

longer. A recent follow-up study of a large, multisite trial found that significantly higher earnings for IPS clients compared to controls persisted over a five-year period after the two-year intervention⁶. Cost-effectiveness analyses of randomized controlled trials of IPS have generally found the aggregated costs of vocational and mental health services to be no higher, and sometimes significantly lower, for IPS than for standard services².

IPS has expanded steadily, spreading to new clinical populations and more mental health settings in the US and worldwide. Recent randomized controlled trials of IPS include six trials for people with common mental disorders, two for people with substance use disorders, and one for veterans with spinal cord injuries. Eight of these nine studies showed employment outcomes significantly favoring IPS⁷.

Several large-scale IPS trials in other populations are in progress, including three for people with substance use disorders: Project BEES in the US, the IPS-AD study in the UK, and a similar study in Norway. Several small randomized controlled trials of IPS for people with criminal justice involvement have been completed, with a large-scale US trial, the Next Gen study, to start soon. Following pilot work, large IPS trials are planned or underway for people with autism spectrum disorder, borderline personality disorder, and chronic pain.

IPS also helps young adults negotiate the pathway to meaningful adult roles in employment and education, e.g., as a standard component of early intervention programs for clients with a first episode of psychosis. Other subgroups of the young adult population also appear to benefit from IPS (<https://ipsworks.org/index.php/evidence-for-ips/>).

The effectiveness of IPS has been well established since at least the turn of the century. The key question for IPS, as for other evidence-based psychosocial practices, is how to close the gap between the known population of those who want and need these evidence-based services and those who have access. In the US, approximately 60% of people with serious mental illness want to work, but less than 2% have access to IPS. The primary barriers have been inadequate funding and the lack of methodology for large-scale expansion².

While adequate financing remains elusive worldwide, some governments have made national commitments to fund IPS access⁸. The second ingredient is a mechanism to facilitate adoption, high-fidelity implementation, growth and sustainment of

IPS. Since 2002, our group has led an international learning community that coordinates education, training, technical assistance, fidelity and outcome monitoring, and regular communications through newsletters, bimonthly calls, and an annual meeting⁹.

The learning community has continuously reported employment rates for participating IPS programs in the US every three months for 18 years. During this time, the overall quarterly employment rate has not dipped below 40%, even during the Great Recession. The learning community helps programs sustain IPS services over time: in one prospective study, 96% of 129 IPS programs were sustained over two years. Participation has expanded steadily, with a mean annual growth rate of 26% in the number of IPS programs in the US. The learning community helps to maintain over 450 IPS programs, including 366 in the US and 100 outside the US, most at high fidelity with good employment outcomes.

Rapid expansion of IPS across the world⁸ includes at least 19 high-income countries outside the US over the past 20 years (Australia, Belgium, Canada, China, Czech Republic, Denmark, France, Germany, Iceland, Ireland, Italy, Japan, New Zealand, the Netherlands, Norway, Spain, Sweden, Switzerland, and the UK). The flexibility and adaptability of the IPS model facilitate successful adoption with high fidelity and good employment outcomes in countries with diverse sociocultural conditions, labor laws, welfare systems, and economic conditions⁴.

The steady growth of programs, sustainment of services, and expansion to new populations makes IPS a unique evidence-based practice. We attribute success to client interest, continuous research-based improvements, and a vibrant learning community.

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Delivering on the public health promise of the psychosis risk paradigm

The clinical high-risk (CHR) paradigm was developed in the 1990s as a framework for early detection and prevention of psychotic disorders¹. Now, after about 25 years of experience, it seems opportune to reconsider the goals of the paradigm in relation to its aspired impacts on public health. In particular, it is reasonable to question whether the focus on conversion to a fully psychotic

form of illness as the singular endpoint of interest is well-placed.

Although many *research* goals have been advanced using this endpoint, including the development and validation of individualized risk calculators² and the identification of neural mechanisms associated with the onset of psychosis³, the *clinical* impacts of these advances are at present limited.

The difficulty translating findings on predictors and mechanisms of onset of psychosis into practice is due in part to the intrinsic uncertainties of attempting to prevent a future diagnostic outcome. Such uncertainties include whether widespread application of CHR criteria could ascertain all or most first-episode cases prior to onset, and ambiguity concerning the length of follow-up required to demonstrate prevention.

At the same time, it has become increasingly apparent that the CHR syndrome is itself associated with significant burdens in terms of symptom severity and functional impairments, independently of its role as a predictor of risk for onset of psychosis. Therefore, our public health interests may be better served by developing and testing interventions targeting remission of the CHR syndrome as a primary endpoint.

Doing so first requires recognition of CHR status as a psychiatric condition in its own right and making its diagnosis a routine matter in community mental health settings. In the nosological tradition of our field, diagnostic constructs are based on constellations of co-occurring symptoms that are distressing and interfere with social and occupational functioning. The individuals meeting CHR criteria who have been recruited into observational research studies and clinical trials are distressed and seeking treatment⁴. Although by definition their positive symptoms (i.e., delusions, hallucinations, thought disorder) are of sub-psychotic intensity, these symptoms are nevertheless disruptive and rate-limiting for social and role functioning⁵, on average at about the level associated with major depressive disorder with comorbid alcohol abuse⁶.

Criteria are in fact available in the Section III of the DSM-5 to diagnose a condition – attenuated psychosis syndrome (APS) – that is based on the CHR syndrome defined in the Structured Interview for Prodromal Risk Syndromes (SIPS)⁷ and the Comprehensive Assessment of At-Risk Mental States (CAARMS)⁸.

These two interviews have been extensively used in research settings, where they can be implemented with high reliability among trained diagnosticians. However, the training programs needed to become proficient in their use are somewhat demanding (typically requiring 2+ days of in-person training), and the instruments themselves take quite a bit of time (typically, 1.5 to 3 hours) to administer, primarily because they include ratings for many symptoms that are not actually used in the clinical diagnosis of APS. These features create too large a burden for the SIPS or CAARMS to serve as “front-line” vehicles for the clinical diagnosis of APS in the community. Thus, there is an urgent need to develop a significantly streamlined interview and training module for APS diagnosis that could be feasibly and reliably implemented in community mental health sites around the world.

Assuming we can reach agreement on APS as a diagnostic construct and make its reliable diagnosis a matter of routine, developing and testing interventions that can bring about its remission is the next major challenge. Currently available treatments may be helpful in this regard for part of the APS population. In about 30% of such individuals enrolled in observational studies and receiving usual and customary treatment, positive symptoms decline to below-prodromal intensity during the 12 to 24-month follow-up intervals typical of these studies⁹. While this percentage no doubt

includes some who remit spontaneously (some of whom may have been “false positives” from a psychosis risk perspective), the fact that “usual and customary” treatments tend to be crisis-oriented and non-specific suggests that there may be room for improvement with more intensive therapeutic approaches that include a focus on the development of thinking and social skills.

It would be useful for data from randomized clinical trials involving APS cases to be re-analyzed using remission (on symptomatic and/or functional grounds) as the endpoint of interest. Any indication that targeted interventions increase remission rates over and above those achieved during a waiting period or with usual and customary treatment would be a useful initial signal that could be pursued in future treatment trials.

That only about 30% of APS cases remit with usual and customary treatment also means that 70% of these individuals have outcomes that imply a continuity or worsening of symptoms, distress, and functional impairment (such as maintenance of APS or conversion to a psychotic disorder). Together, these features seem consonant with the requirements of a diagnostic construct and imply the need for more intensive and targeted treatment.

Paradoxically, a corollary benefit of re-focusing on remission of APS as a primary endpoint may in fact be a reduction in psychosis risk in the population. Given that the APS criteria are a potent predictor of psychosis, risk is much lower among the population that does not meet these criteria. Though it is not known precisely what the risk is among those cases who previously met the criteria and then remitted – this issue needs to be systematically evaluated – the risk is much lower than among those who currently meet APS criteria. It follows that treatments that cause remission of APS would also likely result in a delay or reduction in risk for progression to full psychosis.

The CHR paradigm continues to be a useful approach for studying mechanisms associated with psychosis onset. As such, observational studies will no doubt continue to focus on conversion to a fully psychotic form of mental illness as a key outcome. Nevertheless, recognizing APS as a diagnostic construct in its own right, and focusing on its remission as a primary endpoint in intervention studies, would more readily facilitate translation of findings emanating from this approach into clinical practice, and thereby help address the unmet health needs of a vulnerable population.

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