The ethics of experimental heroin maintenance

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Authors’ abstract

In response to widespread concern about illegal drug use and the associated risk of the spread of HIV/AIDS, a study was undertaken to examine whether it was, in principle, feasible to conduct a trial providing heroin to dependent users in a controlled manner. Such a trial involves real ethical issues which are examined in this paper. The general issues examined are: should a trial be an experiment or an exercise in public policy; acts and omissions; countermobilisation; termination of a trial, and payment for drugs and for a trial. The specific issues examined are: selection of trial participants; privacy; issues for staff working on a trial; coupling the trial with other treatment, and issues for researchers. A number of alternative approaches to the various ethical issues are presented and discussed.

In Australia, as in many other countries, there is widespread concern about illegal drug use. In recent years this has been exacerbated by fears about the spread of HIV/AIDS within the illegal drug-using community through needle-sharing and sexual practices, and from this group to the general community. There is a common perception that current drug policy is ineffective and that new policies need to be explored (1–4). These range from stronger enforcement of anti-drug laws to legalisation of these substances.

The available evidence indicates that heroin, when provided in pure form, is a relatively safe drug (5). Hence it is primarily the illegal nature of the drug, rather than its pharmacological properties, which leads to the health and social problems associated with its use. It seems then that there is a potential for a reduction in those problems if heroin is made legally available in a controlled manner. Whether or not this potential would actually be realised, however, is hotly contested.

In 1990, the Government of the Australian Capital Territory (ACT) appointed a select commit-

Key words

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surrounding a trial, rather than upon ethical aspects of the broader policy questions. We did not discuss, for example: the advantages and disadvantages of current policy; whether heroin use is, or should be, seen as a criminal, social or medical problem; the morality of drug use and drug users or of legislation; why some drugs are illegal and others are not, and so on. Such issues have been widely discussed by others (see, for example references 1, 7–12).

We are not aware of other papers that deal with the full range and complexity of ethical issues on this more micro level. Many people have advocated controlled availability, in various guises (2), but they have not dealt with the ramifications, including the ethical questions posed. Specifically they have not dealt with the peculiar ethical issues posed by controlled availability in a trial setting.

There are real ethical issues in providing heroin in a controlled manner, especially experimentally. We discuss a number of these and outline ways in which they could be addressed. Given that ethical considerations are now a standard part of research design, particularly through the work of institutional ethics committees, this study provides one possible template for how such considerations could be incorporated.

The first part of the paper deals with more general ethical issues raised by the proposed trial and the impact that these issues have on the structure of a trial. The second part of the paper deals with specific detailed problems that need to be addressed for a trial to be run in an ethical manner. Conclusions often depend on the exact nature of a trial, not yet determined at the time of our deliberations. Therefore, as wide a range of alternative approaches as possible had to be considered.

This paper is written in the spirit of setting out considerations, much more than of reaching firm conclusions. That is inevitable given the political role in which we have been cast: policy advisers necessarily advise on options, rather than trying to pre-empt decisions. But it is also inevitable, given the nature of ethical analysis.

General issues for a trial

SHOULD A TRIAL BE AN EXPERIMENT OR AN EXERCISE IN PUBLIC POLICY?

A supervening issue is whether a trial is to be conceptualized primarily as an ‘experiment’ in a scientific context (13), investigating the effects of a trial on users and/or the general community, or as a direct exercise in public/social policy. Pearn (14) suggests that when a new idea arises the most ethical approach is to conduct a short but well planned pilot study and then to proceed directly to a detailed controlled study which will resolve the issue; that logic argues strongly for conducting the trial as an experiment. However, the question ultimately centres on how adequate a trial, conceived as an experiment, would be in terms of fulfilling the rigorous demands of scientific method. The informational demands required for the confident implementation of social policy are much less rigorous. A trial seen in that light might be nonetheless useful even if its outcomes were substantially less clear-cut.

It is unethical to use people as ‘subjects’ for scientific research unless it is reasonably clear that the results can be adequately evaluated and that they will have a meaningful bearing on later policy considerations (15). Whatever moral objections we have to ‘using’ people, we object twice over to using people to no good end. Ultimately, there is a difficult balance to be achieved between obtaining clear results with a minimum of confounding variables and producing results that are generalisable and meaningful in terms of instituting policy.

A number of issues militate against conceiving a trial as an experiment.

- It would not be possible to obtain a random sample of heroin users because the exact number and composition of the total population of heroin users is unknown. This would also make it difficult to know how representative the trial participants were of the general heroin-using population.
- It may be difficult to devise an ethically acceptable way of randomly assigning volunteers to a comparison group, where this assumes that controls will actively persist with criminal and health-endangering behaviours.
- In some ways any locale, including Canberra, which is the proposed site for a trial, is socially and demographically atypical. This may limit the generalisability of any results that a trial might produce. While this in itself would not invalidate a trial, it may limit its wider usefulness.
- The limitations inherent in trials, including the limited time span, might not allow all the conditions that would occur in a fully-fledged programme to emerge.

The size and scale of a trial are important for a variety of reasons. First, there should be sufficient participants to allow outcomes to be clearly demonstrated. The sample should, however, be small enough to minimise the number of people who might be adversely affected by an unsuccessful trial or the premature termination of the trial for political reasons. Second, the size of a trial may in itself influence the likelihood of its success. A small trial might be seen as relatively innocuous and therefore be less subject to pressures from local, national and international interest groups, such as illegal drug suppliers and governments opposed to any reduction in sanctions. However, the participants in a small trial could be subjected to harassment from users not in the trial, who also wanted access to high quality heroin. Further, limiting a trial to one locale could
attract users from the rest of the country. Even though they might be debarred from participation in the trial by residency criteria, they could contribute to hassling trial participants and be a source of community problems, especially crime, as well as a drain on welfare services.

There are also numerous pressure groups with strong interests both for and against a proposed trial. The result is that a trial might well run in a highly politicised atmosphere, making it difficult to arrive at a considered judgement on whether the trial should proceed to a full-scale programme. In addition, those opposed to a trial may have an interest in contriving to affect adversely the trial results: participants in a trial may behave in a manner that would not be sustained once a full programme was instituted, being very conscious that ‘good behaviour’ is essential for the success of a trial.

Furthermore, should a trial demonstrate the efficacy of this form of intervention in a way that is reasonably generalisable, it would be unethical not to proceed to the policy implementation stage. Not only is it unethical to ‘use’ people uselessly: if no action is to follow from positive results, there is no legitimate reason to undertake the experiment. Of course, the outcomes of a trial would most likely be mixed; for example it might be successful in reducing harm-related behaviours, but it might not be cost-effective. Hence, the criteria for success and failure of a trial should be determined before it begins (and these determinations should include resource considerations). A commitment to running a trial should include a commitment to implementing the resultant policy, if the trial proves successful.

If a trial is conceived as an experiment all the considerations raised above must be carefully balanced. Ethical advisers can merely raise those issues, not resolve them: experimenters must be the ones to provide the necessary assurances regarding the likely conclusiveness of any experiment; politicians must be the ones to provide the necessary assurances regarding the political will to act upon experimental results, if sufficiently conclusive. The role of ethicists here is merely to draw attention to the need for such assurances.

The alternative to treating the trial as an experiment is to make a policy implementation decision directly, based on the best information available. This option would not be hindered by the methodological constraints of the experimental paradigm. Furthermore, it ought to be done completely rather than piecemeal, since past experience (16) has shown that gradual implementation of politically sensitive policy results in an exaggerated build-up of opposition. This in turn means that the policy is never fully implemented and the rationale for the policy becomes irrelevant in the face of such public opposition (17).

Militating against direct policy implementation is the fact that there is little ‘hard data’ which can be used to decide either whether or not controlled availability of heroin is likely to be successful, or to structure the details of a policy. In addition, should the outcomes of change be detrimental, either to users or to the community at large, it is likely that more people would be affected than if a trial conceived as an experiment was instituted. Also a trial could probably be terminated more easily than a policy, should that be necessary.

**ACTS AND OMISSIONS**

The issue of acts and omissions concerns the distinction between the blame attaching to harms which one has somehow caused to happen, as compared to those which one has merely let happen (18). The distinction is, for example, between a person’s overdosing on heroin received as part of a trial as compared to overdosing on heroin bought on the streets, or between someone’s being involved in a car accident after receiving heroin as part of a trial as compared to crashing after taking heroin illegally. Researchers or service providers who have supplied the heroin in question are arguably implicated in the first case in each example, in a way they would not be in the second cases.

Philosophers themselves are deeply divided on the moral importance of any distinction between such acts and omissions. Some argue for a more deontological approach, insisting that there is an enormous difference between causing harm and allowing harm to happen, so that harm resulting from intentional intervention is a major problem, even if similar or even greater harms might otherwise have happened. Other philosophers argue for a more utilitarian (or more broadly consequentialist) approach which judges the harms caused by the intervention in light of those which would have happened had there been no intervention (19).

Taking the utilitarian approach, the following arguments could be made with regard to the initial examples given. A person who overdosed on the trial might well have overdosed on street drugs; overdosing on street drugs in fact may have been more likely, since the drug provided in any trial would be of pharmaceutical quality and of known strength and purity, unlike street drugs. Therefore the risks of overdose are lessened on a trial. Similarly, people who drove after administering their drugs in a trial might well have driven after administering their drugs on the street, probably with equal risk of having an accident. (It is, of course, also possible to implement strategies to minimise risks, for example by providing transport for trial participants.)

The non-utilitarian approach, taken to extremes, would seem to preclude any interventionist research which involved a significant level of risk, even if it were directed at a major social problem such as illegal drug use. Even in its less extreme forms, the deontological approach would set a presumption against any intentional interventions designed to
alleviate such social problems. By weighting those harms which we have caused considerably more heavily than ones which happened independently of anything we have done, deontologists are in effect saying that social programmes must do very substantially more good than harm before they are prepared to regard them as morally justified. While even utilitarians might find grounds for agreeing that we should be reasonably sure that our interventions will do more good than harm before undertaking them, too heavy a bias in that direction seems difficult to defend, not least to those being asked to continue suffering needlessly.

COUNTERMOBILISATION
Opposition to a trial would be likely to come from two sources. The first is from people who feel such a trial is wrong or who have genuine anxiety about its likely outcomes. This opposition is legitimate and ought to be respected. The second is from people who have a vested interest in heroin remaining illegal, for example, because they benefit financially from the sale of illegal drugs. Countermobilisation from this group is less legitimate. People in the second group however, would be likely to attempt to use the legitimate concerns of the first group for their own ends; in other words legitimate concerns could be illegitimately exploited.

Countermobilisation could be avoided by instituting the programme directly as social policy rather than by first conducting a trial (16). While this might be effective in circumventing those who have a vested interest, it also stifles legitimate opposition.

It is therefore important to consider carefully the arguments and values of those who legitimately oppose a trial and to balance them against those of the trial supporters. It is important that both sides have equal access to information about a trial and its supporting and opposing arguments. In the course of a trial, the evaluation should, where possible, include measures of variables considered to be problematic and/or important by trial opponents as well as supporters.

This does not overcome the concern that manipulation of public opinion by those with vested interests might compromise the effectiveness of a trial and hence the possibility of a trial proceeding to a full-scale programme. The best ethical advisers can do here, is to flag the problem and alert evaluators of any trial to the need for a sensitive interpretation of negative experiences within it.

TERMINATION OF A TRIAL
A trial would probably be easier to terminate than a policy, if detrimental effects occurred. On the other hand, it might be easier to modify a policy than a trial (especially a trial conceived as an experiment) where any detrimental effects are more arguable and less obvious.

It is crucial to have in advance a list of reasons for halting, or perhaps for modifying, a trial, even before detrimental effects could be shown to be statistically significant. (In that sense, it might be necessary to compromise the scientific integrity of a trial.) To minimise undue political interference during the course of the trial itself, it is important that these termination criteria be determined, and agreed on, by both proponents and opponents of a trial, well ahead of the trial itself. When and how a trial is terminated will have important political ramifications which need to be taken into account when deciding whether or not to proceed with a trial (20).

There is also the issue of what happens to participants at the end of a trial. One view is that with this trial we can be quite confident that it will have benefited participants for its duration, so there is minimal post-trial obligation to them. In this case participants would need to provide informed consent to clean-break termination at the outset of the trial. It has, however, been recommended elsewhere (21) that new therapeutic procedures - especially when at an early stage of evaluation, and when they may have long-term effects - should not be undertaken unless appropriate provision has been made for long-term care and observation. There is also some room for doubting the meaningfulness of consent obtained from people for whom a short-term inducement far outweighs possible long-term ill-effects (22). Yet another view is that a trial would probably prove successful for at least some participants, particularly in allowing them to stabilise their lives in terms of family relationships and employment; in such cases, it would be ethically desirable to continue to provide assistance as long as it was needed.

FINANCIAL CONSIDERATIONS
There are at least three issues here. Should trial participants pay for the heroin? If so, how should the price be determined? And how should the costs of a trial be covered?

As regards the first issue, there is something to be said on both sides of the question of whether participants should be required to pay for heroin received as part of the trial. If the trial is conceived primarily as an experiment, it could on the one hand be argued that participants should not pay, since it is unusual for people to have to pay when taking part in an experiment. On the other hand, it could be argued that the conditions of the experiment should be as close as possible to those which would obtain if policy were instituted, which could well entail payment for drugs.

If payment is required, the issue then becomes one of how the price should be determined. It could be argued that heroin should be treated in the same way as other pharmaceuticals with the same consumer charges applied to them. The major expense in a trial however, is likely to arise from staff, security
and administrative costs rather than from the cost of the drug itself; furthermore, many (though certainly not all) of those costs arise from the peculiar nature of such a trial and would be representative of the costs of instituting fully-implemented policy along the same lines. Requiring participants to cover these costs is likely not only to make the expense of participating in a trial prohibitive to them but also significantly to diminish the value of a trial.

How should these larger costs of a trial be covered? Ideally, a public subsidy (sufficient, at least, to cover the costs of staff, security and administration) would come from a budget separate from those of other heroin treatment programmes. Ideally, those other programmes should not suffer financially from a trial of alternative approaches. Realistically, however, the trial's funding may well have to be provided at the expense of some other area, whether it be the health, law-and-order or research budget.

In any case, it is important for a trial to justify its funding. In practical terms, this will best be done only after the trial has been completed and any effects on improved health or reduced crime demonstrated. Initial funding of the project can, therefore, only be justified under the rubric of basic funding for applied research. Under that rubric, funding ought to depend on, and be justified in terms of, how well the project meets standard requirements for research funding; those requirements would, of course, include a detailed rationale and outline of the project.

**Specific issues for a trial**

**SELECTION OF TRIAL PARTICIPANTS**

**Informed consent**

Informed consent is the fundamental principle that must underlie participant selection and, depending on the design of a trial, allocation to 'heroin' or 'control' groups (13, 23). While here as elsewhere some question may remain as to how 'informed' participants can be, there is an obligation to provide as much information as possible in as clear a manner as possible to the participants at the outset (21). In this way participants can be under as few illusions as possible about what they are consenting to.

**Volunteers**

Another fundamental principle is that trial participants should be volunteers. There is considerable literature on what constitutes volunteering, particularly in certain situations, such as recruitment from actual or potential jail inmates.

One option would be to recruit trial participants from the court system, so that people would be given the option of participating in a trial or being sent to jail or given some other punishment. Diversion from the courts may be considered to be consent under duress. On the other hand, it can be argued that the individual has the choice: he or she would not be threatened with punishment for not participating; rather he or she would be presented with an alternative to punishment. The basic issue here is whether or not the person really has a choice and is given clear and complete information on which to make it.

**Selection criteria**

More people may want to participate in a trial than could be accommodated in it, and certain groups might need to be excluded to enhance interpretation of the trial's outcomes. Several issues arise from this.

One is that some people who volunteered to participate would have to be rejected. The issue of rejecting volunteers can be defended on the basis of the reasons for the selection criteria, and/or on the basis of random selection so that no favouritism is shown in the selection process.

Selection criteria could also be seen as a form of discrimination, positive or negative. Positive discrimination would generally be defended on the grounds that those meeting the criteria are at highest risk or in greatest need of the trial conditions. Negative discrimination would generally be defended on the grounds that people in such groups are unrepresentative of the total population and that they would make evaluation of outcomes more difficult, thus threatening the utility of a trial.

The particular groups for whom selection criteria are most likely to be important are: people who are HIV-positive; users who are mentally ill; users who are very violent; women who are pregnant; women likely to become pregnant (ie virtually all fertile women), and users under the age of consent (though it should be noted that the age of consent varies with what is being consented to).

An argument against negative discrimination towards these groups is that they are either particularly in need of intervention (for example HIV-positive people or women who are pregnant), that they are a significant section of the population (for example fertile women), or that intervention may be particularly successful in preventing problems from escalating (for example young people). An argument against positive discrimination for people who are HIV-positive or women who are pregnant is that it may provide a socially undesirable incentive for heroin users to attempt to become HIV-positive or pregnant. Incentives are dealt with in more detail in the next section, and pregnancy in a later section.

The aims and underlying conception of a trial, as experiment or exercise in public policy, will be important in determining the resolution of these issues. It should be noted, however, that some forms of discrimination may be justifiable (or even necessary) in a purely experimental context or even a policy trial, that would not (or not necessarily) be justifiable in a fully implemented policy.
Incentives
Specific ethical problems arise from the possibility of a trial providing incentives for people to engage in undesirable behaviours, simply in order to be recruited into a trial. Examples — assuming that both the use of heroin and dependent use of heroin are in and of themselves problematic — include initiation of heroin use by people who had not used it before, formerly dependent users restarting use and low-level, non-dependent users increasing use and developing dependence.

There is also the possibility of a ‘heroin trap’, analogous to the ‘poverty trap’, whereby a trial would provide a disincentive for people to reduce their heroin use. Alternatively, people who might otherwise have stopped using the drug because of the highly unpleasant aspects of the lifestyle associated with it, may remain dependent because of the relatively congenial nature of a trial.

Ultimately it may not prove problematic that a programme provides incentives for dependent use if, at the same time, it makes dependent use broadly tolerable, both for users and the larger society. In any case, it is never enough simply to say that incentive effects exist. Balancing undesirable incentive effects against the positive outcomes of a trial requires that it be possible to measure both of their extents. If a particular incentive effect did remain a problem, even after that balancing, then it might be necessary to adjust the trial design. One way might, for example, be by not making dependent use an entry criterion, although international treaty obligations might make this difficult.

The comparison group
Allocation of people to a comparison group is another important issue. If people were randomly allocated to ‘heroin’ and ‘comparison’ groups, the most reasonable option would be to proceed in a similar manner to that suggested for selection procedures (13). Specifically, this means that participants give informed consent to participate in a trial on the basis that they may be allocated to a comparison group, and the allocation process itself must not be seen to show favouritism or punishment to any person or group of people.

It may also be necessary to provide some incentives for people in the comparison group to participate, both pragmatically and as a matter of justice (24). After all, it is unfair to use people without there being some benefit to them.

Inclusion of pregnant women
The question of whether or not women who are pregnant should be allowed to participate must ultimately rely on medical, pharmacological and social advice and would also be determined by the exact nature of a trial. The issue is a question of what is best for the woman and baby.

Competition with other programmes
A trial may be seen as a ‘competitor’ for clients in other treatment programmes. But where any given client should go should be determined by which programme would most benefit the client. Placing restrictions on a trial — by stopping participants from leaving other programmes to join it, for example — may bias results. It is also possible that a trial could be a conduit into treatment for people who could not otherwise be reached.

Service providers in abstinence programmes might oppose a trial, not on the basis of competition for clients but rather on the basis of a clash of treatment philosophies. One of the important unknowns of a trial, however, is whether or not it would produce changes in its participants which would ultimately lead to increased levels of abstinence.

Distributive justice
There are a number of areas with respect to recruitment where issues of distributive justice arise (24, 25). For example, assuming that unadulterated heroin is much safer than adulterated, then denying some heroin users access to unadulterated drugs available to others, would pose an issue of distributive justice.

Still, any distributive injustices must be judged in light of the temporary and investigative nature of a trial. There is an analogy here with similar trials of vaccines for serious diseases: there, too, we have reason to believe vaccines are beneficial (otherwise a trial would not be morally permissible); but a control group is, for the time being, deprived of the benefits of that vaccine, in order to demonstrate those benefits conclusively. Furthermore, it is not yet proven that provision of heroin in a controlled manner would be successful in reducing health problems and criminal behaviour: settling these issues is in fact the purpose of conducting a trial.

Privacy
In terms of privacy issues, it is important that information only be collected from people with their knowledge and consent, and only for specific purposes directly connected with the aims of the trial (21, 23). Information must only be used for the purposes for which it was gathered. Only information demonstrably needed for a trial to function should be kept on any register, and there should be strict controls on the sharing of information with other public agencies (26).

There may be a fear of people being forced to identify themselves as illegal drug users by having to attend the trial’s distribution point(s), and this might prove problematic despite the fact that it was the participant’s choice to be there. To mitigate these effects, however, distribution point(s) could be sited so as not to draw undue attention to trial participants.
This is related to the problem of participants – having been identified – being at increased risk of prosecution if and when the trial programme ends. This could be dealt with by specific legislation, perhaps providing a moratorium from prosecution after a trial ends. Alternatively, this potential difficulty could be seen as further support for the direct implementation of policy without a prior trial.

A certain amount of sensitive information, both as regards personal histories and criminal behaviours, must be collected from participants in order to evaluate the effects of a trial. A particular example is requiring people to undergo HIV tests before being accepted for a trial. This might be a permissible intrusion if the participants are given the opportunity to provide informed consent, are given pre- and post-test counselling, and if there is good reason for the tests, such as being part of the data required to determine the efficacy of a trial.

Intrusiveness of this sort should be kept to a bare minimum. Experimenters should collect only such information as has been determined to be necessary on a priori scientific grounds. Such intrusiveness as inevitably remains in the very nature of the trial must be subject to informed consent on the part of participants who have been told clearly in advance what information will be collected concerning them and who have consented to those arrangements. Ideally data would be protected from subpoena by legislation.

Issues relating to staff working on a trial
The question of potential risks to trial staff and indemnification for the service providers has two aspects relevant to ethics. The first is that a trial should be designed to minimise the risk for service providers. For example, universal precautions (27) would have to be taken to minimise the risk of contracting HIV or hepatitis through needle-stick injuries. The second is that the staff should be fully informed as to the nature of their responsibilities and the risks involved, and should have the opportunity to provide informed consent for working on a trial. Assuming that a trial was run through the existing public health care and/or social welfare system, staff should be allowed the possibility of transferring, at any time, to work not involved with the trial. This last condition is aimed at ameliorating the effects of ‘burn-out’, which are possible, as working on a trial can be highly stressful.

Coupling a trial with specific forms of treatment
It is possible that trial participants would be required to undergo counselling or specific forms of treatment, depending on the aims and structure of (or the political realities surrounding) a trial. The question of informed consent is again involved. A further issue is that it may be unreasonable to attach unrelated ‘strings’ to a trial: that might constitute unethical manipulation of people. Clear reasons would therefore have to exist for any supplementary treatment or interventions.

Rights of researchers
People evaluating the outcomes of a trial must not have restrictions placed (through either internal or external pressure) on their ability freely to publish the results of their investigations. Further, any empirical data collected should be made publicly available after a reasonable period, with appropriate protection to prevent identification of individual participants.

Conclusions
As indicated earlier, the way that specific issues are addressed depends largely upon how a trial is structured. In this paper, we have attempted to deal with a broad range of ethical issues that may be potentially relevant; in the end some may prove unproblematic. Some ethical criteria which would have to be met have been identified. Other criteria which would be important in shaping a trial have also been highlighted.

There are minimum ethical standards which must be met, regardless of the nature of a trial. These include that:

- there is a reasonable chance that a trial would ‘settle’ something, that is, the outcomes of the trial could be adequately evaluated;
- there is a list of reasons for halting or modifying a trial, which is drawn up before the trial begins;
- participants and trial staff are volunteers who have given informed consent;
- selection of trial participants and their allocation to ‘heroin’ or ‘comparison’ groups is without prejudice or bias;
- information is collected only from people with their knowledge and consent, only for specific valid purposes, and is used only for the purposes for which it was gathered;
- trial conditions do not involve needless manipulation of participants; and,
- the conclusions of a trial and the evidence on which they are based be made publicly available.

One of the main reasons for proposing a trial of the controlled availability of heroin is to obtain hard data, which is currently unavailable, about alternative regimes for dealing with heroin dependency. However, given the highly political nature of drug policy, a trial could be no ordinary experiment. Whether controlled availability is attempted as an experiment, as a policy option, or at all, will ultimately therefore be a political decision – and the ethics of political decision-making is another question altogether.

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