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Review article

The evidence–practice gap in specialist mental healthcare: systematic review and meta-analysis of guideline implementation studies

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Background
Clinical practice guidelines are not easily implemented, leading to a gap between research synthesis and their use in routine care.

Aims
To summarise the evidence relating to the impact of guideline implementation on provider performance and patient outcomes in mental healthcare settings, and to explore the performance of different strategies for guideline implementation.

Method
A systematic review of randomised controlled trials, controlled clinical trials and before-and-after studies comparing guideline implementation strategies *v.* usual care, and different guideline implementation strategies, in patients with severe mental illness.

Results
In total, 19 studies met our inclusion criteria. The studies did not show a consistent positive effect of guideline implementation on provider performance, but a more consistent small to modest positive effect on patient outcomes.

Conclusions
Guideline implementation does not seem to have an impact on provider performance, nonetheless it may influence patient outcomes positively.

Declaration of interest
None.

Clinical practice guidelines have become a standard tool in the attempt to increase the quality of clinical care. Surprisingly, whereas the pathway from evidence generation to evidence synthesis and guideline development is highly developed and sophisticated, the pathway from evidence-based guidelines to evidence-based practice is much less developed.[1] Implementation methods range from simple interventions, such as dissemination of educational material, to more complex and multifaceted interventions, including tutorial and consultation sessions, use of treatment algorithms, reminder systems, audit and feedback and use of psychological theories to overcome obstacles.[2] Whether these implementation strategies are effective in terms of better provider performance and patient outcomes in severe mental illness has been researched in previous systematic reviews.[3–5] Although these reviews found insufficient high-quality evidence to draw firm conclusions on the effects of implementation of psychiatric guidelines, they report modest effects towards an improvement of healthcare provider performance and the clinical conditions of the patients.[3–5] In spite of these findings, guidelines are used to develop quality indicators for healthcare. These indicators usually measure adherence to guideline recommendation under the assumption that an increased adherence to an evidence-based guideline would subsequently lead to improved patient outcomes. Therefore, there is need for up-to-date evidence on guideline implementation in order to verify this assumption. Furthermore, it is relevant to understand how guidelines should be best implemented into practice. In order to shed light on these issues, the present systematic review updated previous research and summarised the evidence on the effects of guideline implementation on provider performance and patient outcomes.

Method

This review followed an *a priori*-defined protocol that was published on our institutional website in 2012.[6] The protocol was developed following the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA).[7]

Study inclusion criteria

Types of studies and participants

This systematic review included randomised controlled trials (RCTs), controlled clinical trials (CCTs) and before-and-after studies. We considered lack of a control condition an exclusion criterion. We included non-RCTs because guideline implementation is complex and often investigated in non-RCTs. Only including RCTs would therefore miss large parts of the evidence available. However, we only conducted the meta-analyses for the RCTs. Study participants were adults of either gender, with a primary diagnosis of schizophrenia or related psychotic disorder, unipolar and bipolar affective disorders and severe depression. As our main interest was the care of patients with severe mental illness, we only included studies with participants recruited and treated in specialist mental healthcare settings. We excluded studies in non-adult populations because of the different treatment process in children and adolescents, which may involve parents.

Types of intervention

We considered any active or passive guideline implementation strategy. For the purposes of this review, we defined guidelines as 'systematically developed statements (or algorithms, flow charts or tables) prepared to assist decisions about appropriate healthcare for specific clinical circumstances'.[4] An implementation strategy was defined as 'any planned process and systematic introduction of guidelines with the aim of giving them a structural place in professional practice'.[4] We classified the interventions for implementing guidelines according to a taxonomy developed by the Cochrane Effective Practice and Organisation of Care Review Group (EPOC).[8] The following comparisons were included: (a) guidelines implementation strategy *v.* usual care to

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examine the impact of guideline implementation on provider performance and patient outcomes; (b) guidelines implementation strategy A *v.* guidelines implementation strategy B to understand if effects can be augmented by enhanced implementation strategies.

Outcome measures

The primary outcome measure was provider performance, because clinical practice guidelines are developed to improve the performance of healthcare providers in accordance with the best available scientific evidence. The secondary outcome measures were patient outcomes, such as psychopathological symptoms, satisfaction with care, treatment adherence, attitude towards psychiatric medications, and quality of life, as defined by each of the studies.

We hypothesised that guideline implementation may have a positive impact on healthcare provider performance and that this would subsequently influence patient outcomes. Furthermore, we expected that outcomes would differ in different studies according to the characteristics and purposes of the guideline under scrutiny. Only one outcome for provider performance and one patient outcome for each study (where available) was selected for the analyses. The criterion used to select the outcomes was their strength to shed light on the impact of guideline implementation strategies in real clinical practice. Furthermore, we made the selection of the outcomes on the basis of their coherence with the other selected measures. With regard to the performance of healthcare providers we selected outcomes that clearly indicated the level of adherence to the implemented guideline (for example proportion of patients with polypharmacy). Psychopathological symptoms measured by validated scales were considered the primary indicator of the impact of the implementation process on patients (patient outcomes).

Search strategy for identification of studies

We performed a literature search of the following electronic databases: EMBASE, Ovid MEDLINE, PsycINFO, PSYNDEX, Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials. The electronic search was run using the comprehensive search strategy listed in online supplement DS1 and was last updated in November 2015. Additionally, we screened the references of all included studies for further relevant literature. We did not apply language restrictions.

Data collection

We screened all titles and abstracts, and obtained full texts of potentially relevant papers. Working independently and in duplicate, two reviewers (F.G. and I.F.) read the papers and determined whether they met inclusion criteria. Two reviewers (F.G. and I.F.) carried out data extraction, using a standardised sheet. The information collected included study design, patient characteristics (such as diagnosis), provider characteristics (profession), setting of care, type of intervention (such as purpose of recommendation, guideline development process, implementation strategy) and outcome measures (process and patient outcomes). We solved disagreements by discussion. If no consensus could be reached, the final decision was taken together with a third reviewer (M.K.). For continuous outcomes we extracted the mean score at end-point (for RCTs), the mean change from baseline to end-point (for CCTs) and the mean score at baseline and end-point (for before-and-after studies), along with the standard deviation of these values and the number of participants included in the analysis. For dichotomous data we recorded the number of patients rated as responders and the total number of participants included in the study.

Study quality

Two reviewers (F.G. and I.F.) independently assessed the quality of the included studies using the Downs & Black checklist, an instrument suitable for assessing the methodological quality of randomised trials and non-randomised studies.[9] The scale is composed of 27 criteria and assesses five domains: study reporting, external validity, internal validity (bias), internal validity (confounding) and power. In the present review, the Downs & Black checklist was used in a modified version in accordance with previous reviews.[10–12] Specifically, scoring for item 27 dealing with statistical power was simplified to a choice of awarding either one point or zero, depending on whether there was sufficient power to detect a clinically important effect.[10,12] As has been done in the other reviews using the Downs & Black scale,[10–12] we grouped score ranges into the following four levels: excellent (26–28), good (20–25), fair (15–19) and poor ($\leqslant$14). The quality level of excellent can be achieved by randomised studies only. We solved disagreements in the quality assessment by discussion.

Data presentation

We graphically represented the effects of the included studies using a modification of the Harvest plot, which is a flexible method suitable for synthesising evidence about differential effects of heterogeneous and complex interventions, across different variables of interest (such as study design and participant characteristics).[13,14] In our plots, effect size is represented by a bar, amended by the 95% confidence interval. The study showed a statistically significant effect if the confidence interval is not including the null.

Effect sizes and meta-analyses

Only randomised studies were included in the meta-analysis. We entered and analysed data using comprehensive meta-analysis. We calculated dichotomous outcomes on an intention-to-treat basis, taking into account the initial number of participants included in each study. For the analysis of dichotomous outcomes we used odds ratios (ORs) with 95% confidence intervals, in order to use direct estimates from cluster randomised trials accounting for clustering wherever possible. We analysed continuous data using standardised mean differences (SMDs), as this measure of treatment effect allows combining scores from different scales. If end-point data were unavailable, we analysed change score data. Where intention-to-treat (ITT) data were available we preferred these over 'per-protocol analysis'. Effect sizes were converted to SMDs for all outcomes in the harvest plot. In contrast to the protocol, we combined effect sizes for provider performance and patient outcomes across diagnoses, because of the small number of studies and the studies with mixed populations.

We investigated statistical heterogeneity by visual inspection of the forest plots. This was supplemented by the I^2 statistic, which provides an estimate of percentage of variability because of heterogeneity rather than chance alone. When the I^2 estimate was greater than or equal to 50%, we interpreted this as indicating the presence of high levels of heterogeneity.[15]

Results

Characteristics of included studies

The search yielded a total of 1750 records potentially relevant for this review (online Fig. DS1). Of these, we excluded 1668 records based on the review of titles or abstracts. We retrieved the remaining 82 articles in full text and assessed them for inclusion. Of these, we

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excluded 63 studies for the reasons reported in online Fig. DS1. The remaining 19 studies[16–34] met the inclusion criteria and were included in the present review. The meta-analysis included six RCTs providing data on the impact of guideline implementation on process outcomes[16,19,23,26,27,31] and three RCTs on patient outcomes.[18,22,26] The main study characteristics are presented in online Table DS1.

We included eight RCTs[16,18,19,22,23,26,27,31] four CCTs[25,30,32,34] and seven studies with a before-and-after design.[17,20,21,24,28,29,33] Nine studies enrolled patients with a diagnosis of schizophrenia or related psychotic disorders,[16,20–23,25,27,29,33] whereas five studies included participants with unipolar and bipolar affective disorders.[18,19,30,32,34] One study[28] included two independent samples of patients diagnosed with schizophrenia or depression. Two studies[24,26] recruited people with mixed diagnoses (schizophrenia or related psychotic disorders, unipolar and bipolar depression). Diagnosis was not reported in two studies.[17,31] The majority of studies[17–19,21,22,24,28,29,31,33] were conducted in in-patient settings, six studies were performed in out-patient settings,[16,23,25,30,32,34] one study[27] reported both in-patient and out-patient settings and two studies[20,26] did not report information on the setting.

Characteristics of the implementation strategies

The implemented guidelines included clinical practice manuals and evidence-based treatment algorithms, which were developed with a structured methodology that included a consensus group of experts, analysis of the evidence base and clinical input. Fifteen studies[16,17,19,21–23,25–33] assessed the impact of multifaceted implementation strategies that included two or more components. All studies implemented the guidelines at a professional level, for example by distribution of educational material, educational meetings, educational outreach visits, reminders and audit and feedback. Five studies[19,25,27,30,32] additionally used strategies at an organisational level targeting patient needs, for example offering an education programme for patients and their families. Two studies[19,26] used provider-orientated implementation strategies at an organisational level, such as through employment of a nurse as coordinator (online Table DS1). Details about implementation

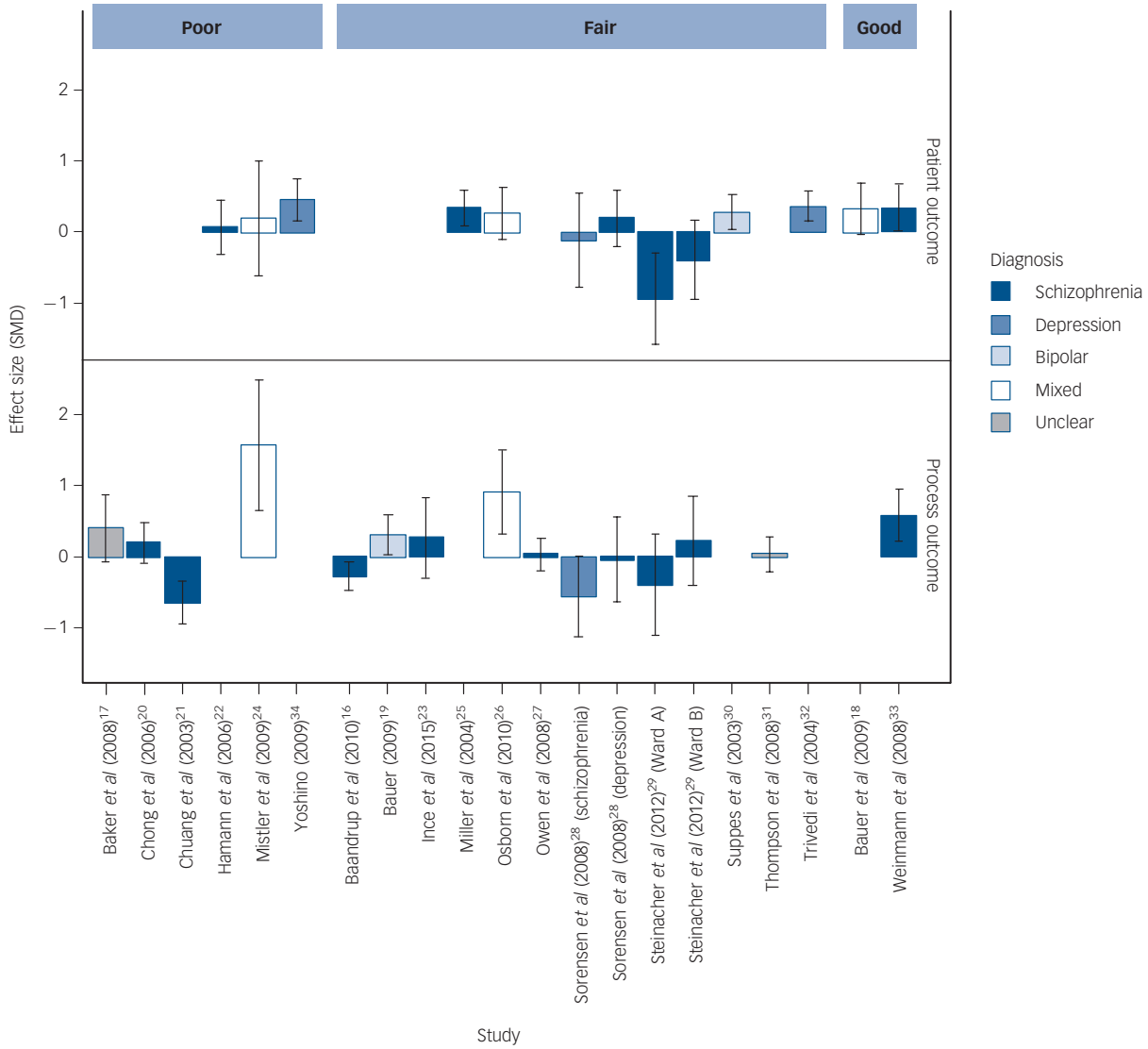

Fig. 1 Harvest plot.

The studies are grouped according to their quality (poor, fair good) and the two rows indicate whether the outcome refers to patients or provider performance. SMD, standardised mean difference.

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strategies were not available in four studies.[18,20,24,34] Fifteen studies[16–22,24,25, 28–30,32–34] compared guideline implementation strategies with usual care, and four randomised studies[23,26,27,31] compared different guideline implementation strategies (online Table DS1). According to the Downs & Black quality check, the quality of included studies was graded as fair in eleven[16,19,23,25–32] and poor in six studies.[17,20–22,24,34] Only two studies[18,33] achieved a good-quality score.

Impact of guideline implementation on provider performance

Twelve studies assessed the impact of guideline implementation on provider performance[16,17,19–21,24,26–29,31,33] (Fig. 1), including four studies comparing implementation strategies.[23,26,27,31] The quality of the majority of studies was judged to be fair.

Guideline implementation *v.* treatment as usual

In comparison with usual care, a positive effect of guideline implementation was shown in six studies,[17,19,20,24,29,33] but in only three of them[19,24,33] was this difference statistically significant. With the exception of one study,[24] showing a large statistically significant effect size, the effect sizes were small to modest. A negative effect of guideline implementation strategies on provider performance was found in four studies.[16,21,28,29] This negative effect was statistically significant in two studies.[16,21] One study[29] examined two different implementation strategies (active *v.* passive), but did not compare these strategies directly. The study showed a small positive effect size for the active dissemination strategy and, by contrast, a larger negative effect for the passive strategy, but both results were not statistically significant.[29]

Two RCTs comparing guideline implementation with usual care were included in the meta-analysis.[16,19] These studies (Fig. 2) did not show a statistically significant effect of guideline implementation on provider performance (OR = 1.01, 95% CI 0.37–2.79) (Fig. 2). The statistical heterogeneity of these two studies was high ($I^2 = 91\%$).

Enhanced guideline implementation *v.* basic implementation strategy

All four studies[23,26,27,31] comparing different guideline strategies showed positive effect sizes, but in two of these[27,31] the effect was negligible. One study[26] showed a large effect size and a statistical significant advantage of the enhanced implementation strategy (Fig. 2). All four studies were included in the meta-analysis, which did not show a statistically significant advantage of enhanced implementation strategies (OR = 1.47, 95% CI 0.86 to 2.52) (Fig. 2).

Impact of guideline implementation on patient outcomes

Guideline implementation *v.* treatment as usual

The impact of guideline implementation on patient outcomes was investigated in ten studies[18,22,24,25,28–30,32–34] (Fig. 1). Three studies[25,30,32] presented the results of the same project separately for patients with different diagnoses. The quality of the majority of studies was judged to be fair. Two studies[28,29] showed negative effects of guideline implementation on patient outcomes. Four non-randomised studies[25,32–34] showed a statistically significant effect in favour of the guideline implementation strategy (Fig. 1). With the exception of one study,[29] showing a large and statistically significant, but negative effect for a passive implementation strategy, effect sizes were small to modest. Two randomised studies[18,22] were included in the meta-analysis of patient outcomes (Fig. 3). The meta-analysis did not reveal a statistically significant effect of guideline implementation on patient outcomes (OR = 1.46, 95% CI 0.91–2.35). There was no statistical between-study heterogeneity ($I^2 = 0\%$) (Fig. 3).

Enhanced guideline implementation *v.* basic implementation strategy

One RCT comparing two implementation strategies assessed patient outcomes.[26] The effect reported in this study was not statistically significant (OR = 1.62, 95% CI 0.83–3.15), but numerically in favour of the enhanced guideline strategy (Fig. 3).

Discussion

Main findings

The present systematic review revealed that the pathway from evidence-based guidelines to evidence-based practice is still a neglected research area and that convincing evidence for beneficial effects of guideline implementation is scant. This is consistent with results from previous studies in other fields of medicine,[35–37]

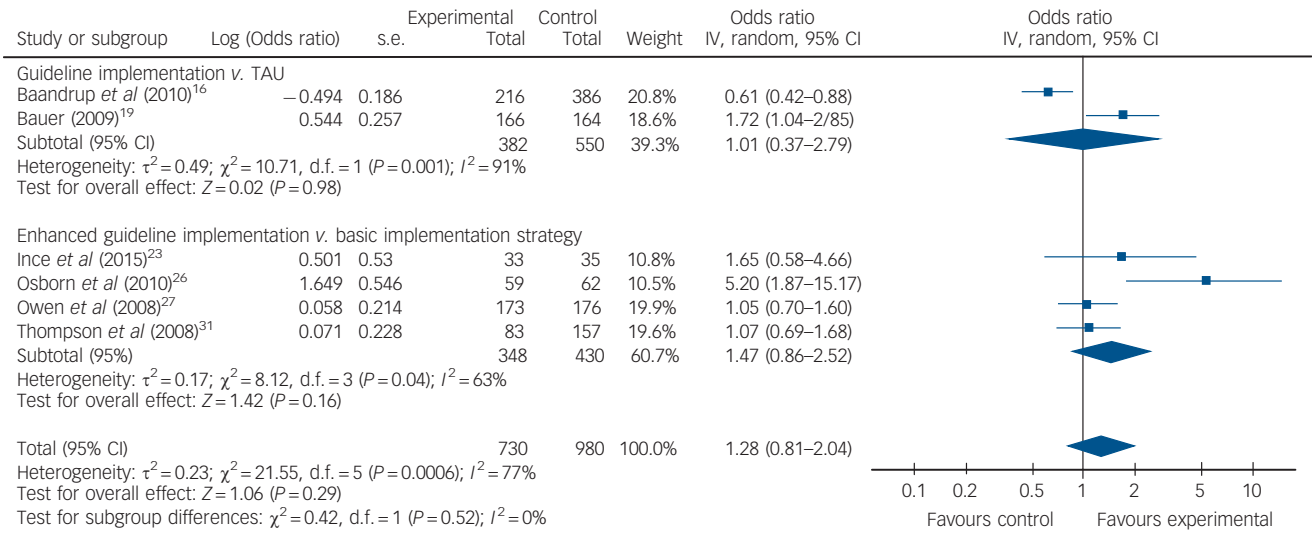

Fig. 2 Forest plot for process outcomes.

s.e., standard error; IV, inverse variance; CI, confidence interval; TAU, treatment as usual.

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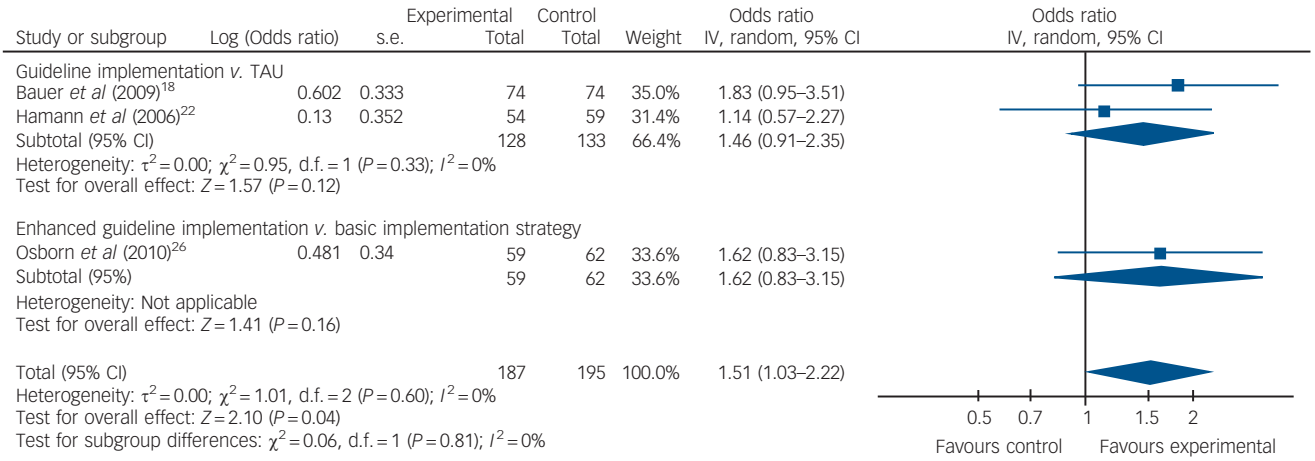

Fig. 3 Forest plot for patient outcomes.

s.e., standard error; IV, inverse variance; CI, confidence interval; TAU, treatment as usual.

which showed that guidelines are still not adequately implemented. Only a minority of the studies included in our review showed a positive statistically significant effect of guideline implementation on provider performance or patient outcomes, and often these studies employed a non-randomised design. In contrast to previous reviews, our data, including the meta-analyses of randomised trials, do not suggest an impact of guideline implementation on provider performance. In other words, efforts to implement guidelines did not modify healthcare provider performance in terms of better adherence to clinical practice guidelines. Despite this finding, the studies showed a more or less consistent positive effect of guideline implementation on patient outcomes, i.e. clinical condition, remission rate and satisfaction with care. Although the meta-analysis did not reveal a statistically significant effect of guideline implementation strategies compared with usual treatment or basic implementation strategies, the magnitude of the effect sizes and the consistency of the effects across studies seem to speak in favour of an effect on patient outcomes, which may not have been revealed as a result of low power.

Interpretation of our findings

The surprising result of a missing effect of guideline implementation on guideline adherence may, in part, be explained by differences between the studies included in meta-analyses and by the methodological difficulties of evaluating complex interventions. One reasonable explanation may be that guideline adherence is already high in treatment-as-usual patient groups, and thus may not be sensitive for change. However, this raises the issue of why a majority of studies have suggested positive effects on patient outcomes. Modest clinical improvement of patients may reflect a Hawthorne effect. However, the development of guidelines based on RCTs is criticised for poor external validity, as a result of highly selective inclusion criteria and selective trial settings.[38] Furthermore, in a small survey of clinicians in the USA Perlis *et al*[39] found that the most frequently cited reason for not using guidelines was that they do not adequately reflect features of patients that are relevant in making treatment decisions. Thus, the effect on patient outcomes may reflect (some) thoughtful and well-founded clinical decisions of non-adherence for a particular patient. To shed light on the limited effects of guideline implementation, reasons for guideline deviations should be researched. Only one of the studies[18] included in our review reported having documented reasons for non-adherence with the guideline in the intervention group, but these results were not included in the analyses. Clinical practice guidelines neither are intended to overrule practitioners' experience, nor are they unequivocal reflections of the scientific evidence. Our review reveals a clear gap of knowledge on how guidelines may influence the process of clinical care. Nevertheless, if quality of care is understood as actions increasing the likelihood that best patient outcomes are reached, our results challenge the use of guideline adherence as a quality indicator.

In the light of the low level of evidence in general, we were not able to determine which implementation strategies perform best. Both studies that were showing a substantial and significant effect on provider performance implemented the guideline at an organisational level by introducing a nurse as coordinator.[19,26] However, our results do not clearly indicate that multifaceted implementation strategies are superior to simple strategies. This is consistent with findings from a systematic review of guideline implementation strategies in other fields of medicine that failed to report either superiority of multifaceted interventions over other types of implementation or any relationship of number of intervention components and implementation effect.[2] Furthermore, evidence on the cost-effectiveness of such organisational changes is currently not available.

Limitations

The present systematic review has some limitations. First, the included studies were substantially heterogeneous in terms of the focus of the guideline, target of the intervention, population, implementation strategies and control group definition. Consequently, it may be difficult to assume that an implementation strategy that proved to be successful in a specific local setting would be similarly successful in a different setting. A second concern is the selection of only one outcome for provider performance and one patient outcome for the purposes of this review (although most studies reported several outcomes). This selection process was based on the background logic of focusing on primary outcomes, but we acknowledge that the included studies analysed a wide range of secondary outcomes that generated clinically interesting insights. The search strategy may have missed some studies as publications may not have used common keywords or may have used keywords that our search failed to capture. Furthermore, the definition of guideline that

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we employed (systematically developed statements or algorithms, flow charts, tables to assist decisions about appropriate healthcare for specific clinical circumstances)[4] left some subjectivity in deciding whether a publication or document could be considered a guideline.

Implications

In conclusion, mental healthcare professionals are faced with little safe ground regarding the best use of available guidelines, and further efforts should be made to understand the effects of guidelines on clinical practice. Also, developing guidelines and having them available (and performing studies on their implementation) could change routine practice in domains not related or not coinciding with provider-guideline adherence. If having guidelines available or being involved in studies on guideline implementation were related to improvements in clinician (or team) motivation, qualification or behaviour, patient outcomes might improve without enhancing guideline adherence. This possibility highlights the conundrum of how clinical effects come about and what makes clinicians and interventions effective in everyday practice.

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EXTRA CONTENT ONLINE

reflection

Camus and modern psychiatry: *The Myth of Sisyphus*

Thom Proven

Albert Camus (1913–1960), aside his onetime great ally Sartre, was an important post-war French existential philosopher, although he later rejected that label. He was French-Algerian and spent his early years in North Africa, later moving to France and playing an active role in the French Resistance during the Second World War. He went on to establish himself in the Parisian intellectual left-bank scene before dying in a car crash in 1960. An unused train ticket for the same journey was found in his coat pocket having changed his travel plans last minute.

Camus did not shy away from tackling the big issues of life head on: 'There is only one really serious philosophical problem, and that is suicide. Deciding whether or not life is worth living is to answer the fundamental question in philosophy. All other questions follow from that'. These are the opening lines of his 1942 essay *The Myth of Sisyphus*, where he seeks to further the themes of 'the absurd' explored in the classic *The Outsider*. His thesis is that given that life will, without exception, end, what is the point? Man searches for reason, meaning and order, only to march irreconcilably towards his own demise. Surely everything we do is absurd, and once resigned (or enlightened) to this decision examples of this absurdity can be seen everywhere.

The question that Camus addresses is how can we find meaning in a meaningless world? Philosophers before him had sought this meaning from a higher source, a greater power, from God. Camus however would reject this conclusion, feeling it to be a contradiction of the absurd, and hence not a reconciliation – 'philosophical suicide'. Camus would extend the same argument to suicide. He views it as a 'not legitimate' choice, a side step away from dealing with the paradox presented by an absurd world (human striving for meaning in a meaningless world); without man, the absurd cannot exist.

So what's left? How can we live a satisfactory life whilst at the same time accepting the absurdity of our condition? Camus suggests giving oneself over to the absurd, revelling in it, enjoying the tension that it creates and living in the moment. He suggests finding meaning by becoming, to quote from *Introducing Camus* (Mairowitz & Korkos, Icon Books, 2007): 'a great sensualist for whom sun, sea, sex, football, and theatre were the answer to life's absurdity'.

Camus finished the essay with the story of Sisyphus – the king of Ephyra punished by the gods for believing himself above their power to roll a great boulder up a mountain each day, only to watch it roll back to the base after his day of toil. He is interested however, in Sisyphus' return journey down the mountain where he is faced with his wretched condition: 'The lucidity that was to constitute his torture at the same time crowns his victory. There is no fate that cannot be surmounted by scorn', writes Camus before concluding (with a nod to the words of Oedipus) 'all is well . . . One must imagine Sisyphus happy'.

What is the relevance of this to the practice of psychiatry today? Should we be guiding our patients towards a celebration of the absurdity of existence when they struggle to see a meaning? Maybe there is a message to take from this, that there are small glimmers of meaning in a patient's life to hold on to and it should be a priority to identify these? Maybe we should view treatments as merely adjuncts to improve the patient's ability to find meaning in life rather than a cure? Maybe as a profession we should be more keenly aware of absurdity in our own actions?

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