Research recommendations for assessing potential harm from universal school-based mental health interventions

Lucy Foulkes[1], Jack L. Andrews[1], Tessa Reardon[1,2] and Argyris Stringaris[3]

[1]Department of Experimental Psychology, University of Oxford, Oxford, UK

[2]Department of Psychiatry, University of Oxford, Oxford, UK

[3]Division of Psychiatry, UCL, London, UK; Division of Psychology and Language Sciences, UCL, London, UK

*Corresponding author: lucy.foulkes@psych.ox.ac.uk

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Abstract

There is growing evidence that universal school-based mental health interventions can lead to negative outcomes in young people. This is a critical ethical issue, especially when young people cannot easily opt-out of interventions run during school hours. To date, however, there is no guidance available about potential harms for researchers designing and running these interventions. In this Perspective, we set out five research recommendations: (1) acknowledge the possibility of potential harms; (2) identify types of potential harms; (3) measure and report potential harms in all outputs; (4) consider adverse events (e.g. a suicide attempt) and (5) consider participant dropout and disengagement. Using simulated data, we demonstrate that even if trials show small negative effects, this could lead to considerable harm if interventions are scaled up across the population. Furthering research in this area will help ensure the field delivers interventions that are most effective and least harmful for everyone.

Two main goals of clinical trials are to assess the efficacy of the intervention and to assess whether it is safe, and decisions about whether an intervention is acceptable concern the balance between the two[1]. To establish the viability of an intervention to individuals and society, it is therefore essential to measure and report any instances of potential harm that occurred to participants during the trial. Here, we define *potential harm* as any negative effects or undesirable events that could plausibly be linked to the intervention itself. This can include deterioration in the primary outcomes, deterioration in any other measured variables, and specific adverse events (e.g. hospitalisation or suicide attempt of a participant)[2–4]. For pharmacological treatments, reporting of negative outcomes and events is mandatory[5,6], but when it comes to trials of psychological and behavioural interventions, reporting is inconsistent and there are no regulatory reporting equivalents to drug trials[2,7,8].

Universal school-based mental health interventions are designed to reduce or prevent mental health problems in young people, and involve psychoeducation and practical exercises taught to whole classes of school students regardless of need[9]. Meta-analyses have demonstrated that, on average, these universal interventions lead to small positive improvements in young people's anxiety and/or depression[9–11]. For example, one meta-analysis found an effect size of g = .17 (95% CI = .13-.21) for universal depression interventions and an effect size of g = .16 (95% CI = .12-.21) for universal anxiety interventions[9]; although note that some meta-analyses have found null effects or moderate positive effects[12,13]. There is also variability in outcomes of individual studies and some evidence of moderator effects, for example that effects are stronger when interventions are delivered by external mental health professionals rather than school teachers. Meta-

analyses indicate that, when follow up data are collected, there are small or moderate positive effects on average[9,10].

In these school interventions, mentions of harm in published outputs are rare. For example, although it is typically a requirement to report adverse events to ethics committees, one review of 12 such studies found that only one provided information about recording adverse events in the final paper[14]. However, there is evidence that universal school-based mental health interventions may indeed cause harm: these trials sometimes report negative effects in their primary or secondary outcome measures, indicating that at least some young people may experience some degree of harm from these interventions[15]. In one school-based trial, a universal CBT-based intervention taught to adolescents was found to increase internalising symptoms in the intervention group, but not in the control group, at six and 12 months post intervention[16]. A CBT-based depression prevention programme led to a decrease in prosocial behaviour in adolescents; there was no change in prosocial behaviour in the control group that received their usual lessons[17]. Lastly, a school intervention based on dialectical behavioural therapy (DBT) found that there was a deterioration in anxiety and depressive symptoms immediately post-intervention, and a deterioration in parent-child relationship quality post-intervention and at six-month follow up[18]. Other studies have found negative outcomes for specific subgroups. One CBT-based intervention for anxiety led to an increase in anxiety in the subgroup of children eligible for free school meals (an indicator of low parental income) and not in comparable children who received their usual classes[19]. Another CBT-based intervention led to an increase in internalising symptoms in those who already have elevated symptoms at baseline, in the intervention group but not in the control group[20]; the same result was found in a mindfulness-based intervention[21]. To date, it is

unclear what specific components of these interventions may lead to negative outcomes; this is an important avenue for future research.

Qualitative studies have provided further evidence of how young people are affected by universal school-based mental health interventions, including some negative experiences (and thus potential harm). These studies serve to highlight the considerable individual differences in how these interventions are experienced. For example, some young people report finding interventions relaxing, enjoyable and helpful[22,23]. Others say that the lessons helped them understand themselves and others better, and gave them useful tools for managing difficult emotions, such as before a test or after an argument with a sibling[24]. However, for other individuals, these qualitative studies highlight potential cases of harm.

For example, an ethnography-informed study indicated a number of ways in which mindfulness lessons can be distressing or confusing for young people[25,26]. In a study assessing non-positive experiences in a mindfulness intervention, participants described how attempting mindfulness exercises made them focus on negative thoughts more, made them cry, or made them frustrated because they felt they couldn't do the exercise[25]. Others said they didn't understand why they were doing the lessons, or felt the lessons limited their time for practical problem-solving, which would have been more helpful for managing their feelings[25]. Interview studies have found that, in parallel with some reported benefits, the focus on negative thoughts in CBT-based universal interventions made some young people feel low, even when they had initially felt positive[24,27]. A large-scale mixed-method surveys conducted after a CBT-based school mental health intervention found that while some young people found it enjoyable and helpful, others considered it unengaging or irrelevant[28].

Together, this quantitative and qualitative evidence indicates that universal interventions can cause potential harm, and thus this should be considered and addressed by all researchers working in this field. In particular, potential harms should not only be recorded and reported to ethics committees during the trial (which should be standard protocol) but also reported in published outputs. However, while there are helpful guides for conducting mental health research in schools more generally[29,30], no guidelines for researchers exist on the specific topic of harm.

In this paper, we provide five recommendations for researchers designing and evaluating universal school-based mental health interventions: (1) *acknowledge the possibility* that harm can occur in such interventions, even those considered low-intensity; (2) *identify types* of potential harm; (3) *measure and report* results regarding potential harm in all outputs; (4) consider *adverse events* and (5) consider *participant dropout and disengagement* (see Figure 1). Together, the recommendations discussed here will allow the field to gather more evidence and understanding of a previously overlooked phenomenon. This will enable researchers to analyse the cost-benefit ratio of universal school-based mental health interventions: since all interventions have the capacity to lead to some negative consequences at least some of the time, decisions about what potential harm is acceptable must occur in the context of knowing what overall benefits might be gained[31]. If these interventions are indeed a worthwhile approach to reducing mental health problems in young people, then knowledge about potential harms will also enable researchers to design interventions that are optimally effective and minimally harmful for as many young people as possible.

Recommendation 1: Acknowledge the possibility of potential harm

Our first recommendation to researchers designing and evaluating universal school-based mental health interventions is to be aware that harms are a possible outcome[32]. Often, there is an assumption that school interventions will either work (positive effects) or not work (null effects). The third possibility, of negative effects, must also be considered. This is true even when interventions are considered 'light touch'. If researchers consider an intervention to be potentially psychoactive in a positive way – which they must do, for the trial to have ethical grounds of being conducted in the first place – then they should hold in mind the possibility that it may very reasonably also be psychoactive in a negative way[33].

Based on the existing evidence, any negative effect sizes from universal school-based mental health interventions are likely to be small[15]. However, small negative effects are still worthy of serious attention. These effects might equate to a relatively small number of young people deteriorating in one trial, particularly if the effect is only found in a subgroup of participants[21], but the same effect size can be very impactful when interventions are scaled up to reach large proportions of young people, as is the goal with universal school interventions[15,34]. For example, if delivered to all the 3.6m students at state-funded secondary schools in the UK[35], an intervention with a negative effect size of d=0.1 (comparable to that found in a recent study[16]) could lead to 62,765 additional young people scoring above threshold for high levels of internalising problems (see Box 1 for simulated data).

In addition, small negative effects, null effects or indeed negligible positive effects represent an *opportunity cost:* young people have wasted their time doing something ineffective when they could have spent that time doing something more enjoyable or more productive for their education or mental health[15,36,37]. The concept of opportunity cost is especially relevant in psychological interventions such as universal school-based mental health interventions (relative to pharmacological trials), because participating involves considerable time as well as mental effort. For example, a popular mindfulness-based intervention in the UK involves students attending 10 lessons (each 30-50 minutes in length) across a school term, as well as completing exercises at home[38]. The potential opportunity cost is particularly relevant when the intervention is taught outside of school hours, for example as an after-school club, when young people might otherwise engage in more enjoyable activities of their choice. Thus researchers in this space should consider whether they can measure or quantify this opportunity cost, for example by tracking what participants in a passive control group choose to do with their time, or by asking intervention participants what they might have been doing instead, and estimating the costs and mental health benefits of these alternative activities[36,37].

In sum, considering the potential number of young people who might ultimately receive universal school-based mental health interventions, potential harms must be carefully considered, even if effect sizes are small. In addition, even if interventions are merely ineffective, this means that potentially more helpful options have been forgone – which could be considered a harm in itself[39]. Recognition of potential harm is therefore our essential first recommendation for any researcher designing and evaluating school-based mental health interventions.

Recommendation 2: Identify *types* of potential harm

Researchers should then consider what those potential harms might be. The first possibility is that participants will deteriorate on the primary or secondary outcomes (e.g. mental health symptoms), rather than improve as hoped. The second possibility is that other, unexpected negative outcomes will occur, which may not be measured because they are not hypothesised positive outcomes[40]. For example, a group intervention focused on reducing depressive symptoms might conceivably affect social relationships in a negative way (as has been found[17]), perhaps because it encourages self-focused introspection. It is also conceivable that interventions might improve or have no impact on symptoms, but negatively impact daily functioning i.e. the ability to engage in social, occupational (including school) and recreational activities[41]. However, there is no evidence on this to date because daily functioning is typically not measured in school intervention trials[42]. Thus, we suggest that reasonable effort should be made to consider potential harms beyond the planned primary and secondary outcomes, and to include additional measures in the protocol to assess these. One simple way to measure potential harm could be to ask participants (or their parents or teachers) a single question of whether they had experienced any distress during the intervention.

We recommend two means of identifying potential harms beyond planned primary and secondary outcomes. The first is to examine the existing literature of universal school-based mental health interventions. We recommend that researchers search full texts of relevant interventions, as some trials have found negative effects but these have not been reported in the title or abstract. In addition, we recommend that researchers familiarise themselves

198 with qualitative research that has asked young people for detailed insights into their
199 experience of school-based mental health interventions[15,28,43]. Based on the existing
200 literature, we recommend that depressive symptoms, anxiety and prosocial behaviour are
201 always included as outcomes that can show potentially harmful effects[16,17,19–21].
202
203 The second way to identify potential harmful outcomes is to consult with people in schools
204 that may have useful insights into how interventions will be delivered and experienced[40,44,45].
205 This input can be sought before, during and after the intervention. In advance of running a
206 trial, either when preparing a grant application, developing a trial protocol or conducting a
207 feasibility study, researchers could consult with individuals who are the target demographic
208 for the intervention (i.e. young people) and/or embedded in the context in which the
209 intervention will be run (i.e. school staff and parents). Schools are complex ecosystems, with
210 rigid timetables, limited resources and staff and students facing multiple competing
211 demands on their time; this inevitably affects how interventions are implemented and
212 experienced[29]. People already in the system will have important perspectives on how an
213 intervention in this context may have limited effectiveness or potentially lead to harm.
214 Gathering their perspectives, ideally as part of a feasibility study, will enable researchers to
215 map potential harms and whether these might arise from the intervention itself, practical
216 barriers to implementation within schools, or both.
217
218 Throughout the trial, individuals with relevant experience can be involved via *coproduction*,
219 a more intensive collaborative process between individuals and researchers that can last
220 throughout the design, delivery and evaluation stages of the project[46], or via lighter-touch
221 options, such as an advisory board who meet occasionally throughout the project[47,48]. After

the intervention delivery, researchers can gather data from relevant parties to evaluate the acceptability of the intervention, for example via interviews or focus groups with study participants or teachers[45]. However consultations are sought, topics could include, for example, whether young people think the intervention is relevant to them, what they perceived to be beneficial or harmful, and whether school staff and parents think it is feasible to implement with regard to the existing routines and time constraints in young people's lives[28,44,45,49]. Engaging in this consultation before, during and after the intervention can maximise the chances that interventions will be effective and minimise the risk that they could lead to null or negative outcomes.

Recommendation 3: Measure and report potential harms

Researchers should ensure analyses relating to potential harm are specified in protocols in advance[50]. This is the case for negative effects found across the intervention group on average, but it is also essential to assess and report whether specific subgroups are experiencing negative outcomes, even if overall effects are positive or null. Based on the existing literature, subgroups that are at elevated risk of harm are those with higher levels of baseline mental health symptoms[20,21] and those from families with lower income[19], and thus we recommend that these subgroup analyses should be included in researchers' analysis plans. We also recommend that researchers analyse gender differences: as rates of mental health problems are higher and increasing more rapidly in girls relative to boys[51], it is a reasonable hypothesis that school mental health interventions may have differential effects in different gender groups.

If trials are underpowered to test for these subgroup effects, it may nonetheless be helpful to report the results as exploratory analyses, with sufficient caution, as these could be included in meta-analyses and related future studies. If any negative effects for subgroups are found, either in the primary or exploratory analysis, we recommend that these be openly reported not only to ethics boards but in all study outputs, including in the abstract of resulting journal articles, as such transparency is vital for progressing the field[50].

Recommendation 4: Consider adverse events

In medical trials, it is mandatory to report adverse events (AEs; defined as unfavourable medical occurrences) and serious adverse events (SAEs; those that include death, hospitalisation or disability)[7,50]. It is important to consider such events in universal school-based mental health interventions. Because they can be rare or unpredictable, these events would not be captured by only assessing deterioration in primary or secondary outcome measures – thus measuring these events is an important way to assess potential harm. In psychological and public health interventions, however, there is little consistency with regard to how AEs and SAEs are defined and whether or not they are reported at all[7,50,52]. In clinical trials of psychological therapy for children and adolescents, only half report that they measured adverse events[2]. In universal school-based mental health interventions, they are typically not reported in final outputs at all, even if they have been shared with ethics boards as it often stipulated, so we have a very limited understanding about the frequency and nature of adverse events in this context[14].

In one-to-one cognitive behavioural therapy and mindfulness-based therapy, potential adverse events can include suicidal ideation, self-harm, distress, trauma re-experiencing,

dissociation, psychotic symptoms and negative impacts on family relationships[2,53–57]. Since universal school-based mental health interventions often involve principles and techniques taken from these therapies, it is reasonable to predict that the same adverse events might occasionally be seen. Even if only one child in a trial experiences such an event, this still requires careful consideration about what could be done differently in the future. Indeed, even if no adverse events are found in the sample of participants who take part in a trial, this does not mean they will be absent in larger population. Trials are often underpowered to detect rare side effects, and such events could emerge when the intervention is delivered at scale. For example, finding that no adverse events occurred in a trial of 100 people (i.e. having a zero numerator) entails a maximum risk that is approximately 3 divided by the sample size (for a 95% confidence interval) [58]. For a study (N=100) that found no adverse events, there is still a risk that the true rate of adverse events is 3/100 people (3%) – i.e. if a random sample of N=100 people were given the intervention, up to 3% could experience an adverse event[58].

Before definitive guidelines can be provided regarding adverse events in universal school-based mental health interventions, a number of issues need to be explored and addressed. First, there would need to be some agreement about how to define AEs and SAEs in the context of school-based mental health interventions. As an initial recommendation, based on our own experience with these trials, we suggest that researchers consider the following events in their definition, particularly if these are not captured in the study's primary or secondary outcomes: admission to psychiatric hospital, safeguarding concerns, suicidal behaviour, self-harm, deterioration of existing mental health problem, development of a new mental health problem and participant distress during data collection, intervention

sessions or homework activities. As researchers, we have personal experience of unexpected participant distress occurring during pre- or post-intervention data collection sessions and during homework activities (completing questionnaires at home), highlighting the need to consider AEs and SAEs during these sessions as well as during the intervention itself. Indeed, it is important to be aware that completing the evaluation component of the trial (i.e. reflecting on one's own mental health), rather than participating in the intervention itself, is what may cause some young people distress. For example, one study found that asking participants to complete questions about self-harm was reported to be upsetting by 16% of young people with a history of self-harm[59].

Researchers would then need to determine whether events that occur during the time period of the intervention were plausibly related to participating in the trial, for example by conducting a causality assessment (the most common rating scale used in other psychological trials is "Definitely related, probably related, possibly related, unlikely to be related or unrelated"[7]). However, we acknowledge that causality can be challenging to establish in psychological interventions (relative to pharmaceutical interventions)[53]. This might especially be the case in universal school-based mental health interventions, because researchers have limited contact with individual participants and may be informed about events some time after they have occurred.

A third issue relates to whether information regarding AEs and SAEs should be recorded actively or passively[33]. Recording these events actively, i.e. systematically seeking out information about events from all participants via questionnaires or interviews, is likely to be impractical in the context of a school trial. There are large number of participants and the

317 interventions are often delivered by school teachers or other professionals (e.g. mindfulness
318 teachers), meaning that research staff do not have regular in-person contact with individual
319 participants. In addition, completing further questionnaires or interviews about possible AEs
320 and SAEs could potentially be burdensome for young participants, and also raises the ethical
321 issue of whether staff have capacity or expertise to respond appropriately to all identified
322 difficulties (e.g. by referring individuals to additional help, which may not be available). Thus,
323 for pragmatic reasons, it may be more appropriate to gather information about AEs and SAEs
324 passively (i.e. participants, parents, school staff and researchers spontaneously report these
325 events as they arise). This will mean some information will be missed, but over multiple
326 trials, findings regarding passively-recorded AEs and SAEs could still be valuable if they
327 indicate potential areas of risk, particularly if these events are more likely to occur in
328 particular subgroups.
329
330 A fourth issue relates to who should be asked to report AEs and SAEs. Any researcher who is
331 involved in data collection or delivering the intervention should certainly be required to
332 record and report any AEs and SAEs that they are made aware of (e.g. to the university
333 ethics board, trial steering committee, and/or school safeguarding lead). However, other
334 adults will be involved in the trial: intervention sessions might be delivered by school
335 teachers or external professionals, other school staff might offer practical assistance, and
336 parents might support participants with home-based tasks such as practical exercises or
337 completing questionnaires. Thus, in theory, many adults may observe AEs/SAEs and could
338 record and report such events to the research team, who would then pass on the
339 information further as outlined above. However, there is a practical issue with regard to
340 what can reasonably be expected of these other adults, particularly staff who will be in

charge of 20 or 30 students in each intervention class. These decisions will need to be made on the basis of the details and constraints of each individual trial, ideally in consultation with school staff.

Whatever decisions are made, we recommend that all trials should have a standard operating procedure (SOP) with regard to defining, recording and reporting AEs and SAEs, and all adults involved in the trial should follow the SOP. We also recommend that the details of the SOP should be specified in protocols in advance and reported in all final outputs, even if no AEs and SAEs were recorded[33]. Similarly, each trial should establish a 'duty of care' procedure with any school staff involved in the trial, including a standardised procedure for reporting adverse events to the research team but also guidance regarding how to address and manage any acute instances of harm that a young person may experience; although this must take into consideration staff's capacity and expertise to implement the procedure, as described above. If this becomes standard practice for school-based mental health interventions, as a field we can begin to build an evidence base about AEs and SAEs that will guide best practice for future researchers.

Recommendation 5: Consider participant dropout and disengagement

It is common for individuals to withdraw from psychological interventions before the full course of treatment has been completed[60]. For example, a large percentage of children and adolescents terminate psychological therapy early (estimates range from 28% to 75%[61]). Sometimes this is for practical reasons, but patients also withdraw from therapy because they find it ineffective or, most problematically, because they find it distressing or otherwise harmful[33]. Recording and investigating participant dropout from universal school-based

mental health interventions is essential for the correct (i.e. unbiased) interpretation of statistical findings, but could also provide vital information for understanding potential harm. However, as with AEs and SAEs, there is very limited evidence regarding dropouts in this context. Below we recommend a number of considerations for future research, so that the field can ultimately develop guidelines about this important aspect of trials.

The first consideration is whether young people are actually *able* to drop out of universal school-based mental health interventions. Full withdrawal might be difficult or impossible, because many of these interventions are taught as lessons that are part of the school day, and young people are required to stay in school. In line with this, there is some evidence that adolescents are more likely to complete CBT-based intervention modules in a school-based, supervised setting compared to adolescents who are able to voluntarily access the same modules in an online, unsupervised setting[62]. Even if the intervention is being taught as an after-school club, the power imbalance that exists in schools (and between researchers and participants) may mean young people feel unable to withdraw from the intervention[2,63,64]. It is also worth noting that, in some school-based trials, young people who ask to opt-out are only able to withdraw from the evaluation component (i.e. pre- and post-intervention questionnaires and tasks); they are still exposed to the intervention itself, because it takes place during typical school lessons and there is limited staff capacity to provide individuals with alternative activities. The result is that even young people who have officially opted out of the trial still end up receiving at least part of the intervention.

In addition, some young participants are incentivised to take part in universal school-based mental health interventions, for example in the form of voucher payments. This is for good

ethical reason, since they are giving up their time, but there is evidence that some young people primarily or exclusively take part in mental health interventions because of the financial incentive[65], and thus some may feel unable to stop attending sessions because they want or need the payment. There is existing evidence that fewer adolescents drop out of an intervention in the context of a paid research trial relative to the same intervention delivered in an unpaid, naturalistic context[66]. It may be that a careful balance needs to be struck between incentivising retention and not placing young people in a situation that means they feel obligating to keep attending sessions even if they find them harmful.

For these practical reasons, total withdrawal from universal school-based mental health interventions may be rare. It may therefore be more realistic and informative, in terms of understanding potential harm, to investigate those participants who disengage from the intervention. For example, there is plenty of evidence that some young people do not find school-based mental health interventions interesting or helpful, and do no or very few homework exercises[28,49]. This group might represent the participants who, in a more voluntary setting, would have dropped out of the intervention altogether. Together, participants who have dropped out of the intervention entirely and/or participants who have disengaged from it could provide researchers with useful information with regard to harm. We suggest that reasons for disengagement in both groups should be assessed where possible using qualitative methods, in order to gain richer insights into potential harms[25,28]. Reporting such information in resulting publications can provide additional valuable clues to other researchers designing and planning universal school-based mental health interventions in the future.

Whether participants drop out altogether or disengage, it will be important to understand who they are, since this might indicate particular groups who are at increased risk of harm from universal school-based mental health interventions. It may be that there are certain demographic characteristics that are associated with dropout or disengagement: for example, racial and ethnic minority status, socioeconomic status, gender or sexual orientation. One school-based CBT intervention found that girls showed greater adherence than boys (as measured by the number of online modules and exercises completed), and this was also the case when the same intervention was delivered in the community[62]. There may also be baseline psychological characteristics, including mental health symptoms, that are predictive of likelihood of dropout. One study of a single-session digital mental health intervention delivered in schools found no evidence that baseline psychological characteristics predicted engagement in the activities[66], but more research needs to be conducted, particularly for interventions that involve multiple sessions. If the field can build a more detailed picture about why some young people dropout or disengage and who they are, this will provide crucial evidence for understanding which participants might be at increased risk of harm from universal school-based mental health interventions.

Concluding remarks

There is a growing body of evidence indicating that young people can respond in different ways to universal school-based mental health interventions. Meta-analyses indicate that, on average, these interventions show small positive effects that can be maintained over time, with individual trials demonstrating a range of positive, negative and null effects, either in whole groups or subgroups of young people[9–13,16,21]. Likewise, qualitative studies indicate that while some young people find interventions useful and helpful, others describe negative

experiences, including increased distress[22,23,25,26,45]. It is crucial that researchers developing and testing these interventions recognise these individual differences, acknowledge that the interventions have the potential to cause harm, and seek a balance between benefit and harm should be sought. In order to build a better picture of what harmful outcomes might be and which young people are most at risk, we encourage researchers to implement the recommendations laid out in this paper. Building this body of evidence will enable the field to understand the cost-benefit ratio of universal school-based mental health interventions: to determine what degree of harm should be tolerated for what degree of overall benefit. This research will also clarify what works (and does not work) for whom, ultimately delivering interventions that will safely and effectively address the urgent issue of mental health problems in young people today.

Contributing author statement

LF conceptualised the manuscript and wrote the original draft. All authors reviewed and edited subsequent drafts, and read and agreed to the final version.

Competing interest statement

The authors declare no competing interests.

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