

Perspective

**General Practitioners Tackle Complex Addictions:
How complex interventions can assist in dealing with addiction**

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ABSTRACT

Substance use disorder treatment is a complex problem. Complex problems require complex interventions, ideally tested via randomised controlled trials. Complex interventions are best developed in stages, using established implementation frameworks. **Starting with a historical patient case study, we explore how treatment of this challenging population group has been approached, how an evidence-based framework has informed formulation of a complex health intervention and how this has been progressed via the U.K.'s Medical Research Council (MRC) approach.**

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So there he was, with the boy's head in his hands. The boy was 12, but looked no more than 10 years old. He was deeply jaundiced and in a heroin withdrawal (Ryan, Arthurs, Kelly, & Fielding, 1982). It was 1981; Fergus O'Kelly was a family physician at the Coombe Family Practice in the inner city Dublin, Ireland.

Three years ago, there was no drug problem. As the shocked O'Kelly wrote in a report to the authorities: "During this period and especially the last eighteen months there has developed a widespread and very serious drug problem (O'Kelly, O'Doherty, Bury, & O'Callaghan, 1986)." He knew this was a burning, complex issue, but where to start? What aspect of the problem to address first? Is it the overall heroin epidemic? How to handle overdose in medical settings? How to prevent and/or intervene in drug problems? This article offers a perspective on the development and evaluation of complex interventions in the context of services for substance use disorders within the health care system, according to the U.K.'s Medical Research Council's recommendations and following experiences of Dr O'Kelly and his successors.

Complex problems require complex interventions, ideally tested via randomised controlled trials (**RCT**). Designs of trials to "evaluate the benefits of specialist stroke units," or clinical guidelines, are good examples (Campbell et al., 2000). By translating scientific knowledge to advance the practice, controlled evaluations of complex interventions bridge the implementation gulf between scientists and practitioners. That's exactly what O'Kelly desired. His problem needed improvements at the level of patient, access to treatment, organisation of care and coordination between services.

Complex interventions are best fashioned in stages, says the Medical Research Council in U.K. They came up with a six-step recipe for “cooking” complex interventions (Campbell et al., 2000). The recipe can help researchers and providers define their interventions and evaluate their implementation.

First, explore the background. Address the design of the intervention and potential confounders. For example, Cochrane researchers from University of Limerick queried scientific literature to see what **works** for people who drink heavily and use other drugs at the same time (Klimas, Tobin, et al., 2014). Finding little to suggest what worked best, they asked the experts (Klimas, Cullen, & Field, 2014).

Both the scientific evidence and the experts’ opinions informed clinical guideline for primary care. Meanwhile, their colleague, Elisabeth Schaffalitzky and partners found that “nobody really gets it” for disadvantaged, at-risk adolescents and young adults with mental health problems (Schaffalitzky et al., 2014). Both teams discovered cracks in **the health care** system, **such as negative attitudes**, that hindered care of vulnerable populations and could inform the next steps in the development process.

Second, understand how your new intervention works. What are the underlying mechanisms and how do they interact with each other? Niamh Ryder and her colleagues found that one third of people attending **general practitioners (GPs) in Ireland** for addiction-related care were also heavy drinkers (Ryder et al., 2009). Because many of them had Hepatitis C infection, their livers were in danger. In this example, the medicine that the patients received for their **opioid** addiction (methadone) did not keep them drug-free. Every week, a person overdosed on opioids, as another team of researchers from Centre for Emergency Medicine found (Klimas, O’Reilly, Egan, Tobin, & Bury, 2014). What’s more, most of these

overdoses happened in one small area – a hotspot. Observational studies like these help us assess the current practice or map the environmental and structural factors determining the health of people with substance use disorders. **The clinical guideline created in the first phase of the process was ideal for developing a complex solution that would target excessive drinking by people receiving methadone in primary care. Since heavy drinking was linked to higher risks of overdose and death in this population, using clinical guideline in the complex solution would also reduce the risk of overdoses (Johnson et al., 2015). The guideline advised GPs to ask, assist, advice and arrange referrals specialists for patients with serious alcohol use disorders because of the weakness of evidence for medication-assisted therapy for this patient population attending primary care.**

Next, run the new intervention in a handful of practices. Pilot tests may or may not have control groups and are generally underpowered to test the interventions. What's the point of such studies? - to determine interventions' feasibility. **The clinical guidelines, as part of the new complex intervention to be tested in a pilot project, recommended psychosocial interventions.** Are psychosocial interventions for drinking among people who also use other illicit drugs feasible? An initiative called The Problem Drug Use In General Practice, **formed from the same experts who developed the clinical guideline**, turned to **patients and their GPs** for help with this question (Field et al., 2013). **Only a few GPs** agreed to participate in a pilot trial, **but adhering to the MRC's** stepwise approach **yielded key ingredients for** the process of development and evaluation of complex intervention (**i.e., clinical guideline with manualised support and education**), including **numbers needed to screen and recruit** for a definitive trial.

Fourth, run a definitive clinical trial. For example, in such a trial, you may want to check whether primary care providers are willing to and actually use the clinical guidelines - your newly designed complex solution. Back at the Coombe Family Practice in Dublin, **an earlier** guideline for treating Hepatitis C (HCV), **by Dr Cullen's group**, recommended patients with addiction get their treatment in primary care (Cullen et al., 2006). This kind of guideline could have helped the desperate O'Kelly treat his 12-year old patient. Although many other guidelines were published earlier, nobody used them.

In a setting where integration of services and comprehensive care is paramount, a subsequent large scale controlled trial showed that doctors using the new guidelines, and receiving support in following them, were better serving their patients than the control group. The key was to sustain the momentum once the clinicians were willing to **actively** manage **HCV** in primary care.

Last, help clinicians keep using the intervention when the researchers leave. The **main** ingredients in the **last** step of the recipe are practical impacts. Is your staff happy with the sudden influx of complex patients? Dr Bury's research team in **Dublin** introduced treatment with an opioid agonist medication, methadone, **to** general practice. Getting the **GPs'** buy in for this treatment in the **early** nineties wasn't easy, but none of them had concerns over patient workload, or treating opioid use disorders, three months later (Langton et al., 2000). **Qualitative follow-up** studies like this help make findings usable and interventions sustainable. **Finding complex solutions to complex problems might also require the use of complex, more innovative methodologies. In particular, qualitative or mixed-methods approaches might explore issues of feasibility, acceptability and implementation.** What are the implications for addiction-care providers in other jurisdictions?

Substance use disorder treatment is a complex problem. Complex problems require complex solutions. Complex interventions are best developed in stages, using established implementation frameworks. Apart from the U.K.'s Framework for the phased development of complex interventions, the providers can use **the** Comprehensive Framework for Implementation Research (CFIR) (Damschroder et al., 2009). This meta-framework attempts to unite all published implementation models. It has five major domains: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. Its generic nature allows studying underlying concepts, thus overcoming barriers between specialties, nations and individual "theories".

The unfortunate boy has long since gone to God. Two of his brothers and one sister are still attending the same inner-city doctor. In healthcare, we should do our best to help people. Just like the wood-fired ovens make the best pizzas, we should put our complex interventions through evaluation trials by fire **too**. Investments into robust, complex interventions are needed because substance use disorders are beyond simple solutions.

Conflict of Interest

None reported.

Ethical Standards

The author asserts that all procedures contributing to the work described in this perspective piece comply with the ethical standards of the relevant national and institutional committee on human experimentation with the Helsinki Declaration of 1975, as revised in 2008. The institutional review board of each participating institution approved the study protocols of work described in this perspective piece. Written informed consents were obtained from all patients participating in studies described in this perspective piece.

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