Consent to contraceptive treatment among clients with epilepsy

Rohit Shankar and colleagues discuss findings from an audit of local GP surgeries' practice in prescribing oral contraceptives to women with learning disabilities who take anti-epileptic drugs

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Abstract

Aim To improve the treatment, care and monitoring of women with learning disabilities who receive oral contraceptive pills and long-term anti-epileptic drugs.

Methods A questionnaire based on standards from national and good-practice guidelines was devised and sent to all GP surgeries in the Cornwall. The questions concerned:

- The rationale for birth control and/or behaviour management in the client group.
- Whether anti-epileptic drugs interactions and adverse effects were being considered
- Whether clients demonstrate sufficient mental capacity to make informed choices about birth control and, if not, whether best-interest processes are being followed.

Results 1. Please provide a brief summary of the findings

Conclusions To ensure that GPs follow a single process in securing the consent of women with learning disabilities to birth-control, and thereby avoid any physical, financial and legal problems, copies of an easy-read

leaflet for clients and a flowchart describing the best way to manage such patients were sent to GP surgeries around Cornwall.

Keywords
Anti-epileptic drugs, informed consent, learning disability, oral contraceptive pills

People with learning disabilities are among the most vulnerable members of society with some of the greatest health needs (Department of Health (DH) 2008), and are especially vulnerable to breaches of their human rights in health care (Healthcare Commission 2007).

Many women with learning disabilities lack a clear understanding of sexual health and do not benefit from mainstream education about contraception, why it is required and its potential side effects. Concerns about the use of oral contraceptive pills apply especially to women with learning disabilities who also take antiepileptic drugs. Such women may have difficulties making informed choices about treatment that are based on assessments of benefits, risks, and short and long-term side effects. In addition, women prescribed oral contraceptive pills and anti-epileptic drugs over the long term are less likely to be monitored.

The risks associated with oral contraceptive pills (Prior et al 2001, Hartard et al 2007, Scholes et al 2011) and anti-epileptic drugs (Mattson and Gidal 2004, Beerhorst et al 2005) are well documented. Oral contraceptive and the older anti-epileptic drugs are known to cause major long-term adverse effects, including reduction in bone density, which may increase the risk of fractures (Mattson 2004, Hartard et al 2007). Hip fracture can in turn lead to disability, loss of independence and premature death, and has associated medical and social care cost implications (National Institute for Health and Care Excellence (NICE) 2011).

More importantly, oral contraceptive pills and anti-epileptic drugs can interact and become less effective, increasing the risk of unexpected pregnancy and seizures (Dutton and Foldvary-Schaefer 2008). To control the seizures, women may require higher doses of anti-epileptic drugs , which can have undesirable side effects 2. Such as?.

For these reasons, how such complex prescribing is being handled in primary care and whether informed consent is being secured are important issues. People with learning disabilities are often vulnerable and sometimes isolated, and can have difficulties understanding why they need specific treatments or interventions. In addition, the family members and carers who support them may make misunderstand their capacity to make decisions and make inappropriate decisions on their behalf. In some situations, clients may conform to the suggestions of others due to a lack of confidence about expressing their own views, or they be excluded from decision-making processes altogether.

Mencap (2002) provides protocols that GPs can follow in such situations, and suggests processes for monitoring in the short term and long term. 3a. This sentence appears to be contradicted by the next one... There is no national or local protocol, strategy or pathway for clinicians to help women with learning disabilities make decisions in this area. 3b. ...which in turn appears to be contradicted by the next one Under the Mental Capacity Act 2005, clinicians must secure clients' consent to treatment or, if consent cannot be secured, ensure treatments are in clients' best interest. These rules apply to the treatment of epilepsy in people with learning disabilities (Jackson and Winterbottom 2012) and NICE (2012) has issued guidelines in this area.

Audit

Objectives The authors decided to audit how GPs in Cornwall prescribe oral contraceptive pills to women with learning disabilities who take anti-epileptic drugs and how they secure such women's consent to treatment. Good practice in this area was derived from DH (2009), Jackson and Winterbottom (2012) and NICE (2012)

guidelines, and from the Mental Capacity Act 2005. They expected their audit to have a direct health benefit to women with learning disabilities.

The objectives of the audit were to:

- Gather baseline evidence of good practice among GPs.
- Demonstrate the effectiveness of shared-care arrangements in primary care.
- Speculate about potential legal and financial implications of prescribing oral contraceptives to women with learning disabilities who take anti-epileptic drugs.
- Clarify the benefits of, and risks involved in, taking oral contraceptives for women with learning disabilities who take anti-epileptic drugs.
- Provide guidance on securing clients' informed consent.
- Draw up pathways and strategies that GPs can follow.

Method The authors drew up a simple and concise questionnaire based on DH (2009), Faculty of Sexual and Reproductive Healthcare (FSRH) (2011) and NICE (2012) guidelines, and the Mental Capacity Act 2005, and was emailed to a local GP surgery. Feedback was collected and recommended changes were made in a revised version.

In 4. What month?, the authors emailed the adjusted questionnaire (Table 1), an explanation of the purposes of the audit and criteria for the inclusion of service users to all 67 GP surgeries in Cornwall. GPs were given 5. How long? to respond, although this period was extended to 6. How long? to ensure as many GPs as possible participated in the audit. Twenty nine (43 per cent) responded, most by email but some by post.

The anonymised data were collated 7. How? and forwarded to 8. Where (ie which trust)? clinical audit department for analysis. 9. What kind of analysis?

Results Of the 29 GP surgeries that responded, 19 (66 per cent) stated that none of their patients were eligible for audit according to the selection criteria. Each of the other ten (33 per cent) GP surgeries stated that one patient fitted the criteria and sent in a completed questionnaire. Of these ten, seven (20 per cent of the surgeries that responded) stated that the woman in question was having regular periods.

All ten GP surgeries provided information about the types of contraceptives they prescribe (Table 2) and the rate at which they prescribe them (Table 3). Nine of the ten surgeries stated that they undertake annual physical examinations of all recipients of oral contraceptives, including those with learning disabilities, but do not check against biochemical parameters. Eight of the ten women in the audit had been examined 10. If 'examined' here and later in this sentence are the wrong words to use, we need a brief explanation of the differences between 'examining', 'reviewing' and 'monitoring' in the three-month period before the audit, one had been examined about a year before 11. What about the tenth woman?.

Seven of the ten GP surgeries provided information on the types of anti-epileptic drugs prescribed (Table 4) and four different drug types were identified. 12. We need drug types, not trade names, here. In the table you sent in, Rohit, Levetiracetam is mentioned twice and, as I understand it, Keppra is a trade name for a Levetiracetam-type drug, so the numbers here would become: 4 drug types, either 2 or 3 women taking Levetiracetam and either 7 or 8 women altogether. See the other PDF for tables

13. Given the information in Tables 2-4, are any of the women especially at risk of unexpected pregnancy and/or seizure? I think finding this out was one of your objectives

The audit was limited because, despite assurances that the questionnaire would take only 15 minutes per patient to complete, only a small number of surgeries responded. As a result, its findings cannot be generalised to other areas of practice.

After analysing the data, the authors contacted the ten surgeries that had responded made to enquire further about how they had sought the consent of the women concerned to treatment. The authors found that,

although the surgeries indicated that nine women had given their consent to being prescribed oral contraceptives and anti-epilepsy drugs, they could not demonstrate that they had followed an appropriate system or protocol. This suggests a lack of awareness of the importance of obtaining consent for treatment from vulnerable women. The authors are concerned about the possible risks to the individual women 14a. In your original text you say 'woman' here. Are you referring to one woman in particular? concerned, as well as the possible financial and legal implications for the health community.

14b. In Table 1 one respondent states that explaining the reason for taking oral contraceptives to one woman was 'not appropriate'. Did they say why? Is this the woman you were referring to (see previous query)?

As a result of the audit, the authors produced a flyer about oral contraceptives and their potential interaction with anti-epileptic drugs and a flowchart poster for GPs describing good practice.

The flyer is in an easy-read format so it can be understood by women with learning disabilities and so can help them to making informed decisions about the drugs they take. It has been reviewed by a local learning disability service user group and an expert in the management of epilepsy in women, and should be made available to service users at GP surgeries before their consultations 15. Do GPs give the women the flyers or pin them up on their waiting room noticeboards?. The flowchart poster makes clear that GPs should hold best-interest meetings if they do not know whether patients can make informed choices.

Copies of the audit findings, flyer and flowchart have been sent to all local GP practices in Cornwall. In 16. What month, approx?, the authors expect to carry out a second audit of GP surgeries in the county to see if there have been any changes in practice. Meanwhile, they hope that larger studies will be undertaken to add to the evidence base on this important topic.

Please send copies of the flyer and flowchart!

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