

HARKNESS FELLOWSHIPS IN HEALTH CARE POLICY

By Carmel M. Hughes, PhD, MRPharmS, and Nicola J. Gray, PhD, MRPharmS

The Harkness Fellowships in Health Care Policy is an international exchange programme that allows health service researchers to spend 12 months in the United States conducting original research and working with leading US health policy experts. The authors of this article hope to encourage others to apply to the programme by describing their personal experiences as follows

The Commonwealth Fund is a private foundation in New York City established in 1918 by Anna M. Harkness with the broad charge to “enhance the common good”. The fund supports independent research on health and social issues and

makes grants to improve health care practice and policy. One of the fund’s central initiatives is the world’s oldest international exchange programme in health care — the Harkness Fellowships in Health Care Policy. This programme provides a unique opportunity for mid-career health services

researchers and practitioners from Australia, New Zealand and the United Kingdom to spend up to 12 months in the United States, conducting original research and working with leading US health policy experts. Fellows can expect to gain an in-depth understanding of the US

Fellowship experience: prescribing in US nursing homes

Name: Carmel Hughes, School of Pharmacy, Queen’s University of Belfast

Project title: Evaluation of prescribing and related clinical outcomes in US nursing homes as a basis for a UK model

US mentor and placement: Vincent Mor, Centre for Gerontology and Health Care Research, Brown University, Providence, Rhode Island, 1998–99

Home mentor: James McElnay, School of Pharmacy, Queen’s University of Belfast

I spent my year in Providence, Rhode Island with Vince Mor, one of the leading experts in American long-term care. The United States has legislation that limits the prescribing of antipsychotics, anxiolytics and hypnotics in elderly residents in US nursing homes because these drugs have been used to sedate and subdue residents. Using data that had been collected from 1993, I carried out a series of analyses to assess the impact of this legislation on clinical outcomes in nursing home residents. One study comparing US data with data from Denmark, Iceland, Italy, Japan and Sweden found that residents

in US homes were less likely to receive these drugs compared with residents in other countries without equivalent legislation. A further study also revealed that facility characteristics, such as staffing levels, also influenced nursing homes’ prescribing patterns.

One of the major benefits of the fellowship was to be able to step back from the world of pharmacy and view issues in a different way, facilitated by extensive travel throughout the US to meet experts in my field of interest. I was also working with disciplines outside pharmacy, such as epidemiology, health services research and sociology, and I believe this exposure has encouraged me to think more broadly about my own work.

The fellowship has led to ongoing research collaboration with colleagues at Brown University and we are continuing work on prescribing quality in nursing homes. The fellowship has also had major benefits in terms of my research and career in the United Kingdom. I have been able to apply research skills gained in the US to work that I am undertaking in the UK and I was awarded a National Primary Care Career Scientist award, as well as the *Chemist & Druggist* practice research award in 2001.

Fellowship experience: adolescent information-seeking

Name: Nicola Gray, School of Pharmacy, University of Manchester

Project title: Study of adolescent information-seeking on the internet about health and medicines

US mentor and placement: Jonathan Klein, University of Rochester School of Medicine and Dentistry, Rochester, New York, 2001–02

Home mentors: Judith Cantrill and Peter Noyce, School of Pharmacy, University of Manchester

I spent my fellowship year working with Jonathan Klein, a leading United States adolescent health researcher and advocate. I was adopted into their “Leadership education in adolescent health” programme of seminars and interdisciplinary clinics alongside LEAH fellows from medicine, nursing, nutrition, psychology and social work. I valued this opportunity to work in a multi-professional environment, gaining a better appreciation of the contribution that pharmacy could make to youth health. I also contributed to research regarding adolescents’ use of complementary and alternative medicine, adding my expertise in medicines to their expertise in adolescent health and well-being.

I undertook a series of focus groups in US high schools, and used the fund’s generous travel budget to interview key United Kingdom and US health and education policy-makers. Their doors opened to me because of the reputation of the fellowships and the fund. Seminars that I attended in New York City, Washington DC, Boston, and Ottawa/Montreal were highlights of the year. My “fellow fellows” came from a range of disciplines, and their expertise in subjects like the health of first nation peoples, eg, Maori, made me step back from the consuming, yet often insular, concerns of pharmacy to consider wider issues of health inequalities.

The fund encouraged us to contact US leaders of our own professions and funded me to attend the American Pharmacists’ Association’s sesquicentenary conference in Philadelphia. I also visited its headquarters to discuss the surprising number of common challenges that UK and US pharmacists face in radically different health systems, such as the lack of a service-based contract. As a group, we UK fellows were sceptical about the US system. The fund campaigns hard for universal health insurance coverage for Americans: a dream over there that we take for granted. But we have a lot to learn from the US regarding youth health, and I hope to advocate for better health services and access for adolescents here.

health care system and policy challenges, enhance their methodological skills and develop valuable contacts and opportunities for ongoing cross-national exchange and collaboration. Previous Harkness fellows have come from an eclectic mix of disciplines, including law, journalism, economics, public health, general practice, nursing, health services research, policy, NHS management and pharmacy. A common aspiration for this disparate group of fellows is to learn from another system and to apply those lessons to health care in their own countries.

We continue to collaborate with our US mentors, and to participate in seminars and meetings organised by the Commonwealth Fund and the Nuffield Trust, their UK partner, as members of an international network of health services and policy enthusiasts and researchers.

The fellowships are aimed at a broad cross-section of individuals involved in

health care. Previous fellows have ranged in age from mid 20s to early 50s and, although a postgraduate degree is not a pre-requisite, many fellows do have master's degrees and doctorates. Under a new partnership between the Commonwealth Fund and the PPP Foundation (an independent UK charity that funds health care research, education and training), two additional UK fellowships have been established, bringing the total in the UK to seven. The Harkness/PPP Foundation fellowships are targeted specifically at health care practitioners, including executive clinicians and health service managers, as well as senior civil servants involved directly in health policy development.

Alan Milburn, the former Secretary of State for Health, has stated that work carried out by Harkness fellows "plays a valuable role in informing and advancing the work of the NHS". The fellowship is also unique on a personal and professional level

and many fellows view their time in the US as the defining experience of their career. We have been fortunate to have been awarded a Harkness fellowship, but general awareness of the opportunity for pharmacists is still low. We hope that our personal accounts of our fellowship experience will encourage other pharmacists to apply and we are happy to provide further advice and guidance.

More detailed information on the fellowship programme can be found on the Commonwealth Fund website at www.cmwf.org

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TABLET CRUSHING AND THE LAW

By Richard Griffith

In this article, the author explores the legal implications of crushing tablets

Medicines management seeks to maximise health gain through the optimum use of medicines. It encompasses all aspects of medicines use, from the prescribing of medicines through to the ways in which medicines are taken or not taken by patients. The effective use of medicines is also reflected in the strict legal framework regulating the supply and administration of medicines.¹ Public safety is at the heart of the regulation, yet despite this some 10,000 serious adverse drug reactions are reported each year with half of these arising from avoidable medication errors.² Recent disquiet over administration errors has focused on a study by David Wright that highlighted the widespread practice of crushing of tablets.³

Inappropriate crushing of tablets could lead to liability in four separate, but not mutually exclusive, areas of law:

- Society through the public law, ie, Medicines Act 1968, Consumer Protection Act 1987
- The person through the civil law, ie, trespass to the person, negligence
- The employer through contract law
- The profession through codes of conduct

Recourse to crushing tablets tends to occur in two main instances:

- To disguise the administration of the medicine
- To assist a patient with swallowing difficulties

COVERT ADMINISTRATION OF MEDICINES

As a general principle of law, every human being of adult years and sound mind has a right to determine what shall be done with his or her body.⁴

Therefore, even though a properly completed prescription gives the practitioner the right to administer medicine, it can only be given to the person with his or her consent. That person has a right to refuse the medicine (however unreasonably) and those caring for him or her must respect that right.⁵ Crushing a tablet to disguise its administration from a capable adult would constitute a tort or civil wrong of trespass to the person. Were the covert administration malicious then a criminal offence under the Offences Against the Person Act 1861 would be committed. In addition, the employer may take action for misconduct and breach of contract and the relevant regulatory body would take action for professional misconduct. It can be seen, therefore, that the non-consensual covert administration of a medicine to a capable adult could result in all four areas of law collectively holding the practitioner to account.

Where a person is unable to consent due to incapacity through being unconscious or some other impairment of mental function-

ing, such as a learning disability or dementia, then the law allows medicines to be given in the absence of a valid consent in that person's best interests.⁶

An inability to make a decision will occur when either the patient is unable to comprehend and retain the information that is material to the decision, especially as to the likely consequences of having or not having the treatment in question, or the patient is unable to use the information and weigh it in the balance as part of the process of arriving at the decision.⁷

In England and Wales relatives have no legal right to consent on behalf of incapable adults so the decision to act in the best interests of the patient rests with the person in charge of the patient's care.⁸ Here covert administration by crushing a tablet could occur if shown to be safe and justified in the person's best interests.

In the case of covert administration to an incapable adult there would be a need to demonstrate that:

- The patient is incapable of consenting to the treatment
- The medication is necessary in the patient's best interests
- All other methods of administration have been unsuccessfully tried
- The doctor and pharmacist and those that have to administer the medicine agree on the method to be used
- The form of the drug is safe to use covertly (medicines in tablet form will usually need to be crushed if administered covertly by disguising in food or drink)

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SWALLOWING DIFFICULTIES

Crushing a tablet to assist a person with swallowing difficulties appears to be a less contentious issue. However, medicines for human use are subject to a product licence.⁹ An unlicensed use would occur if the dose, route or form were outside the licensed terms. Administration of a medicine by crushing a tablet could be using the medicine in an unlicensed form. If harm occurs then liability in negligence would arise.¹⁰

The law of negligence imposes a duty of care on practitioners towards their patients.¹¹ When administering medicines the standard required must be in accordance with a respected body of professional opinion and stand up to logical analysis.¹² Breaching this duty and causing harm could give the patient a right to compensation.

The Medicines Act 1968 requires that prescription only medicines must only be given in accordance with the directions of an appropriate practitioner who has prescribing authority.¹³ Crushing a tablet contrary to the instructions of an appropriate practitioner would be a breach of the Medicines Act 1968 and could result in a finding of professional misconduct.

Giving advice and communicating information is also subject to the professional standard of care. Inappropriate advice to a patient or poor communication with other professionals or patients that results in harm would also give liability in negligence.¹⁴

It can be seen therefore that any decision to crush a tablet needs to be given full and careful consideration. In order to pro-

tect the safety of the patient and avoid liability it is essential before crushing a tablet, to consider whether:

- There are alternative products available such as liquid preparations
- The appropriate practitioner is consulted about the method of administration and gives approval for the crushing
- A pharmacist is consulted about the safety of crushing the tablet
- The person is told about the risks involved and gives consent
- The tablet crushing is an action in accordance with a respected body of professionals that stands up to logical analysis

Logical analysis requires the action to be the only option in the circumstances. Blindly following a trust or other protocol will not necessarily protect you from liability.¹⁵ The courts have been known to have rejected such protocols as falling below the required standard. Protocols must be up to date and based on expert evidence if they are to protect those that operate them from liability.

Generally where damages are awarded the vicarious liability of the employer requires that they meet the quantum from their funds. However the law of subrogation allows legal proceeding to be taken against the party responsible for the loss.¹⁶ That is you can be sued for the money paid out in damages. It is essential therefore that you carry an indemnity against such action. (This is often provided by a professional organisation such as a defence union or some health trades unions.)

RECOMMENDATIONS

An essential feature of medicines management is that those who advise or administer medicines to others abide by the legal and professional standards at all times.

The practice of crushing tablets is one that has the potential to endanger public safety and breach legal and professional requirements. It must not be done where there is a safer alternative available, such as a liquid preparation.

Where there is no alternative the practitioner must demonstrate that they have fully considered the safety issues by consulting the prescriber, the pharmacist and the patient, and administer the medicine in accordance with a practice accepted by a responsible body of professional opinion and the drug's product licence. In that way the practitioner will avoid liability and the patient will safely continue to benefit from the therapeutic effects of the medicine.

The consequences of failing to abide by the legal standards will be liability in four areas:

- The civil law through the torts of trespass to the person and negligence
- Professional misconduct
- Breach of employment contract
- In the most serious cases criminal charges under the Offences Against the Persons Act 1861 or for gross negligence

Liability is not mutually exclusive. Where the harm is serious, liability in all areas could arise.

REFERENCES

1. Griffith RA, Davies R. Accountability and drug administration in community care. *Br J Com Nurs* 2003;8:65–9.
2. Department of Health. An organisation with a memory — report of an expert group on learning from adverse events in the NHS. London: Stationary Office; 2000.
3. Wright D. Tablet crushing is a widespread practice but it is not safe and may not be legal. *Pharm J* 2002;269:13.
4. *Schloendorff v Society of New York Hospitals* (1914) 105 NE 92.
5. *Airedale NHS Trust v Bland* [1993] A.C. 789.
6. *F v West Berkshire HA* [1990] 2 A.C. 1.
7. *Re MB (Caesarean Section)* [1997] 2 F.L.R. 426.
8. *F v West Berkshire HA* [1990] 2 A.C. 1.
9. Medicines Act 1968 s.7.
10. Consumer Protection Act 1987.
11. *Kent v Griffiths & Ors.* [2001] Q.B. 36.
12. *Bolitho v City of Hackney Health Authority* [1998] A.C. 232.
13. Medicines Act 1968 s58(2)(b).
14. *Prendergast v Sam & Dee Ltd* (1989) Times law reports March 14th.
15. *Lucy Reynolds v North Tyneside Health Authority* (2002) Lloyds Rep Med 459.
16. *Lister v Romford Ice and Cold Storage Co Ltd* [1957] AC 555