The role of clinical guidelines in improving the safety and effectiveness of treatment

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The provision of opiate substitution therapy for addicted individuals has strong evidence of effectiveness, although poor quality of provision reduces benefit (Strang, 2012)

Core elements of OST

1. **Adequate dose OST suppresses heroin use (MT>60mg/day)**

Other benefits stem from reduction or cessation of heroin use:

1. **Improved health and outlook**
2. **Reduced crime**
3. **Reduced risk of death and disease**
4. **Opportunity for social reintegration**

Core elements of OST II

2. Structure

- **clear objectives and rationale for Rx**
- **program rules and policies relevant to these objectives**
- **systematic monitoring and review**
- **supervised administration as needed**

Core elements of OST III

3. Therapeutic relationship

- **non-judgmental**
- **non-punitive**
- **non collusive**
- **belief in the possibility of change**
  (Dole, 1973)

Core elements of OST IV

4. Safety

- **Minimize diversion and overdose deaths of people not in treatment**
- **Minimize deaths in 1st 2 weeks**
- **Protect patients from exploitation**

How to foster safe and effective OST

- Regulation
- Training
- Financial incentives
- **Clinical Guidelines**

Experience of OST in Australia and UK

OST Australia 1988-1998

Rapidly expanded treatment - inexperienced staff (Bell, 2000)

- Guidelines were loose ("individualised treatment") and were ignored by many practitioners
- Diverse models of Rx proliferated
- Financial pressure shaped much "treatment" - many consultations + little supervision = maximal profit

- Training program introduced (to recruit practitioners, to improve safety)

Consequences 1988-1998

1. Deaths during methadone induction due to too-rapid dose increases and inadequate clinical monitoring
2. Large increase in methadone diversion and diversion-related deaths (60% of methadone overdose deaths were associated with diversion)
3. Loss of public support for OST
4. Wide variation in treatment effectiveness (Capelhorn and Bell, 1991)

1998-2003 - NSW

Stricter regulations introduced (eg maximum 4 unsupervised doses per week)

Clinical audit showed poor compliance and little change in practice

2003 (state of NSW)

1. New guidelines introduced, replacing “clinical judgment” with operational criteria for treatment decisions (similar to federal regulations in USA)

2. Clinics were visited, files audited, and doctors given feedback

   Marked reduction in unsupervised doses followed, and a progressive, sustained decline in deaths due to diverted methadone

Training, guidelines, regulations in NSW

1. Regulation had limited benefit in improving safety and effectiveness
2. Evaluation of training identified 2 issues

   - trainees came with polarised preconceptions

   - many saw need for clinical supervision (Bell, 1995)
3. Guidelines need operational criteria, not “judgement”
4. As in all healthcare, clinical audit may be beneficial

UK Experience (Strang, 2007)

Guidelines published 1996

- **Recommended initial supervision, adequate doses, use of methadone liquid**
- **Appeared to have no initial impact on practice (Strang, 2003)**
- **However, over the following 6 years there was gradual change consistent with guidelines – an increase in supervised dosing, from 0 to 36% doses**

UK Experience (Strang, 2007)(cont'd)

- 1974-1995 increasing deaths due to diverted methadone, rising to 12-13/1000 patients per year

- 1996 onwards - increased supervision from nil to 36% of doses supervised by 2005

- Methadone deaths fell to 3.1/1000 patients per year by 2004 and has remained low

UK Experience (cont'd)

Strang's conclusion – guidelines (slowly) promoted safety

This was based on positive changes in supervision, medication type and formulation

UK Experience (Strang, 2007)

However, in 2005 only 41% of patients were prescribed doses in the recommended range (60-100mg/day methadone)

National average dose 56mg

- Guidelines are only effective where they are congruent with assumptions and beliefs

The impact of financial incentives in UK NHS

Services received financial penalties for failing to achieve specific targets relating to monitoring of treatment, and to retaining patients

This was associated with a high level of compliance with monitoring (Marsden, 2009) and good retention

However, persisting heroin use was common and often without any adjustment of treatment

The impact of training (Strang, 2007b)

RCT of training in equipping doctors to deliver OST

- **On ITT analysis, trained doctors showed small benefits compared to wait list controls**
- **However, many "wait list" doctors received training**
- **Doctors receiving training had marked improvements in knowledge, attitudinal and prescribing confidence**

Lessons from Australia and UK

Financial considerations have a marked impact on how treatment is delivered

Attitudes to addiction make practitioners selective about what evidence they think is important

OST has distinctive issues

- **Treatment involves the interface of biology, psychology and ethics - conflicting paradigms of treatment contribute to variations in delivery**

- **Poor practice – such as no supervision, lax monitoring – does not usually result in consumers complaining**

- **Stigma associated with addiction promotes punitive and controlling responses**

Conclusion

Like other areas of healthcare, OST requires

- **Guidelines**
- **Training**
- **Clinical supervision**
- **Participation in clinical audit**

These measures comprise a package, and without each element the others are much less effective

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