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Clinical Ethics Committee Case 6:

Our patient wishes to take an unlisted drug even though we're not sure of his diagnosis.

Ainsley J. Newson

Senior Lecturer in Biomedical Ethics, Centre for Ethics in Medicine, Department of Community Based Medicine, University of Bristol, UK

E-mail: ainsley.newson@bristol.ac.uk

Biographical Information

Dr Ainsley Newson is Senior Lecturer in Biomedical Ethics in the Centre for Ethics in Medicine at the University of Bristol. She has a PhD in Medical Ethics and Bachelors degrees in Science and Law. Her research interests include clinical and reproductive decision-making in genetics and synthetic biology. Ainsley is a member of the European Clinical Ethics Network and the Editorial Committee of this journal. She has been a member of Clinical Ethics Committees for 6 years; first at St Mary's Hospital in London and since 2006 at the Royal United Hospital in Bath.

Introduction

This is the sixth of a series of cases provided and discussed by UK clinical ethics committees. This series developed from the Virtual Ethics Committee, which discussed a case in each issue of the first two volumes of the journal. We invited all clinical ethics committees registered with the UK Clinical Ethics Network to volunteer to submit and then discuss a case, with cases allocated according to the experience of the committee. Committees have not discussed their own cases. The committees were given some guidance on how to generate a case, including the advice that unless consent from *all* parties to a case could be obtained, we would prefer fictional cases. The editorial committee took this decision to safeguard patient confidentiality. To the same end, we decided that the committee referring a case would not be identified (as this would provide a geographical indicator of identity), but we would name the committee discussing the case. A member of the editorial committee attends the discussion of the case and writes the summary to be published in *Clinical Ethics*, once the discussing committee and the journal editors have approved it. All committees and all of our readers individually, are invited to respond to the summary of the discussion once printed. Following the journal's usual review process, we welcome short articles or letters expanding upon points raised by the discussing committee or sharing similar experiences. We are also interested in publishing examples of good practice or

guidelines on difficult areas that have been generated by clinical ethics committees during the course of their work.

We have had a terrific response to the invitation to participate in this series from clinical ethics committees based all over the UK, and have seen some lively case discussion. **Future report series (starting with volume 5) will examine the contributions of Clinical Ethics Committees to organisational policy-making.** Committees which would like to participate should contact the Case Studies editor: Ainsley Newson (ainsley.newson@bristol.ac.uk).

The St George's Clinical Ethics Committee (CEC) agreed to discuss the case presented here. The Committee was established in 2006 and grew out of its predecessor, the Clinical Ethics Forum, established in 2000. The Committee provides a service for St. George's Healthcare NHS Trust, St. George's, University of London and South West London and St. George's Mental Health NHS Trust.

The CEC was established with a comprehensive remit in relation to clinical ethics. Its mode of operation is both reactive and proactive, including developing links with the framework of clinical governance. The Chair of the CEC sits on the Trust's Patient Safety Committee; however to maintain trust and neutrality, the CEC does not formally report to clinical governance committees.

The CEC comprises over twenty five members, drawn from a wide range of professions, specialties and services (including doctors, nurses, allied health professionals and support department workers), with varying levels of seniority (including two medical students). There are also lay members and members with formal training in medical ethics, a lawyer and a chaplain. The CEC is currently trying to increase the diversity of its membership to better reflect the local population.

Referral to the Clinical Ethics Committee: A 30 year-old man with suspected ADHD

Case description

A 30 year-old United States citizen, Mr D, who successfully studied in the USA was referred to a consultant psychiatrist in the UK two years ago. He had been given a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) in the USA and tried various stimulants there before settling on Adderal (a mixed amphetamine/ methamphetamine). Upon arrival in the UK he paid for this drug out of his own pocket but when he could no longer afford it, he approached his general practitioner (GP) to ask for a prescription for it. The GP then requested a psychiatric opinion as to the drug's suitability, and ongoing psychiatric supervision if it was felt the drug was clinically indicated.

The consultant psychiatrist was not persuaded that the patient did in fact have ADHD, but agreed to continue the treatment whilst assessing him further to review the diagnosis. There was no way of obtaining third party information about Mr D from his childhood or from his treating psychiatrist in the USA. He concluded that the patient had difficulties in his personality and with forming close relationships and that the diagnosis of ADHD was obscuring the main problem. Mr D would not accept the suggested revised diagnosis of personality disorder nor would he contemplate any alternative treatment.

He passed examinations for Microsoft during the next year, but remained isolated, doing maths at home and corresponding with friends in the USA. Eventually he got a job in information technology, which he had held for a month. At around the same time, the GP declined to prescribe the drug any further, questioning the psychiatric indication, and saying it was expensive, and had to be ordered from the USA. The patient went for two weeks without the drug and felt his mind was wandering, that he was distractible, that he tended to waste time, and was worried about losing his job.

His medication was then recommenced. However a second opinion was sought from another psychiatrist who concluded that, although the diagnosis could not be reliably established, it could not be discounted. His apparent benefit from medication argued for its potential continuation. A further opinion was recommended from a substance misuse specialist. This consultation confirmed that Mr D evidenced no signs of dependence or misuse of the stimulants, that he understood the potential long-term consequences of stimulant use and was competent to make that treatment decision.

Mr D was able to continue work and, in fact, subsequently secured a better-paid job. Although he claimed to have good relations with work colleagues, he has not formed anything like a trusting friendship and remains fairly isolated.

Dilemma prompting referral to the Clinical Ethics Committee

Our team has approached the CEC to discuss the case with the following dilemma in mind:

The key difficulty is that the psychiatrist does not feel he has a clear diagnosis which would justify the prescription and is authorising a prescription based purely on the balance of benefit and harm as perceived by the patient. Aside from the cost-benefit calculation, the question is: who should decide what constitutes the patient's best interests?

Response from St George's Clinical Ethics Committee

Thank you for your referral, which we considered at our meeting on 4th December 2008. This case represented a departure from our standard process, in that it is usual for referring health professionals to attend our committee meetings for interactive discussion. However, this case still prompted a great deal of discussion and debate. The aspects of this case that we considered to be particularly relevant were:

- The uncertainty over Mr D's diagnosis;
- The fact that he has received NHS funding for Adderal treatment in the United Kingdom;
- Mr D's apparent unwillingness to engage in dialogue about alternative diagnoses or treatments;
- The benefits and risks of taking Adderal to Mr D;
- The assessment of Mr D as not being prone to addiction to this drug and that he appears competent to weigh up the risks and benefits of taking it.

The lack of diagnostic certainty

We began by discussing the lack of certainty over Mr D's diagnosis. There have been three different clinical opinions on Mr D's diagnosis, with no confirmation of any particular condition. He may have Attention Deficit Hyperactivity Disorder (ADHD), Personality Disorder, both disorders, or

neither disorder. Clearly additional clinical information is needed to formulate a more definitive diagnosis.

ADHD can be difficult to diagnose, although recognition and diagnosis of this condition is increasing. There are a variety of problems, including inattention, impulsivity and hyperactivity; and two of these issues are generally required to present across two functional domains (such as home, school or socially) before a person is 7 years old. The condition can, however, persist through adulthood. There is also some relationship between childhood ADHD and adult Personality Disorder: children with undiagnosed ADHD often experience disapproving interactions with peers and adults that can impact on their personality development.

The drug Adderal, a mix of methamphetamines and amphetamines, is not generally available in the UK. It has not been validated for treatment by the National Institute for Health and Clinical Excellence (NICE). Ritalin, in contrast, is comprised of methamphetamine only. Drugs of this kind, if administered to a person without ADHD, would cause a person to become much more alert, but in a person with ADHD paradoxically the opposite effect is observed. Other treatments, such as other tri-cyclic drugs and cognitive behavioural therapy are available and we would be interested to know the length to which these have been discussed with Mr D or the extent to which his GP has tried to elicit this information.

One indicator that may suggest that Mr D has ADHD instead of personality disorder is that he does seem to experience an improvement in his functioning or mood when taking Adderal; if he suffered from Personality Disorder this would be less marked. However, if personality disordered he may also experience an increase in some associated behaviours, such as dishonest acts to obtain funds to buy more supplies of the drug, which we have no evidence of.

The advantage of Adderal is that it is a slower-acting drug so it does not have to be taken as frequently as a drug that is made from pure methamphetamine. However a disadvantage is that as they are all amphetamine derivatives, these are drugs of addiction. There are also potentially harmful long-term effects of taking this drug, for example an increased risk of psychosis; either transient or as a chronic psychosis indistinguishable from schizophrenia. It is therefore pertinent to examine why Mr D is so committed to this particular therapy. Even though Mr D has been observed to have no signs of dependence or misuse of Adderal, this situation could change in the longer term.

Ideally the GP should continue to seek information about Mr D's childhood and clinical history prior to his emigration to the UK, as this is pivotal to attempting to resolve questions over his diagnosis. We also wonder why Mr D appears unwilling or unable to disclose his relevant history or to allow access to those in the USA who could provide relevant information. Is this behaviour worthy of our suspicion or is Mr D protecting himself from potentially painful information?

The status quo for Mr D is therefore one of diagnostic uncertainty, with discomfort among the treatment team over prescribing a drug that is not licensed for use in the UK. There could be a risk of harm in treating a particular condition with licensed drugs if it transpires that this is the incorrect diagnosis. The two options are to accept Mr D's decision (even though this is not necessarily what a UK doctor would prescribe) or for the treatment team to undertake further

investigations before adopting this patient-centred approach. It is relevant that Mr D feels better when taking the drug, but a tension remains between what Mr D wants and what his treatment team feel is best for him. Whatever option is chosen, consistent follow-up will be required.

Who should decide what constitutes Mr D's best interests?

The nature of an objective 'best interests' calculation for Mr D is problematic, as he has been deemed to be competent to weigh up the putative benefits and harms of taking this treatment. This suggests that Mr D would be the best person to determine what constitutes his own best interests. However, the treatment team's obligation to respect the patient's request is tempered by their obligation not to act in ways contrary to their considered professional judgement. The medical team should determine best interests in light of the patient's wishes, but cannot rely solely on this information.

Further, making this determination of best interests is by no means straightforward. Mr D likely has greater insight into parts of his life and the values that guide him than the treatment team, particularly given the lack of background information. He will also have a better idea about what kinds of treatments suit him given the relatively recent period of his UK treatment. But this should not translate into a right to demand a specific ongoing treatment, particularly one such as Adderal. Further, not all patients are capable of conceptualising their future, preferring instead to take a shorter term view. This potential problem should be explored with Mr D and if this transpires to be his situation, his doctor has to explain the risks and the need to take a longer-term view to find a good alternative treatment.

Although 'best interests' can be broadly construed, the medical paradigm is important. It is arguably irresponsible to prescribe a drug to a patient that medically harms him in the longer term despite the fact that it makes him feel better. Mr D may be asserting that he is better-off outside the typical paradigm for this treatment within the NHS, but we should be mindful to balance improving Mr D's overall welfare with the long-term clinical uncertainty from taking Adderal.

We also could not overlook the fact that Mr D remains isolated. This prompted us to consider whether he really was indeed better when he was on Adderal. With time, he may get better treatment to feel and function better than he does while taking this drug. Adderal may improve his function but this may not help Mr D to be as well as he could be. If at all possible, a more thorough history should be obtained, to provide further information on other treatment attempts and the time allocated to them. This information will help to obtain a sound and accurate diagnosis and to enable the treatment team to provide care to Mr D as a 'whole person.' This will also help you to determine whether there may be a better alternative to optimise Mr D's quality of life.

Another relevant consideration is Mr D's background as a United States citizen who has moved to the United Kingdom only relatively recently. Mr D may not fully appreciate that his UK care team will wish to thoroughly review his condition and the long-term effects of any medications before prescribing, particularly given the absence of background information. The prescription from the USA may indeed maximise Mr D feeling good in the shorter term, but it may never have been meant as long term therapy. Now that he is in the UK, Mr D's care would need to be completely

reviewed. Treatment with Adderal may indeed be reasonable, but without further information, it would be impossible for any UK doctor to make an informed judgement.

You should also bear in mind that the judgement about what lies in Mr D's best interests will in effect be made every time the prescription is renewed. This places a significant burden of responsibility on the GP.

Ethical issues arising when patient-centred wishes for medication conflict with medical opinion

One method by which the ethical issues in this case can be systematically assessed is that 'Four Topics' method.¹ Contrary to principle-based theories in medical ethics, this approach starts with the facts of the case and then analyses the issue according to four specific categories of deliberation: (1) medical indications, (2) patient preferences, (3) quality of life and (4) contextual features. The summary of our discussion of this case using the 'Four Topics' is presented in **Box 1**.

Box 1: A proposal for a 'Four Topics' analysis of the case of Mr D	
<p>Medical Indications <i>What is the Diagnosis & Prognosis? What treatment options exist? What are the medical goals?</i></p> <ul style="list-style-type: none"> • There is reasonable professional disagreement over Mr D's diagnosis • Options for treatment include medication (both licensed and unlicensed) and cognitive behavioural therapy (which has a long waiting list) • The treatment goals are to maintain Mr D at a good level of functioning. • The benefits of providing the drug may outweigh the harms, as he is not dependent on the drug nor does he appear to misuse it. This should be revisited at a later stage. 	<p>Patient Preferences <i>Assuming competence, what does the patient want? What are his/her values? What is in the patient's best interests?</i></p> <ul style="list-style-type: none"> • Mr D is competent and well informed • The dissenting diagnosis could be discussed with him to determine why he doesn't accept it • Mr D could be asked whether he might accept a compromise whereby an alternative treatment is tried in the short term, pending further assessment. He could be reassured that the other drug will be available should this not be successful
<p>Quality of Life <i>What effect might the proposed treatments have on the patient's quality of life?</i></p> <ul style="list-style-type: none"> • Mr D's quality of life is enhanced when he is on the medication. If he refuses the compromise of alternative medication his quality of life may be affected • Withdrawal of the drug in the recent past lowered his quality of life, increasing his anxiety and distractibility. • The longer-term harm from taking this drug is uncertain 	<p>Contextual Features <i>What social, economic, legal and policy considerations are relevant?</i></p> <ul style="list-style-type: none"> • Of relevance is the fact that Mr D was initially diagnosed in the United States, which has different diagnostic criteria for certain mental health conditions. This may explain the disagreement between the psychiatrists, as well as influence Mr D's perception of his mental health and his expectations for treatment in the United Kingdom

¹ Jonsen AR, Siegler M, Winslade WJ. (2006) *Clinical ethics: A practical approach to ethical decisions in medicine*, 6th Ed. New York: McGraw Hill.

<ul style="list-style-type: none"> • If the patient refuses to compromise, treatment with the current medication seems preferable to non-treatment in terms of quality of life. 	<ul style="list-style-type: none"> • There are certainly economic and resource allocation considerations here, but these should not outweigh the benefit Mr D obtains from taking this medication.
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From this analysis, a conclusion that you might like to consider is that given the reasonable professional disagreement over Mr D’s diagnosis, a balancing of benefits and harms suggesting overall benefit, and the potential impact on his quality of life, Mr D should be asked to consider a compromise of a trial period with an alternative treatment, but if the new treatment should fail or if he resolutely refuses then he should be provided with Adderal. This would be underscored by regular follow-up.

That said, this proposal did generate much discussion among our Committee, and there was no consensus. Concerns were expressed about what kind of alternative treatment could be proposed, as this would itself be reliant on a clear diagnosis. There was also concern that this amounted to prescribing to make a patient feel better without reference to a clear evidence base. Many members of our committee felt this was an unacceptably patient-centred proposal, which does not account for the medical stake in determining Mr D’s best interests. Mr D should not have the right to ‘order’ medications.

The resource allocation implications of prescribing a drug that is not available in the UK also need to be considered. The decision to prescribe Adderal to Mr D will affect other patients and may set a precedent for future prescribing in patients with a similar presentation. If you are to prescribe for Mr D at all, then perhaps he should be tried with an approved British drug first under the supervision of his UK team. The doctor-patient relationship should also be developed to allow the team to know Mr D as a whole person rather than simply providing him with a pharmaceutical of uncertain value. A more detailed risk-benefit assessment could also then take place over a period of time, particularly as his condition is chronic as opposed to acute. However a counter to this position is that Mr D has already been prescribed Adderal in the United Kingdom and has found it to be of benefit despite his diagnostic uncertainty. It may therefore be seen as unreasonable to withhold it now. Changing his treatment could also cause a rift in the doctor-patient relationship as well as potentially disrupting the securities in his life such as his current job.

Reaching a consensus

We have established that Mr D does require some kind of regular treatment and follow-up, but the nature of this then needs to be established. Our deliberations on this led us to an admittedly pragmatic solution.

Regardless of which treatment Mr D is eventually prescribed, you should attempt to firmly establish his level of functioning via an ongoing dialogue with him. Diagnostic and treatment uncertainty should be acknowledged and the resulting period should be used to pursue this further, including seeking information from others in the United Kingdom and the United States. This will help the doctors involved in his care to move beyond mere prescribers.

While this ongoing exchange is taking place, some form of drug treatment would seem appropriate, despite the diagnostic uncertainty, given that Mr D has been taking medication fairly constantly. After discussing the merits of prescribing a drug or prescribing Adderal, we concluded (taking into account the risks, Mr D's broader interests and those of the health service) that it would be appropriate to provide a drug that is already available and approved for use in the United Kingdom. This provision would be coupled with an ongoing discussion with him about treatment, a commitment to reduce uncertainty in his diagnosis and to build a more complete doctor-patient relationship. There could well be a move to revised treatment (including Adderal, or withdrawing drug treatment altogether) pending further investigations and clinical deliberation; this should be communicated to Mr D.

We believe this course of action is appropriate even though it does not concede to Mr D's expressed preference. Adderal may well be low risk but until you can be absolutely sure of this it is not justifiable to provide this drug in place of something that has been approved for use in the United Kingdom. If Mr D is committed to staying well, then hopefully he will want to engage in the process of dialogue required to help his clinical team to reach agreement with him as to what lies in his best interests. In time it may emerge that the unlicensed drug is the one that is the most suitable for Mr D; however this conclusion should not be reached too quickly.

Members of St George's Clinical Ethics Committee who contributed to this case:

Nigel Eastman, Professor of Law and Ethics in Psychiatry (Chair); Barbara Philips, Senior Lecturer/Honorary Consultant ICU (Deputy Chair); Hilary Johnson, Chaplaincy Team Manager (Joint Secretary to Committee); Robert Elias, SpR in Renal Medicine; Mary Franklin, General Practitioner; Ann Gallagher, Lecturer; Ellie Galloway, Student member; Rehana Iqbal, Consultant Anaesthetist; Wendy Nash, Lay member; Laura O'Regan, Bone Marrow Transplant Coordinator; Penelope Radcliffe, Solicitor from Bevan Britten; Frances Raphael, Consultant Psychiatrist; Daniel Sokol, Lecturer in Medical Ethics; Sarah Thurlbeck Consultant Paediatrician; Lizzie Tuckey, Medical Student; Nicola Walker, ICU Nurse Specialist; Daniel Wilmer, Student Member.