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CLINICAL ETHICS

A new prescription for empirical ethics research in pharmacy: a critical review of the literature

R J Cooper, P Bissell, J Wingfield

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Empirical ethics research is increasingly valued in bioethics and healthcare more generally, but there remain as yet under-researched areas such as pharmacy, despite the increasingly visible attempts by the profession to embrace additional roles beyond the supply of medicines. A descriptive and critical review of the extant empirical pharmacy ethics literature is provided here. A chronological change from quantitative to qualitative approaches is highlighted in this review, as well as differing theoretical approaches such as cognitive moral development and the four principles of biomedical ethics. Research with pharmacy student cohorts is common, as is representation from American pharmacists. Many examples of ethical problems are identified, as well as commercial and legal influences on ethical understanding and decision making. In this paper, it is argued that as pharmacy seeks to develop additional roles with concomitant ethical responsibilities, a new prescription is needed for empirical ethics research in pharmacy—one that embraces an agenda of systematic research using a plurality of methodological and theoretical approaches to better explore this under-researched discipline.

(p xxii). Community pharmacists, in particular, represent a point of access for patients and customers to many services associated with medicines and healthcare advice. At the same time, their roles are changing, and the traditional activities of medicine preparation, dispensing and over-the-counter sales have been augmented by many additional services. In England, for example, community pharmacists have a new contract with the National Health Service and are being encouraged to undertake supplementary prescribing, drug use reviews, near-patient diagnostic testing, and the sale of an increasing number of deregulated, former prescription-only medicines such as emergency hormonal contraception and statins.⁶ In a recent review on the scope of the international ethics literature on pharmacy, Wingfield *et al*⁷ identified several concerns and omissions, including a preponderance of scenario-based studies from pharmacy practice and a paucity of substantive literature on ethics and values in pharmacy. Wingfield *et al* did provide an example of empirical ethics research but, because of specific search dates, omitted other relevant empirical studies. This paper aims to review the extant empirical ethics literature in pharmacy, heeding Marx's⁸ advice that "...we are not only creators of new knowledge, but protectors and transmitters of old knowledge [...] Seek an appropriate balance between appreciation and advancement of the literature" and also to identify opportunities for further research. Three key areas emerge from the review. Firstly, earlier studies typically used questionnaire-based quantitative methods but more recently qualitative approaches have been adopted, using focus groups and semistructured interviews. Secondly, two dominant theories—principlism and cognitive moral development—are identified and explored as approaches to grounding empirical research in normative philosophical and also psychological theory, respectively. Thirdly, samples have often included students and Anglophone, especially American, pharmacists, and few studies have focused on non-community pharmacy settings such as secondary hospital care.

This paper reviews the literature at the confluence of two ethical subjects—one increasingly valued and researched and the other still relatively unexplored. Regarding the first, the use of empirical ethics data and research methods from the social sciences has gained respectability and value both in the applied philosophical field of bioethics and also in health services research generally.^{1–3} Increasingly, empirical research is believed to be important in mapping out the ethical terrain of healthcare and there is a hope that closer integration of empirical and normative ethical study may be achieved, setting aside traditional differences that originated in the "is-ought" debate.⁴ As for the unexplored subjects, although many empirical, and indeed normative, ethical studies have been undertaken in the high drama concerns of medicine and the pioneering technologies of reproductive and genetic medicine, other areas of healthcare such as pharmacy have been relatively neglected. As Brazier⁵ notes, "...philosophers, social scientists and academic lawyers continue to demonstrate a worrying tendency to concentrate almost exclusively on ethical dilemmas of high drama and low incidence [...] The daily round of the pharmacist in hospital or the community simply lacks that drama"

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METHODS

Our study included searches of several electronic databases, initially using combinations of the following keywords: pharmacy, empirical, ethics, ethical, dilemma and pharmacist. Databases searched were Medline, EMBASE, ISI Web of

Abbreviations: CMD, cognitive moral development; DIT, Defining Issues Test

Table 1 Summary of empirical ethics studies in pharmacy

Study	Sample	Methodology	Design	Aims/results
Lowenthal <i>et al.</i> ⁹ Lowenthal ¹⁰	55 US pharmacists, 165 US pharmacy students	Quantitative	Questionnaire	Document pharmacy students' attitudes to ethical dilemmas and compare with pharmacists. Both have high levels of ethical behaviour.
Dolinsky and Gottlieb ¹¹	170 US pharmacy students	Quantitative	Questionnaire	To identify pharmacy students' descriptions of moral dilemmas and use of moral development theory.
Haddad ¹²	869 practising US pharmacists	Quantitative	Postal questionnaire	Compare incidence and difficulty of ethical problems and influencing variables.
Latif and Berger ¹³	113 US pharmacists	Quantitative	DIT Psychometric Test	Pharmacy students scored higher on moral reasoning than community pharmacists.
Latif <i>et al.</i> ⁴	92 US students 114 US community pharmacists	Quantitative	DIT Psychometric Test	Community pharmacists' moral reasoning and components of clinical performance.
Latif ¹⁵	113 US community pharmacists	Quantitative	DIT	Ethical cognition, organisational reward systems and patient-focused care.
Latif ¹⁶	113 US community pharmacists	Quantitative	DIT	Ethical cognition and selection-socialisation in retail pharmacy.
Latif ¹⁷	114 US pharmacists	Quantitative	DIT	Link between moral reasoning and patient care.
Latif ¹⁸	Not stated	Quantitative	DIT	A comparison of chain and independent pharmacists' moral reasoning.
Hibbert <i>et al.</i> ¹⁹	6 UK community pharmacists	Qualitative	Semistructured interviews	Four principles and practical ethical reasoning found. Legal, business, organisational concerns present. Range of dilemmas spontaneously identified.
Latif ²⁰	113 US community pharmacists	Quantitative	DIT Psychometric Test (postal)	Influence of pharmacists' tenure on moral reasoning. Older pharmacists scored lower.
Latif ²¹	69 Canadian and 73 US students	Quantitative	DIT Psychometric Test	Assess moral reasoning of pharmacy students. Unexplained national variation.
Elwell and Bailie ²²	112 US pharmacy students	Quantitative	Questionnaire (3-point scale)	Influence of class and clinical experience on ethical decisions was not relevant for five ethical scenarios.
Wingfield <i>et al.</i> ²³	40 UK pharmacy students	Qualitative	Focus group	Perceptions of ethics among pharmacy students.
Latif ²⁴	1564 US pharmacy students	Quantitative	DIT Psychometric Test	To measure and compare ethical reasoning of 1st-year and 3rd-year pharmacy students and geographical differences.
Wingfield <i>et al.</i> ²⁵	11 UK community pharmacists (5 for focus group)	Qualitative	Focus group and semistructured interviews	Influence of company policy on ethical decision making. Policy created concern but also guided ethical thinking.
Kalvemark <i>et al.</i> ²⁶	5–7 Swedish hospital pharmacists, dispensers	Qualitative	Focus group	Assess extent of moral distress in hospital doctors, nurses and pharmacists. Time/recourse constraints, rule breaking, professional conflict cause pharmacy distress.
Cooper ²⁷	11 UK community pharmacists	Qualitative	Semistructured interviews	Ability of pharmacists to resolve ethical problems varied. Legal controls, the commercial environment and professional isolation precipitated a range of dilemmas.
Chaar <i>et al.</i> ²⁸	25 Australian pharmacists	Qualitative	Semistructured interviews	Common sense reasoning and best interests of patient identified as central. Legal and business dilemmas in community common.

DIT, Defining Issues Test.

Knowledge, SOSIG and BIOME. Hand searches were also carried out on specific journals such as *The Pharmaceutical Journal*, *International Journal of Pharmacy Practice*, *Journal of Medical Ethics* and *Journal of Business Ethics*. Exclusion criteria included pharmaceutical industry or exclusively educational research, normative applied ethical discussions, and studies whose central aim was not related to ethical description or evaluation. Furthermore, an internet search using the above keywords was also undertaken using Google, in response to the EMPIRE project into empirical bioethics research, which recommended that "...it is also important to take into account 'grey' literature such as reports, PhD theses, and government white/green papers" (www.empire.konnu-nikation.aau.dk/Part_A_final.pdf). Several additional studies, often conference presentations, were identified using this search method. Table 1 gives details of the studies that were investigated.

EMPIRICAL ETHICS RESEARCH IN PHARMACY

Results

Having carried out searches in accordance with the method, several relevant studies were identified and are listed in table 1. It should be noted that the relatively prolific output of Latif included the repeated use of one dataset, reported in many publications. The number of distinct studies seems to be similar to other relatively under-researched areas of healthcare such as general

medical practice, for example, where one literature review identified only nine relevant empirical studies.²⁹ Following analysis of the identified empirical pharmacy ethics studies, many important themes emerged and these will now be considered in relation to methodology, ethical theory and samples.

Methodology and methods

A chronological change in research approach and method was apparent over the 19-year period of identified empirical ethics studies. Many of the earlier studies used a questionnaire that contained hypothetical ethical scenarios from which respondents selected options. This allowed statistical analysis of pharmacists' ethical problems and reasoning, whereas almost all later studies adopted interview or focus group methods. Typical of the first approach was the earliest identified empirical ethics study, by Lowenthal *et al.*, that dealt with the attitudes of practising and student pharmacists to ethical dilemmas, with the aim of developing more appropriate undergraduate ethics teaching. A postal questionnaire was used, which included questions that required a simple yes or no response to a variety of hypothetical dilemmas—dilemmas originating from the authors' experiences or from the normative literature. The study concluded that there was broad attitudinal agreement among students and pharmacists in relation to many of the dilemmas posed, but some disagreements did occur. The choice of relevant vignettes or scenarios for questionnaires in empirical ethics research has been

identified as a concern in the business and medical ethics fields and was also apparent in several of the pharmacy studies identified.^{30–31} Haddad,¹² for example, argued that this was due to the lack of available empirical examples of ethical problems and, using a questionnaire adapted from previous work on nursing ethics, included 19 dilemmas that were selected on the basis of their frequency in the normative pharmacy ethics literature, rather than from practice. A free response section was included for pharmacists to provide their own examples, but the study did not indicate whether this section was used. Despite quantitative studies being particularly suited to statistical analysis of variables such as the frequency of ethical dilemmas, the study by Haddad was the only one to investigate this. It was reported that 58% of pharmacist respondents had encountered an ethical problem in the last year but a third of pharmacists simply could not recall when they were last associated with an ethical dilemma.

Quantitative and qualitative approaches have traditionally been considered to occupy distinct and separate epistemological territory, with one privileged over the other. However, this review does not seek to perpetuate such a belief, but recognises that the choice of research approach should be determined by the type of question being asked. The quantitative studies identified in this review, for example, often focused on specific questions or sought to test hypotheses, whereas the qualitative studies are more concerned with understanding and exploring issues in depth or contextually. The chronological variation in research approach is nonetheless apparent and appears to have precluded study designs that triangulate and combine methods.³³ More recent research has tended to use qualitative approaches such as semistructured interviews or focus groups. In the earliest identified study of this type, by Hibbert *et al.*,¹⁹ the authors used interviews to identify and explore the types of dilemma encountered by community pharmacists and to gain an understanding of pharmacists' ethical awareness. The study found a diversity of ethical influences on pharmacists, including business values, ethical codes, organisational values and ethical reasoning, which corresponded to many ethical principles and also common sense. The qualitative studies identified often offered a complex pattern of ethical pharmacy practice. The study by Cooper, for example, found that a variety of dilemmas and approaches to ethical reasoning were apparent among pharmacists—evidenced often by intuitive reasoning and examples that corresponded to a model of ethical decision making that included identifying an ethical problem, using ethical reasoning and also making an ethical decision.³⁴ However, pharmacists' ability to resolve ethical problems varied and factors such as legal concerns, a sense of professional and ethical isolation and the commercial environment seemed to be inimical to developing ethical competency. As well as semistructured interview methods, some later qualitative studies adopted focus group methods, with the advantage of allowing data to be gathered quickly and easily, and using the interactive aspects common to focus group studies.

Ethical theory

In addition to methodological differences between the studies identified, many distinct theoretical approaches were also found in relation to ethics, of both a normative and a psychological kind. For example, although the study by Hibbert *et al.*¹⁹ sought to explore the diversity of ethical understanding, the subsequent analysis of interview data included a comparison of pharmacists' reasoning to only one particular, albeit popular, normative ethical theory. Other values were considered, but the theoretical basis for determining evidence of ethical understanding was based on the principles of biomedical ethics developed by Beauchamp and Childress.³⁵ The study identified examples of each principle—autonomy, beneficence, non-maleficence and justice—although the authors recognised the implied nature of such

inferences and noted that pharmacists did not mention these principles explicitly. The study offered no support for the assumption that the four-principles approach should be the approach for ethical judgement except by reference to secondary texts.³⁵ A similar approach was favoured by Chaar *et al.*,²⁸ who again, despite recognising the range of available ethical theories, gave primacy to the four principles. In our study, no evidence of justice or non-maleficence was found, but patients' best interests were identified as being influential. Although based on the principles of biomedical ethics, neither study considered one of the central aspects of the theory—the process of specification and balancing of the principles. As Beauchamp and Childress make clear in their work, it is not simply the recitation of the principles, *per se*, but rather the coherentist reasoning in selecting a principle in a particular healthcare situation that characterises their theory, in a manner similar to Rawls's³⁶ reflective equilibrium. Both studies found, however, that a range of value sets and common sense appeared to be ethically influential for pharmacists.

In contrast with the normative ethical four-principles theory used by Hibbert *et al.*,¹⁹ a psychological theory was used in the empirical pharmacy ethics studies by Dolinsky and Gottlieb¹¹ and also Latif¹³. This related to cognitive moral development (CMD), and these studies offer relatively detailed accounts of the theory, identifying the work of Piaget,³⁷ Kohlberg,³⁸ and Rest and Narvaez³⁹ in the theory's development. CMD is concerned with the progression of people through various mental stages of moral development over time, and Kohlberg identified three levels of moral development (and two substages of each level) relating to reasoning that could be distinguished as (1) pre-conventional and involving reasoning related to external punishment (stage one) or egoistic self-interest (stage two); (2) conventional and appealing to reasoning that considers our immediate peers (stage three) and then broader social implications and laws (stage four); (3) post-conventional and applying principled reasoning that recognises the social contract (stage five); and (4) universal ethical principles (stage six). The CMD theory has been used extensively in many healthcare settings, and is claimed to have validity in relation to predicting better clinical or professional behaviour.^{40–41} The attraction of the theory for empirical pharmacy research according to Latif¹³ is that CMD may be regarded as a conceptual tool or skill and that "...individuals with more advanced moral reasoning skills are often better able to make sense of and resolve difficult moral and social dilemmas" (p 167). However, Dolinsky and Gottlieb argue that CMD may also be useful in clarifying and developing moral understanding and that the authors use CMD in differing ways. For Dolinsky and Gottlieb, CMD is primarily an analytical tool, to ascribe developmental stages to the responses that pharmacy students provided about ethical dilemmas, in a similar way to that used by Kohlberg (who developed a moral judgement interview that required participants to provide reasoned but open responses to hypothetical questions that were subsequently stage coded); for Latif, the CMD theory is used in a psychometric form called the Defining Issues Test (DIT) developed by Rest.³⁹ Using a self-completion questionnaire format, Rest sought to make identifying moral reasoning both easier and faster to administer, and to provide less potential researcher bias by non-interpretative, pre-coded responses to the dilemmas posed. The DIT is manifestly quantitative in nature and often uses a calculation that assesses the percentage of principled responses chosen over six (but possibly three) hypothetical dilemmas—what is called the P% score. In contrast with Kohlberg's claim that people reason progressively higher, Rest allows for reasoning across stages, and is concerned with recognition and rating of pre-coded reasoning as opposed to Kohlberg's focus upon self-generated responses.

However, no mention is made of such theoretical differences by Latif.

The substantive content of Latif's work has been covered in some detail by Wingfield *et al.*⁷ but across several publications he uses CMD and specifically the DIT instrument to explore the community pharmacy environment and consider what may be responsible for what he describes as the relatively low levels of moral reasoning of practising pharmacists. Following this initial finding, many subsequent hypotheses were considered in further publications, including whether community pharmacists' level of moral reasoning would be, variously, positively correlated to their clinical skills, or related to owner or employee status and number of years practised. The study by Dolinsky and Gottlieb¹¹ appeared to offer evidence of principled, stage-six reasoning, although the lack of empirical data to support such a stage has raised concerns about this aspect of Kohlberg's theory.⁴² Latif does recognise several challenges to CMD, and in particular identifies Gilligan's criticism of Kohlberg's theory that justice-based reasoning neglects alternative moral approaches such as an ethics of care. Latif explored evidence of specific gender differences, and found that female pharmacists obtained "higher" DIT scores, although Gilligan⁴³ has subsequently argued that an ethics of care represents simply a different, and not necessarily female, voice. Latif also identifies several implications of CMD in his work: (1) an economic saving could be made if pharmacists develop more advanced moral reasoning skills; (2) that moral reasoning be tested in the pharmacist recruitment process of organisations; and (3) that litigation against pharmacists may decrease in relation to the level of moral reasoning.

Samples

Having identified methodological and theoretical differences in the empirical pharmacy ethics literature, another relevant theme was the types of respondents or samples used in the various studies. As table 1 indicates, differences in the samples relating to nationality and student cohorts are apparent. Many of the studies identified used American pharmacists and despite more recent studies including UK, Swedish and Australian pharmacists, there is under-representation in many areas of the world, which may limit the scope of our comprehension of empirical ethical issues across different healthcare systems and cultures. In addition, few studies focused specifically on the hospital pharmacy setting, and although Haddad¹² and Chaar *et al.*²⁸ sampled pharmacists from all areas of pharmacy practice, including academia, only the study by Kalvemark *et al.*²⁶ focused on the hospital environment. It was also the only study to include pharmacy dispensers and assistants.

More apparent was the use of student cohorts in the studies identified, either solely or in comparison with practising pharmacists. This may be explained by the fact that many studies set out to inform the teaching of ethics at the undergraduate level. Indeed, even studies that sought to explore practising pharmacists' understanding of ethics, such as the study by Hibbert *et al.*, also aimed to be of use in the undergraduate pharmacy curriculum (Hibbert D, personal communication, 2004). Although most studies valued the ethical views of students by virtue of their not being practising pharmacists, students in the study by Dolinsky and Gottlieb¹¹ appeared to be used as proxies in relation to ethical dilemmas. Students were asked to describe two dilemmas that included altruism and self-interest but these could be drawn from either first-person experience or what students recalled about the dilemmas of other pharmacists. The authors concede that "...the inferred reasons for actions probably tells us more about the pharmacy student doing the inferring than about the level of moral judgment of the pharmacist" (p 57). By contrast, and more transparently, the aim of the study by Wingfield *et al.* that included pharmacy students was simply to determine their

perceptions of pharmacy ethics, and they concluded that exposure to practice (as students progress through the four-year UK course) led to an increased awareness and understanding of ethical issues.²³ Despite the direct pedagogical aims of some studies, it may also be argued that student cohorts are used partly because they represent an easier research group to recruit and investigate, and are, in effect, a convenience sample. They are usually logistically, financially and temporally easier, as they may be closer to the researcher on campus, require less remuneration (if any) for participating, and also have perhaps more time to spare in comparison with practising pharmacists.

Dilemmas and themes

Having so far offered a critical review of the empirical ethics literature in pharmacy in terms of methodology, theory and sampling, the actual results of these studies and advances in knowledge that they have generated must not be ignored. What was evident from many of the studies was that the pharmacy environment seemed to be important in terms of shaping the types of ethical dilemmas or problems encountered and also relevant in terms of influencing the ethical reasoning of the pharmacist. This appeared to be especially important for community pharmacy, and Chaar *et al.* noted that problems occurred more often in the community setting than in other areas of pharmacy practice. Haddad similarly identified more ethical problems in the community setting but also found that actual work experience shaped pharmacists ethically. By contrast, Latif's work repeatedly suggested that the community pharmacy environment was detrimental to moral reasoning—pharmacists who had remained in practice longer tended to have lower moral reasoning scores and there were also some differences between scores for independent pharmacists and those who were employees; pharmacy students, who had not been exposed to the community pharmacy environment, also scored higher. However, the qualitative studies in this literature review provide a more complex picture of ethical influence. For example, Wingfield *et al.*²⁵ found that although business and commercial values led to ethical issues such as controlling profit and customer pressure, company and organisational policies were also helpful in terms of dealing with ethically problematic issues and in "guiding their thinking in difficult areas such as supply of emergency hormonal contraception". The pharmacists interviewed by Hibbert *et al.* appeared to be even more variously influenced—by self-interest, commercial and organisational values, and also legal concerns. The study also offered a considerable number of pharmacist-generated ethical concerns that provide a wealth of information about UK community pharmacy and that, for example, pharmacists often have to deal with patient representatives and encounter confidentiality issues; regulations relating to emergency supplies and controlled drugs lead to conflicts between benefiting the patient and complying with legal requirements; supplying syringes to addicts to prevent health risks must be balanced by a concern about theft from the pharmacy; and that the code of ethics was not often referred to. The study by Cooper identified similar concerns among UK pharmacists, along with additional commercial ethical dilemmas relating to charging for monitored dosage systems, branded medicine substitution, pressure to link-sell medicines, concern for customer poverty and selling confectionery. In the study by Kalvemark *et al.*,²⁶ Swedish pharmacists appeared to experience moral stress from issues that were related to time pressures in a hospital dispensary and to staff shortages. Similar concerns emerged in the study by Hibbert *et al.*, in that pharmacists expressed concern about challenging prescribing doctors because of the perception of professional hierarchy and also having to balance breaking a regulation to benefit a patient.

CONCLUSIONS

What conclusions may be drawn from this review of the empirical ethics literature in pharmacy? Apparently, this is still a relatively under-researched area of healthcare ethics and many questions remain unanswered. For example, it was reported that a third of pharmacists sampled in one study could not remember when they last encountered an ethical dilemma, but further research is needed to explore this finding, perhaps in relation to concepts such as ethical attention.⁴⁴ The dominance of CMD and the “four-principles” approach to ethical theory in the studies identified may be explained by their popularity, but do these adequately reflect how pharmacists make ethical decisions? The importance of other ethical theories such as narratives, virtue ethics and casuistry has been identified in relation to other healthcare professionals and may be relevant to pharmacy.⁴⁵ No systematic programme of research seems to have been attempted and this has meant that certain difficulties have emerged. For example, earlier quantitative studies encountered problems in relation to the selection of authentic dilemmas, whereas arguably the appropriate use of qualitative approaches may have identified ethical problems or dilemmas. As Cribb and Barber⁴⁶ conclude in relation to how research can facilitate the development of ethical understanding and values in pharmacy: “... it would be advisable to foster a coordinated programme of interdisciplinary research studies in the field. This would allow for the benefits of multiple perspectives while avoiding some of the problems of repetition or fragmentation.” The absence of a dedicated ethics journal for pharmacy (unlike many other healthcare professions) may be relevant, and is possibly detrimental to research and its effective dissemination and discussion. Moreover, the identification of several relevant, non-published studies indicates that attention should also be given to the “grey” literature to further inform understanding in pharmacy but also in healthcare ethics, more generally. Despite the recent use of qualitative approaches, no studies on ethnography or participant observation were identified. This may be compared with other areas of healthcare, where ethnographic research has increasingly been undertaken—to increase understanding in that area of healthcare generally but also allow ethical issues to be understood more clearly as the basis for normative study.^{47–49}

In relation to future studies, then, it is hoped that a new prescription can be written for empirical ethics research in pharmacy—one that encourages more research and also coordinates it and considers where a range of theoretical insights and research methods may be beneficial in exploring this under-researched discipline.

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