Barriers to the implementation of expedited partner therapy

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Accepted 17 May 2011

INTRODUCTION

Beginning in the late 1990s, investigators in the USA and UK began evaluating new approaches to ensure the treatment of sex partners of persons with curable sexually transmitted infections (STI). Both countries had longstanding partner services programmes affecting at least some STI, but confronted a mismatch between the resources available to provide partner services and the scale of the STI problem.[e1] Moreover, although systematic reviews of partner services interventions are often cited as showing that traditional partner services are effective,[1] the evidence supporting the intervention comes almost entirely from studies of male sexually transmitted disease (STD) clinic patients,[e2 e3] and studies evaluating partner services provided to women and outside of STD clinics have not consistently found them to be effective.[e4–6]

Over the past decade, four randomised controlled trials, three of which were conducted in the USA, have evaluated expedited partner therapy (EPT) as a means to increase partner treatment among persons with gonorrhoeal and chlamydial infection.[2 e7–10] In most instances, these studies focused on patient-delivered partner therapy (PDPT), the practice of giving patients medication to give to their partners. All three US trials found that EPT increased the number of partners treated and all reported lower rates of persistent or recurrent infection in EPT recipients, although this difference was statistically significant in only two trials. The sole UK trial found that PDPT significantly increased the number of persons who notified all partners, but did not show an increase in partner treatment or an effect on re-infection rates. However, the trial was very much smaller than the US studies, and was consequently substantially underpowered.[e10] Here we address some of the major outstanding issues affecting the development of new, lower cost approaches to partner services, considering the USA, UK and Australia, and lower income nations.

EPT IN THE USA

Most recent work on EPT in the USA has focused on operational considerations. Legal concerns have been paramount. The use of EPT in the USA is largely governed by state, not national, law. As a result, the legal status of the practice varies across the country and, depending on existing laws, making EPT legal often requires either new laws or new administrative rulings. A review of laws affecting EPT in 2006–7 concluded that PDPT was clearly legal in only 12 states. However, the legal environment has changed dramatically in the past 5 years, and as of January 2011, PDPT was thought to be legal in 28 US states, of unknown legal status in 14 states, and illegal in only eight states.[3] Recently developed tools should help public health officials further reduce legal barriers to the use of EPT.[3]

The greatest single impediment to EPT use in the USA is now funding. Ensuring access to medication for partner treatment requires that insurance companies routinely pay for it or that public health agencies provide the medication through a centralised programme.

Insurance companies, including the US government insurance programme for low income persons (Medicaid), do not consistently pay for EPT and, to our knowledge, EPT is available through central funding only in Washington state, where it is paid for using public health funds in Seattle and the surrounding area, and with federal research money in the rest of the state. Investigators estimate that, including the costs of medication and pharmacy fees, the Washington state programme treats approximately 12 000 partners per year at a cost of approximately US$105 000, less than the cost of employing two full-time disease intervention specialists. However, this estimate relies on purchasing medications through a low cost federal programme (340B) open to agencies providing care to low income persons, and it not clear whether population-based public health programmes can purchase medications through this mechanism. Ensuring that public health programmes are eligible for 340B pricing, and addressing public health needs as part of healthcare reform, should be federal STI priorities.

Beyond the issues of legality and funding, the major unmet needs in the USA related to EPT are optimising the intervention and instituting and evaluating large-scale EPT programmes. Important topics include: (1) increasing the uptake and acceptability of EPT to index cases, their sex partners, and medical providers; (2) cost-effectiveness analyses; (3) evaluations of new models of EPT delivery that extend beyond STD clinics; (4) assessments of the effect of EPT on STI incidence, prevalence and associated morbidity; and (5) ongoing reconsideration of PDPT for gonorrhoea based on changing antimicrobial susceptibility patterns. Progress has been made on some, but not all, of these topics.[e11–14] Also, EPT does not solve the problem of inadequate partner treatment. It is part of a solution. Even when EPT is readily available, many partners remain untreated. New approaches to increasing partner treatment, perhaps through better counselling or selective triage of cases to receive more traditional partner services, are worth exploring. A recent randomised

trial demonstrated that counselling can improve partner services; whether that intervention can be brought to scale is uncertain, but merits evaluation.[4]

EPT IN UK AND AUSTRALIA

Strategies such as PDPT, which do not provide a medical assessment of the sex partner for whom the antibiotics are intended, do not comply with current prescribing guidance in many countries, the UK and Australia among them. In spite of this, there appears to be considerable support for EPT strategies from both patients and healthcare providers in some settings,[5 e15 16]; some medical providers continue to provide EPT,[e17 18] and in one case conducted a randomised controlled trial of EPT.[e10]

Regulatory issues aside, many patients and clinicians value more in-depth engagement with healthcare services than those afforded by EPT, and highlight that the improved outcomes associated with the EPT strategies described come at a cost. Partners who do not seek a medical evaluation may have STI that go undiagnosed and untreated, infections that might be detected if partners underwent a medical evaluation. The prevalence of STI that would go untreated as a result of PDPT use in heterosexual individuals appears to be very low,[6 e19] although trichomonas detectable through PCR was common in the sex partners of persons with gonorrhoeal or chlamydial infection in one study.[7] Also, the use of PDPT could diminish the treatment of exposed partners' sex partners. There are relatively few data on STI case-finding in second generation partners.[e20] This subject merits further study, as it could be an important limitation to the routine use of PDPT.

As in the USA, one option would be for countries/states to lobby for a change in prescribing guidance to permit PDPT, based upon the public health benefit from improved partner treatment outcomes and the good track record for patient safety with these approaches. However, this could be a lengthy process with no guarantee of success.

An alternative solution is accelerated partner therapy (APT).[8] APT are partner notification strategies that reduce the time for sex partners to be treated and include remote or face-to-face sex partner assessment by an appropriately qualified healthcare professional, thus complying with existing prescribing guidance. Models studied so far include telephone assessment of the sex partner by a sexual health clinic-based specialist nurse/health adviser, usually when the index patient attends for treatment. The index patient then delivers treatment to the sex partner, or the partner is assessed in a community pharmacy by a trained community pharmacist. Both models include a postal test kit for chlamydia and gonorrhoea within the partner treatment pack together with an assertive invitation for the partner to attend the clinic for more comprehensive STI and HIV testing. Data from the exploratory trial suggest that APT is associated with improved partner notification outcomes and shorter time to treatment compared with standard patient referral. However, very few sex partners treated through APT pathways attended for HIV testing. Future developments could include the provision of a point of care test for HIV and other STI at the pharmacy or even a self-test kit. APT is now being evaluated in a community-based randomised controlled trial. Although past APT studies have included index patients with gonorrhoea, in response to an increase in isolates with decreased susceptibility to oral cephalosporins, new UK guidelines recommend that all persons with gonorrhoea be treated with ceftriaxone, a change that will likely prevent the use of APT for gonorrhoea in the UK.

EPT/APT IN LOWER INCOME COUNTRIES

EPT use in lower income countries presents additional challenges. First, large numbers of persons in many lower income nations are treated syndromically without a microbiological diagnosis. While a large proportion of men with urethritis have identifiable and curable STI, most women with vaginal discharge do not. Therefore, in the absence of diagnostic testing, PDPT is likely to be of use only for urethritis. Research from Peru suggests that training pharmacy workers can improve their counselling related to partner notification,[9] and it may be worthwhile to incorporate PDPT training in selected public health efforts designed to improve the management of urethritis through non-medical providers.

Second, particularly in Asia, decreased susceptibility *Neisseria gonorrhoeae* is a growing problem,[e21] and single-dose oral cephalosporins are probably not an adequate therapy for gonorrhoea in nations such as China, meaning that PDPT, at least as currently used, is not appropriate. Third, in some nations, particularly in parts of sub-Saharan Africa, the prevalence of HIV infection among partners of persons with bacterial STI is likely to be high. Insofar as STI treatment can be linked to HIV testing, this effort should take precedence over the use of PDPT. HIV is the priority STD. Therefore, while there is some evidence that PDPT is acceptable and effective in lower income nations,[10 e22] the role of EPT in lower income nations has not been well defined, and should vary based on factors such as HIV prevalence, the availability of diagnostic testing and *N gonorrhoeae* susceptibility.

Competing interests None to declare.

Provenance and peer review Commissioned; externally peer reviewed.

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