverse groups are likely to differ.

To inform the development of this WFD Strategy a series of consultations will be undertaken. To assist that process, this Consultation Paper has been provided to help instigate and guide thinking and discussion on this issue.

Copies of this Consultation Paper are available on the [NCETA website](http://nceta.flinders.edu.au/) at nceta.flinders.edu.au/ and the [NCCRED website](http://nccred.org.au) at nccred.org.au.

Interested parties are welcome to download the Paper and provide written responses to the Paper and the questions contained therein. For convenience, a full list of questions is provided in Appendix 1. Responses can then be emailed to nceta@flinders.edu.au

Submissions close Monday 15 July 2019

The consultation paper is not intended to provide an exhaustive examination of issues relevant to emerging drugs related to clinical research WFD. Rather, it is intended to guide the development of a better understanding of this workforce and its WFD needs and offer some thought-provoking, stimulating and, in some respects, challenging considerations.

Any queries about the consultation process can be directed to Professor Ann Roche at NCETA ann.roche@flinders.edu.au or Ms Florence Bascombe f.bascombe@unsw.edu.au at NCCRED .

Glossary of terms and concepts

Clinical Research: Clinical research increasingly involves a range of different health professionals studying a wide range of matters, including disease prevention and causation, diagnostic methods, treatments, and effects of and response to illness. Such research can occur in a number of settings, including public and private hospitals and clinics, other institutions or organisation, community settings, and general or specialist medical practices (*National Statement on Ethical Conduct in Human Research, 2007, Updated May 2018*).

Emerging drugs: Emerging drugs are new psychoactive drugs appearing on the market. They include novel drug classes which are potentially harmful. They also include new formulations of older drug classes for which problems related to their use are emerging. The situation is rapidly changing. There are hundreds of emerging drugs of concern, and this number is increasing every year. See [here](#) for more information.

Clinical researcher

There are essentially two types of clinical researchers; clinician researchers and non-clinician clinical researchers.

- I. Clinician researchers: Clinician Researchers conduct research and provide direct clinical services in any setting under a formal working relationship, although not necessarily with the same organisation. They must be eligible to undertake clinical practice in Australia through registration with the National Health Practitioner Regulation Agency, the National Alliance of Self-Regulating Health Professionals, or equivalent.
 - II. Clinician research collaborators, or clinician scholars, will have research training and be integrated into a training environment with a university designation. They will more often be collaborators in research programs that support ongoing learning and quality improvement projects for residents in their clinical settings.
 - III. Clinician associate researchers, are a subset of clinician researchers who are sufficiently literate in research to teach others how to critically evaluate papers and integrate research into continuous improvement of practice, support recruitment or data collection, supervise small research and quality improvement projects, and participate in Practice-Based Research Networks.
2. Non-clinician clinical researchers who come to this area with skills in undertaking qualitative or quantitative research

Clinician researchers in emerging drugs can come from a range of disciplines including:

- Medicine (e.g., addiction medicine, psychiatry, toxicology, pharmacology and general practice)
- Nursing
- Psychology
- Social work
- Occupational therapy
- Pharmacists
- Counsellors
- Aboriginal Health Workers.

In the context of emerging drugs, clinical researchers may focus on a range of activities and interventions including:

- Screening brief intervention and referral to treatment (SBIRT)
- Assessment, diagnosis and case management
- Withdrawal treatment
- Psychosocial interventions and support
- Residential rehabilitation
- Pharmacotherapies
- Harm reduction services
- Translational research
- Health services research
- Management of acute intoxication and poisoning.

The settings in which these services are provided include:

- Specialist alcohol and other drug (AOD) services
- Hospitals and emergency departments
- General practice, community health and other primary care settings
- Mental health services
- Telephone and online settings
- Outreach settings
- Forensic settings (including prisons).

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1 The Consultation and Strategy Development Process

In working through the Consultation Paper, the reader's attention is directed to the Questions posed at the end of each section. Responses are invited to these Questions.

The Questions are not intended to be exhaustive or prescriptive; rather, they are designed to act as prompts to the issues flagged in respective sections. Responses and views about these and other issues not covered here are welcome.

NCCRED has commissioned NCETA to develop a Workforce Development (WFD) Strategy addressing the needs of the clinical research workforce that focus on methamphetamine and other emerging psychoactive drugs (henceforth 'emerging drugs').

The WFD Strategy aims to:

1. Identify WFD barriers and enablers to embedding research into clinical practice
2. Enhance understanding of the profile and characteristics of the existing AOD clinical research workforce
3. Assist in the creation of a clinical research workforce that can innovate and rapidly transform research findings into practice
4. Identify characteristics that will be required of the future clinical research workforce
5. Identify the capabilities that will be required of the future clinical research workforce
6. Identify gaps between the existing workforce and future workforce needs and how to fill them
7. Clarify current and potential career pathways for clinical researchers
8. Identify approaches to improve researchers' ability to disseminate their findings and their implications for practice and/or policy
9. Identify approaches to improve mentoring and support for clinical researchers
10. Enhance understanding of the factors that enhance and diminish clinical researcher wellbeing
11. Identify barriers and enablers to engaging clinicians in research and engaging researchers in clinical settings
12. Identify barriers and enablers to extending partnerships between clinicians and researchers across geographical areas involving rural, remote and non-urban areas
13. Identify existing and potential undergraduate and post graduate education opportunities for clinician and clinical researcher skill development
14. Identify researcher WFD gaps and how they could be systematically addressed.

This consultation paper was developed by NCETA as an initial step in the development of the Strategy.

Between June and August 2019 NCETA staff, in collaboration with the NCCRED staff, and the Clinical Research Network, will undertake a consultation exercise with select stakeholders.

The consultation process will involve telephone or face-to-face interviews and possibly workshops with key stakeholders that will include:

- Clinical researchers
- Consumers
- Clinical managers
- Clinical and research funders.

NCETA will synthesise the outcomes of the consultations with findings from previous NCETA research concerning effective workforce development approaches, to develop the WFD Strategy. The Strategy will outline existing workforce development gaps as well as approaches to address those gaps.

2 Factors Influencing Clinical Researcher Workforce Development

Enhancing AOD clinical research capacity in Australia requires a vision involving greater commitment to research in clinical practice. Clinical research in the alcohol and other drug (AOD) field, as with any area of endeavour, needs to continuously evolve and improve its practice in response to changes in societal needs and emerging drugs. Nationally, the provision of AOD services has been impacted by substantial changes over recent decades. Clinical researchers have been required to respond to these changes.

Relevant changes have included:

- Shifting patterns of AOD use, in particular the shift towards the use of stimulants, pharmaceutical drugs and poly-drug use
- New synthetic drugs
- An expanded range of pharmacotherapies and other treatment options
- Greater awareness of co-existing mental health disorders and multiple morbidities
- Greater awareness of trauma and trauma-informed practice in the AOD treatment sector
- Greater awareness of foetal alcohol spectrum disorder, child protection and family inclusive practice issues
- Problematic alcohol and other drug use across a widened age spectrum
- Greater emphasis on cost efficiency, professional practice efficacy, improved outcomes and intersectoral collaboration
- A better understanding of effective preventive measures
- The ability to more closely monitor AOD trends using wastewater testing
- Greater recognition of the wide variety of workers involved in reducing alcohol- and other drug-related harm
- Enhanced awareness of the adverse effects of stigmatisation of drug use
- A better understanding of the impacts of social and geographical disadvantage on drug use problems (IGCD, 2015; Roche, & Nicholas, 2016).

While cannabis remains the most frequently used illicit drug in Australia, at present the major illicit drug threat is posed by crystalline methamphetamine. In the future this may well change. For example, illicitly produced synthetic opioids such as fentanyl and carfentanil (carfentanyl) may pose a substantial future threat. Therefore, clinical researchers involved with emerging drugs need to be able to respond to research needs related to new, and as yet unknown, challenges from drugs which may have stimulant, hallucinogenic or depressant effects and differing profiles of harm.

There have also been broader changes in approaches to workforce development (WFD) in the AOD field. Most important has been the increased recognition of the need for a broad conceptualisation of WFD, incorporating systems, organisational and individual factors. This recognition informed the development of the [National Alcohol and other Drug Workforce Development Strategy, 2015-2018](#) (Intergovernmental Committee on Drugs, 2015) developed by NCETA.

A range of policy frameworks and other developments will shape the WFD Strategy for clinical researchers.

These include:

- [The Australian Clinical Trials Toolkit](#)
- [2016 NHMRC Standards for Guidelines](#)
- [Medical Research Future Fund strategy and priorities](#)
- [National Drug Strategy 2017–2026](#)
- [National Ice Action Strategy, 2015](#)
- [Framework for a National Response to New Psychoactive Substances](#)
- [National Aboriginal Torres Strait Islander Peoples Drug Strategy 2014-2019](#).

In recognition of the need to pro-actively develop the clinical research workforce, a range of other WFD initiatives have recently been undertaken in Australia. Select examples include:

- Development of three e-Learning Modules by the National Health and Medical Research Council (NHMRC) to provide an introduction to the clinical trials environment, clinical research ethics, ethical review and research governance processes. The modules are suitable for researchers, research governance officers or consumers interested in the operation of clinical trials. The learning objectives of the modules are:
 - To understand how clinical trials take place in Australia
 - To understand and promote responsible research practices
 - To ensure quality research outcomes
 - To ensure participant safety is maintained at all times.

These modules can be accessed at <https://www.australianclinicaltrials.gov.au/nhmrc-elearning-modules>

Further examples of WFD initiatives are:

- Provision of support by the NHMRC for clinical trials proponents and clinical trials networks.¹
- Development by the NHMRC of Australia's first V.E.T. accredited course (10562NAT - Course in Clinical Trials Application Preparation, Submission and Review).²
- Development by the NHMRC, in conjunction with Australian Clinical Trials Alliance, of competencies for non-commercially sponsored (investigator-initiated) clinical trials.
- The development by the NHMRC and the Department of Industry Innovation and Science of the [Australian Clinical Trials Website](#).

These initiatives, whilst generic, form an important central backdrop to the development of a WFD Strategy to specifically address the needs of clinical researchers focussed on emerging drugs.

3 Workforce Development: An Overview

What is workforce development?

Workforce development for emerging drug clinical researchers aims to ensure that Australia has sufficient workforce capacity to create and disseminate the evidence base that will enable individuals and organisations to prevent, and respond to, problems related to emerging drugs.

It includes issues such as recruitment and retention, workforce planning, professional and career development and worker wellbeing. Without addressing these underpinning and contextual factors, the ultimate aim of increasing the workforce's effectiveness is unlikely to be achieved (Roche & Nicholas, 2016).

Workforce development can be defined as:

...a multi-faceted approach which addresses the range of factors impacting on the ability of the workforce to function with maximum effectiveness in responding to alcohol and other drug related problems. Workforce development should have a systems focus. Unlike traditional approaches, this is broad and comprehensive, targeting individual, organisational and structural factors, rather than just addressing education and training of individual mainstream workers (Roche, 2002a).

¹ In Australia, and throughout the world, clinical trials networks have been formed as a means of bringing together large communities of clinical researchers with a common interest in advancing the evidence base for a particular area of clinical practice. In Australia there are approximately 60 clinical trials networks. There may be merit in the AOD Sector seeking to establish a clinical trial network (see later Consultation Paper question).

² The course is currently conducted by Swinburne University of Technology.

This broad definition of WFD necessitates a focus on a wide range of individual, organisational, structural and systematic factors that impact the ability of the workforce to effectively prevent and respond to AOD issues.

It is possible to delineate three evolutionary phases of WFD in the AOD field which provide insight into the WFD approaches most likely to be effective for clinical researchers involved with emerging drugs.

Phase 1: Individual workers

The first phase focused on individual workers. Key strategies in this phase were education and training programs and resources to enhance individual workers' knowledge and skills. By the early 2000s, the limitations of this approach were increasingly apparent (Roche, 2002b).

This approach failed to take into consideration the influence of the systems in which workers were located. While education and training can enhance individual workers' knowledge and skills, this does not always translate into sustainable work practice change. Quality clinical research is dependent on a range of organisational, structural, and systemic factors largely beyond the control of individual workers (Roche, Pidd, & Freeman, 2009; Roche, Watt, & Fischer, 2001).

Phase 2: An internal systems approach

The next phase involved WFD strategies which focussed on the *internal systems* in which AOD workers were employed by targeting organisational and structural factors, as well as individual factors (Baker & Roche, 2002). The internal systems perspective included a diverse range of issues such as:

- Recruitment and retention
- Information management
- Leadership and mentoring
- Knowledge transfer & research dissemination
- Workplace support
- Evidence-based practice
- Professional and career development
- Workforce wellbeing
- Clarification of staff roles & functions
- Policy
- Clinical supervision
- Effective teamwork
- Evaluating alcohol and other drugs programs & projects
- Goal setting
- Organisational change
- Legislation
- Scholarships
(Roche & Pidd, 2010)

Workforce development was no longer viewed as just comprising education and training initiatives. Instead, education and training initiatives were increasingly viewed as a subset of WFD activities which, in the absence of broader approaches, were likely to have limited effect (Roche, 2001). Figure 1 illustrates how infrastructure, systems and organisational issues are essential to complement and facilitate training. Figure 2 indicates how education and training programs influence individual factors which, in turn, articulate with a range of system factors.



Figure 1: Levels and components of workforce development. Source: Roche & Pidd (2010)

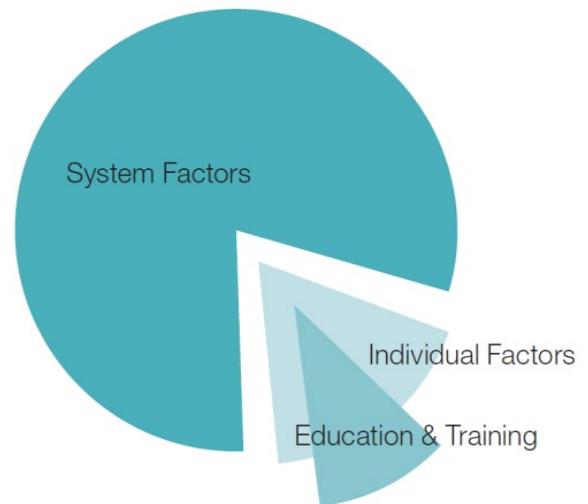


Figure 2: Education and training as one element of workforce development. Source: Roche & Pidd (2010)

It is important not to underestimate the challenges associated with implementing internal systems measures in some environments.

Phase 3: A broader services systems approach

While the AOD internal systems approach represented an improvement over an individual worker approach, it is unlikely to fully meet the needs of the clinical research workforce into the future. There is a growing appreciation of the need to prevent and address problematic AOD use in conjunction with other mental, physical, and social problems (Roche, 2013). There is also a growing awareness that effective clinical research requires greater collaboration between researchers and clinicians and other strategies to embed research into clinical practice.

A more comprehensive approach to WFD has a range of implications for clinical researchers in emerging drugs. The future of clinical research in this area is likely to increasingly lie in more structured relationships between consumers, clinicians and researchers which will help to:

- Ensure that funds are provided to support cost effective research that will maximise community benefits
- Generate research questions of relevance to consumers and clinicians
- Incorporate clinical research into routine clinical practice
- Increase understanding by researchers of issues faced by clinicians and the clinical context
- Increase capacity of clinicians to engage in research and evidence derived from research
- Increase the number of clinical researchers and the clinical research effort.

4 More Information Needed on the Clinical Research Workforce

Little information is currently available on the characteristics of the workforce undertaking clinical research into emerging drugs. This is a major impediment to WFD and planning. Effective workforce development and planning requires information on:

- The existing workforce and its characteristics
- The demand for the workforce; and
- Entries to and exits from the workforce (Health Workforce Australia, 2013).

Development of the Clinical Researcher WFD Strategy will provide some insight into the characteristics of the clinical researcher workforce, but it is unlikely to provide a comprehensive picture. Gaining more comprehensive insights into the workforce is likely to require additional focussed effort.

- Q1. *How many people do you estimate are currently involved in undertaking clinical research into AOD generally and emerging drugs specifically in Australia? For example, out of 100 people working in AOD how many would be involved in undertaking clinical research?*
- Q2. *What backgrounds do those involved in clinical research into AOD generally and emerging drugs specifically come from and what qualifications do they have?*
- Q3. *What is your understanding of the demographic profile of most of those involved in Australian clinical research into AOD generally and emerging drugs specifically?*
- Q4. *What are the funding sources (and volumes) for clinical research into AOD and emerging drugs?*
- Q5. *Should the AOD Sector explore the establishment of a clinical trials network³ for AOD research?*

5 Developing Researchers

Efforts to develop the research workforce have also been undertaken elsewhere. For instance, the United Kingdom (UK) recently implemented a [Researcher Development Framework \(RDF\)](#) to enhance its capacity to build the UK research workforce, develop world-class researchers and build its research base.

The RDF is a professional development framework for planning, promoting and supporting the personal, professional and career development of researchers. It describes the knowledge, behaviours and attributes of successful researchers and encourages them to realise their potential.

The RDF was created from empirical data, collected from interviews with researchers, to identify the characteristics of excellent researchers expressed in the RDF as 'descriptors'. The descriptors are structured in four domains:

1. The knowledge and intellectual abilities required to conduct research
2. Personal effectiveness (personal qualities and approach)
3. Research governance and organisation (knowledge of standards, requirements and professionalism)
4. Engagement, influence and impact (knowledge and skills to work with others and ensure the wider impact of research).

³ Clinical Trials Networks are collaborative groups of practicing clinician that come together to identify important clinical questions and design large multi-centre clinical trials (Australian Clinical Trials Alliance, 2018).

The UK approach to research development is provided as an illustration of the types of conceptual models that could be developed for the current WFD strategy.

In recognition of the importance of clinical research in Australia, a number of Australian initiatives have been implemented which seek to enhance the career development opportunities for clinical researchers.

While not the specific focus of this Strategy, several initiatives aim to support the medical clinical academic⁴ workforce. This has occurred in response to a decline in the proportion of medical clinical academics compared with full-time clinicians that has occurred since 2004 (Windsor et al., 2017).

In 2013, the Australian Medical Association developed a model outlining clinical academic training options in support of a career in clinical academic medicine. The model contains elements that may be applicable to other clinical workforces as well. Key tenets of this model are:

- Medical students must have an opportunity to experience research at medical school
- Clear and well-articulated pathways must be in place for trainees, senior doctors and clinical academics to pursue a clinical academic career
- Strong mentors and role models must support early career clinical academics
- Flexible entry and exit points must be a key feature of the pathway
- Academic promotion and reward schemes must be developed
- More funding for clinical academic positions and research is needed to support academic development
- Support for academic medicine must be embedded in every aspect of the health system.

A more detailed representation of the model appears in Figure 3.

Clinical pathway	Enablers	Academic training pathway options
Consultant	<ul style="list-style-type: none"> • Flexible entry and exit points • Strong mentors and role models • Academic workforce recruitment and retention initiatives, rewards and incentives • Research culture embedded in health system 	<ul style="list-style-type: none"> • Post-fellowship higher degree • Doctorate by publication
Registrar		<ul style="list-style-type: none"> • Combined speciality/Doctorate program • Doctorate as a component of advanced training • Clinical fellowship/lectureship • Medical education registrar
Resident		<ul style="list-style-type: none"> • Combined MBBS/MD-MPH/MCR/PhD program • Academic internships • Research elective • Academic rotations • Intercalated research degrees, combining a Bachelor, Honours, Masters and/or Doctorate degree with the MBBS/MD program
Intern		
Medical student		

▲
Underpinned by

▲
A range of robust funding models and options:

- Project and program grants
- Strategic research awards
- People support awards
- Competitive scholarships/fellowships
- Financial support for sectors appointing new researchers

▲
Supportive host environment in partnership with universities and medical colleges:

- Clinical networks of excellence
- Academic health science centres

▲
Health workforce planning articulates with clinical academic research, education, training and health care priorities

⁴ Clinical academics are clinician leaders who, through training and experience, have decided to make research and/or education a significant part of their professional career (Windsor et al., 2017).

Figure 3: A model to encourage career medical clinician academics in Australia

Source: Australian Medical Association (2013)

Two summits held in 2014 and 2015 sought to understand the challenges faced by medical clinical academics in the current environment, identify current training pathways and decide on future directions. The summits highlighted the need to create a sustainable clinical academic workforce by providing defined and supported pathways for each stage of researcher development. The results of a survey of university medical schools and teaching hospitals that was presented at the second summit, revealed that while 92% of respondents endorsed the importance of clinical academics:

- Only 31% of responding organisations offered a defined training pathway for clinical academics (e.g., PhD programs, intercalated degrees during medical school or mentorship programmes)
- A specific mentoring program was offered by only 43% of responding organisations with established clinical academic pathways
- Only 7% of the respondent organisations were planning on implementing clinical academic training pathways in the future (Windsor et al., 2017).

The summits called for:

- The development of an integrated and defined clinical academic training pathway
- Establishment of meaningful mentoring programmes
- Role modelling
- The profiling of successful clinical academics and their institutions
- Strategic funding for more training positions and administrative support (Windsor et al., 2017).

The [Australian Academy of Health and Medical Sciences](#) (AAHMS) has also established a strong senior mentorship programme that aims to help sustain the medical research workforce into the future. The Academy's one-to-one Mentorship Program provides an independent avenue for career, personal and leadership development for young scientists to help realise their full potential. Future programs will also include career development for mid-career scientists.

The [NHMRC](#) also plays an important role in clinical researcher development. A key focus of the NHMRC is to support the translation of health and medical research into clinical practice, health policy and healthcare delivery.

The NHMRC supports this translation through a number of funding mechanisms, including the [Translating Research into Practice Fellowships \(TRIP\)](#), [Practitioner Fellowships](#) and through the [Recognised Health Research and Translation Centres initiative](#) (RHRTC). There are two programs within the RHRTC:

- Advanced Health Research Translation Centres (AHRTCs) – established in 2014
- Centres for Innovation in Regional Health (CIRHs) – established in 2016 to specifically recognise centres that address regional Australia population needs.

The core aim of the AHRTC and CIRH initiatives is to encourage excellence in health research and translation in Australia by bringing together researchers, healthcare providers, and education and training to improve the health and well-being of patients and the populations they serve.

It is important to note that these initiatives are not confined to meeting the needs of medical practitioners. NHMRC TRIP fellowships for example, provide support for health care professionals (e.g., medical specialists, general practitioners, public health practitioners, physiotherapists, nurses, midwives, radiologists, and other allied health providers), health care personnel (health service managers, hospital department leaders, clinical trial managers) health systems personnel, health researchers and health policy makers to translate evidence into health care and public health improvements.

Q6. *What are the major strengths and gaps in Australia's approach to AOD clinical researcher development?*

6 Recruitment and Retention of Clinical Researchers

Effective recruitment and retention of the emerging drugs clinical research workforce is essential to building capacity in this area. There is currently limited knowledge of factors that impact recruitment and retention of this workforce.

The National Alcohol and other Drug Workforce Development Strategy (IGCD, 2015) made a number of recommendations to enhance recruitment and retention in the AOD field in general. These included:

- Flexible working arrangements (part time work, position sharing, time-in-lieu and working from home)
- Flexible access to education and training opportunities including enhanced use of online learning and other technologies
- Parental leave
- Comprehensive orientation programs to support transition into the sector
- Mentoring and clinical supervision programs
- Management and leadership development programs focussing on responding to the needs and expectations of the workforce
- Pay increments related to competency/ qualification acquisition as appropriate
- Opportunities for service linked scholarships and education cost payments
- Employment exit interviews/surveys to better understand the reasons for leaving the sector
- Portability of long service and sick leave entitlements as workers move between agencies
- Enhanced job security via longer-term employment contracts/permanent positions.

Many of these measures may also be relevant to the emerging drugs clinical research workforce.

Factors influencing recruitment and retention have also been examined among the generic research workforce. Recent research conducted with 1,203 Australian researchers, focussed on identifying the positive and less positive aspects of research careers. It involved an on-line survey and focus group discussions, and sheds light on a range of recruitment and retention issues facing the Australian research workforce.

Respondents indicated that the most positive aspects of a career in research were working on interesting and important issues and working in a stimulating environment (ACOLA, 2012). Concerns identified in the ACOLA (2012) study included:

- *Uncertain job prospects*, nominated as the single worst aspect of a career in research. Most early career researchers faced a succession of short-term contracts. Their chances of winning grants or fellowships were slim, and lower if they had a limited record of publications. This was further compounded by limited institutional funding to 'carry' a researcher from the end of one grant until they succeeded in picking up another. Senior researchers faced similar challenges from the competitive nature of funding.
- *Excessive workloads* were a major issue, which increased with age and seniority. Excessive workloads and job expectations meant having to juggle teaching, supervision, maintaining an active research profile, managing projects and complying with administrative requirements.
- *A lack of career path* was another concern for researchers at all stages of their careers, with minor variations by gender (seen at that time as more of an issue for men).
- *Working conditions*, included the organisation of work and work activities; training, skills and employability; health, safety and well-being; and working time and work-life balance.
- *Too many PhD students being accepted by universities* for the research and teaching positions available.
- *A lack of guidance and advice regarding career development* (e.g., mentoring, professional development activities and definitive sources of career information).

- *The process of winning grants:* Early career researchers reported a paradoxical situation in that they could not win grants or fellowships because their publication record was not competitive, but it was difficult to research or write papers while they had heavy teaching loads, or performing contract work on senior academics' research projects.
- *Excessive bureaucracy and paperwork:* particularly among senior researchers.

Potential remedial measures included:

1. Improving support for researchers in the early stages of their careers
2. Clearer articulation of research career pathways
3. More balanced workloads that addressed the demands of teaching, administrative duties, research and completing applications for fellowships and grants
4. Addressing the teaching-research nexus in universities: Teaching offers a degree of security but reduces time to conduct research and the workload can be oppressive
5. Providing advice, mentoring and information for researchers
6. Having more effective and efficient national research funding programs
7. Enhancing opportunities for research collaborations, mobility and commercial industry experience
8. Enhancing higher degree research training to improve work readiness
9. Increasing tenure, permanency and long-term contracts by:
 - Lengthening contracts and grants, typically from three years to five
 - Creation of more tenured and permanent positions
 - providing more security and stability within research organisations
 - having more positions for younger researchers
10. Having more appropriate salaries and stipends.

Questions arise regarding the extent to which issues similar to those identified above also apply to the AOD clinical researcher workforce. For example, AOD clinicians may be reticent to give up lucrative work roles with stable employment to face the uncertainty associated with a career in research.

This issue has been addressed in some disciplines by the development of clinician buy back schemes. This enables clinicians to buy out protected clinical time to engage in research activities. This involves providing funding to clinicians to conduct research, by either obtaining time to spend on research by foregoing clinical work, or by substituting another practitioner to fulfil clinical duties so that research can be undertaken.

There may be more interest in careers that combine research and clinical practice roles. This would require funding structures that allow both, organisational flexibility, defined research time and roles.

In response to concerns expressed by applicants for NHMRC research funds, in 2013, the Council introduced [several changes](#) which aim to:

- Encourage greater creativity and innovation in research
- Provide opportunities for talented researchers at all career stages to contribute to the improvement of human health
- Minimise the burden on researchers of application and peer review so that researchers can spend more time producing high quality research.

The new grant programs reflect the philosophy that health and medical research is best supported by a diverse portfolio of schemes that:

- Fund across the spectrum of health and medical research.
- Invest in people with outstanding research achievement and promise.
- Support the most innovative research to solve complex problems.
- Meet specific strategic objectives.

- Q7. *What are the key issues that positively or negatively impact the attraction of people into AOD and emerging drugs clinical research?*
- Q8 *How could these issues be addressed?*
- Q9 *To what extent do your employers provide opportunities, information and infrastructure to support the incorporation of research activities into your role?*

7 Career Paths for Clinical Researchers

Available career paths that enable individuals to become clinical researchers in the area of emerging drugs are not well understood. Some researchers come from a clinical background and go on to attain skills and qualifications in research. Others come from a quantitative or qualitative research background and apply these skills to the area of emerging drugs. The career paths taken will also vary by professional affiliation.

The lack of information concerning career pathways also makes workforce planning and development more difficult.

- Q10 *What are the current job opportunities in AOD and emerging drugs clinical research?*
- Q11 *Are you aware of funding schemes and other opportunities available to you to incorporate research into your role? Do you feel encouraged to seek out these schemes?*
- Q12 *How do most emerging drugs clinical researchers progress into those roles? How could these pathways be enhanced? What are the existing alternative pathways into these roles?*

8 Enhancing clinician / researcher partnerships

Enhancing clinician / researcher partnerships can enhance the likelihood that research conducted is clinically relevant and that the findings of research are implemented in clinical settings. It is also important that the development of these partnerships occurs across geographically diverse areas and is not confined to urban settings.

These partnerships also provide an opportunity to embed pragmatic clinical trials into routine clinical care. This can give rise to information and evidence that is of great clinical relevance since it is derived from issues that arise in day to day practice.

Q13. *How could partnerships between clinicians and researchers be enhanced across geographically diverse areas?*

Q14. *What could be done to encourage the incorporation of pragmatic clinical trials into routine clinical care?*

9 Education, Training, Mentoring and Fellowships

The difficulties associated with developing clinical researchers have been recognised for some time. The education, training and mentoring of clinician researchers is particularly challenging as it requires dedicated time away from the escalating pressures of clinical service (Zerhouni, 2005).

This Consultation will seek to identify if greater opportunities are required for education, training and mentoring. If so, the learning and development needs of researchers, or potential researchers, need to be identified on a discipline, as well as, an individual basis. This could occur as part of the employee induction process or annual performance development review. These needs should then be matched with activities specifically intended to address them.

The Consultation will also identify if organisations are providing opportunities and funding to access online and face-to-face training including:

- The NHMRC eLearning Modules
- Monash University's short course *Introduction to clinical trials*
- Swinburne University's 6-month course *Clinical trials application preparation, submission and review*
- The utilisation of experienced clinical researchers to run training forums and programs for workplaces
- Internship programs and clinical elective programs, where clinicians can specialise in a particular clinical or research area.

Mentoring is a particularly important workforce development approach. Mentoring is an informal and flexible approach to leadership, supervision and professional development. It involves the mentor and protégé setting goals that are focused on the protégé's professional and personal development needs. Mentoring relationships can occur between a mentor and a protégé or a small group of protégés, or it may involve peers who act as mentors for each other (Todd, 2005).

Mentoring can occur through formal programs or informal arrangements. Formal mentoring involves the development of structured programs for the progression of the mentoring relationship. In contrast, informal mentoring programs are formed spontaneously and rely on natural rapport between the mentor and protégé. Irrespective of the type of arrangement, mentoring involves:

- The mentor encouraging the protégé/s to find solutions themselves, rather than acting as the expert and simply providing answers
- The protégé/s drawing on the mentor's experience to meet goals (Todd, 2005).

The provision of fellowships is another important clinical researcher workforce development strategy. Fellowships are critically important for the development of the next generation of researchers and for the retention of researchers in a given field and to ensure that their skill are not lost to other countries.

Q15. How could education, training, mentoring and fellowship programs, or awareness of these programs, for clinical researchers focussing on emerging drugs be improved?

10 Funding

The funding of clinical research in Australia is complex. There is considerable pressure on funding bodies to meet the demand for grants and fellowships. It is unlikely that additional resources will be provided to funding bodies in the future.

There is a range of smaller reforms which could enhance the effectiveness of clinical research in Australia. These include:

- The provision of more funding by universities to tide junior researchers over in between grants
- Providing more comprehensive feedback on unsuccessful applications
- Announcing the results of funding programs at such a time (not December) to allow both successful and unsuccessful applicants time to adjust to, and plan for, their new circumstances
- Introducing a new flexibility to cater for the individual needs of applicants such as scholars with limited needs, and those who want to work part-time or to spread their grant over a longer period
- Introducing several funding cycles over the year, so applications can be handed in at any time and assessments are made and announced several times in the year
- Introducing a funding pool where only junior researchers are eligible to apply, and where they do not compete with senior researchers with strong track records (ACOLA, 2012).

Careful consideration should also be given to how clinician researchers can be released from clinical duties to undertake research.

Funding is also required to develop the skills necessary to assist the translation of research findings into practice.

Q16. How could Australian clinical research funding arrangements be enhanced to improve clinical research / researcher outcomes?

11 Management and Leadership Development

Effective leadership and management has long been recognised as a key component of effective research environments (Ajjawi, Crampton & Rees, 2018; Browning, Thompson & Dawson, 2011; Bland & Ruffin, 1992; McInnis, Ramsden, Maconachie, 2014). Among the range of components impacting research environments, effective leaders have a disproportionate impact through their influence on all other components (Browning, Thompson & Dawson, 2011).

Management and leadership support and enhancement are core components of workforce development which warrant attention in the emerging drugs clinical researcher Workforce Development Strategy.

Two important aspects of this issue include:

1. The extent to which potential and existing clinical researchers experience the effective leadership they need to reach their full career potential
2. The extent to which clinical researchers are provided with leadership development opportunities.

Q17. *How effective is management in emerging drugs clinical research in Australia?
How effective is management development in emerging drugs clinical research in Australia?
How effective is the leadership in the emerging clinical research in Australia?*

12 Researcher Wellbeing

Little is known about the levels of wellbeing of AOD clinical researchers. There is a body of work that focusses on the wellbeing of researchers and academics and general. However, no research was found which focussed on clinical researchers in general or AOD clinical researchers in particular.

In general, researchers and particularly younger researchers are under substantial pressure as a result of increased competition for jobs and funding. To forge a career in academia, researchers must publish in peer-reviewed journals, present at international conferences, have extensive networks, win funding and gain professional experience in teaching, administration and project management. Yet, research posts in academia are increasingly insecure, and involve limited fixed-term, poorly paid and part-time positions (Morris, 2013; Court & Kinman, 2009).

These factors can place the wellbeing of researchers, particularly early career researchers, at considerable risk. In addition, well paid established clinicians may be reluctant to forgo income, security and success for the uncertainties of academia.

There is limited published evidence regarding the prevalence of specific mental health conditions among researchers. Nevertheless, a literature review undertaken in the United Kingdom indicated that:

- The majority of university staff found their job stressful. Levels of burnout appear higher among university staff than in general working populations and are comparable to 'high-risk' groups such as healthcare workers
- The proportion of both university staff and postgraduate students at risk of having, or developing a mental health problem, based on self-reported evidence, was generally higher than for other working populations
- A large proportion (>40%) of postgraduate students reported symptoms of depression, emotion or stress-related problems, or high levels of stress (Guthrie, et al., 2017).

However, the same research found academics who spent a larger percentage of their time on research had reduced stress levels. Research-only staff reported lower levels of work-life conflict and had better wellbeing than other higher education institution staff. However, this may be to some extent confounded by other characteristics of such researchers (e.g., they may be more senior) (Guthrie, et al., 2017).

A further factor that warrants consideration is that conducting research in the AOD field may also expose researchers to similar risks of stress and burnout which are faced by AOD workers (Ewer et al., 2015; Roche et al., 2013; Volker et al., 2010).

Q18. *What are the current stressors impacting on AOD clinical researchers in Australia and what are the rewarding aspects of being an AOD clinical researcher? Do these offset each other and is this balance sustainable?*

13 Workforce Diversity

There is a diverse workforce involved in emerging drugs clinical research. At a broad level, this can be divided into two groups:

1. Those who are primarily employed as researchers, and may or may not have clinical training;
2. Those who are primarily employed as clinicians, with variable research experience. These include clinicians from:
 - Medicine (e.g., addiction medicine, psychiatry, toxicology, pharmacology and general practice)
 - Nursing
 - Psychology
 - Social work
 - Occupational therapy
 - Pharmacists
 - Counsellors
 - Aboriginal Health Workers.

Q19. *In what ways do emerging drugs clinical researcher development needs differ between those primarily employed as researchers and those primarily employed as clinicians, and among disciplines (e.g., doctors, nurses, and allied health)?*

In addition, it is also important to ensure that the clinical research workforce comes from a diverse range of backgrounds.

Q20. *How could diversity (Indigenous Australians, CALD, LGBTIQ, rural and regional) be enhanced in the emerging drugs clinical researcher workforce?*

14 Translation of Research into Practice

It is critically important that prevention, early intervention and treatment practices in the AOD field are based on the best available research evidence. For this reason, the effective translation of research into practice, (i.e., knowledge translation) is crucial. Knowledge translation involves numerous processes, systems and interactions between the researcher and practitioner/knowledge user. Successful

dissemination and uptake of research evidence requires the identification of the target audience and tailoring information via suitable mediums (Curtis, Fry, Shaban & Considine, 2017).

AOD clinical researchers and clinicians may come from a broad range of disciplines and backgrounds, and consequently, their educational qualifications, training in AOD issues, and understanding or appreciation of research can vary considerably. Thus, effective dissemination strategies must bridge the conceptual and cultural distance between the researchers and the AOD workforce (Bywood, Lunnay & Roche, 2008).

The changing roles of Australia's publicly funded health facilities has also adversely affected the interface between research and clinical work across a range of disciplines in recent decades. Until the late 1970s, it was generally accepted that the publicly funded facilities, such as hospitals, had an important role to play in bridging the gap between clinicians and researchers and in the training of the future research and clinical workforce. The increasing trend towards health agency funding based solely on health services delivered, has meant that these agencies increasingly focus on service delivery. This has resulted in minimal acknowledgement that research and innovation dissemination are essential for improved health outcomes (Brown & Sorrell, 2009).

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| Q21. | <i>How could research translation occur more effectively in relation to emerging drugs clinical practice in Australia?</i> |
| Q22. | <i>What measures could AOD clinical environments adopt to enhance research literacy and innovation dissemination amongst clients?</i> |
| Q23. | <i>What can Australian AOD workplaces do to increase research literacy amongst their staff, to assist them to bring research into practice?</i> |
| Q24. | <i>Do you feel confident in consuming clinical research literature and evaluating new evidence?</i> |
| Q25. | <i>Do you have someone in your organisation that you can talk to about the clinical literature and evidence?</i> |

15 Conclusion

The challenges associated with which emerging drugs clinical researchers will need to grapple in the future are as yet unclear. As new substances evolve in the future it will be critically important to have a flexible emerging drugs research workforce that can devise and test new approaches to respond to the harms associated with these drugs.

Achieving this will require a comprehensive approach to WFD such as that outlined in this consultation paper.

The Workforce Development Strategy that will be the ultimate outcome of this consultation process will need to meet the needs of clinicians wishing to enhance their role in clinical research and researchers wishing to specialise in emerging drugs.

It will also be important to enhance innovation dissemination processes to ensure that the findings of current and future emerging drugs clinical research are disseminated more effectively throughout the AOD sector.

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Appendix 1: List of Consultation Questions

The series of questions below have been developed to guide the consultation process. These questions appear in blue shaded boxes throughout the Consultation Paper.

- Q1. How many people do you estimate are currently involved in undertaking clinical research into AOD generally and emerging drugs specifically in Australia? For example, out of 10 people working in AOD, how many people would be involved in undertaking clinical research?
- Q2. What backgrounds do those involved in clinical research into emerging drugs come from and what qualifications do they have?
- Q3. What is your understanding of the demographic profile of most of those involved in Australian clinical research into AOD generally and emerging drugs specifically?
- Q4. What are the funding sources (and volumes) for clinical research into AOD and emerging drugs?
- Q5. Should the AOD Sector explore the establishment of a clinical trials network for AOD research?
- Q6. What are the major strengths and gaps in Australia's approach to AOD clinical researcher development?
- Q7. What are the key issues that positively or negatively impact the attraction of people into AOD and emerging drugs clinical researchers?
- Q8. How could these issues be addressed?
- Q9. To what extent do your employers provide opportunities, information and infrastructure to support the incorporation of research activities into your role?
- Q10. What are the current job opportunities in AOD and emerging drugs clinical research?
- Q11. Are you aware of funding schemes and other opportunities available to you to incorporate research into your role? Do you feel encouraged to seek out these schemes?
- Q12. How do most emerging drugs clinical researchers progress into those roles? How could these pathways be enhanced? What are the existing alternative pathways into these roles?
- Q13. How could partnerships between clinicians and researchers be enhanced across geographically diverse areas?
- Q14. What could be done to encourage the incorporation of pragmatic clinical trials into routine clinical care?
- Q15. How could education, training, mentoring and fellowship programs, or awareness of these programs) for clinical researchers focussing on emerging drugs be improved?

- Q16. How could Australian clinical research funding arrangements be enhanced to improve clinical research / researcher outcomes?
- Q17. How effective is management in emerging drugs clinical research in Australia?
How effective is management development in emerging drugs clinical research in Australia?
How effective is the leadership in the emerging clinical research in Australia?
- Q18. What are the current stressors impacting on AOD clinical researchers in Australia and what are the rewarding aspects of being a clinical AOD researcher? Do these offset each other and is this balance sustainable?
- Q19. In what ways do emerging drugs clinical researcher development needs differ between those primarily employed as researchers and those primarily employed as clinicians, and among disciplines (e.g., doctors, nurses, and allied health)?
- Q20. How could diversity (Indigenous Australians, CALD, LGBTIQ, rural and regional) be enhanced in the emerging drugs clinical researcher workforce?
- Q21. How could research translation occur more effectively in relation to emerging drugs clinical practice in Australia?
- Q22. What measures could AOD clinical environments adopt to enhance research literacy and innovation dissemination amongst clients?
- Q23. What can Australian AOD workplaces do to increase research literacy amongst their staff, to assist them to bring research into practice?
- Q24. Do you feel confident in consuming clinical research literature and evaluating new evidence?
- Q25. Do you have someone in your organisation that you can talk to about the clinical literature and evidence?