

Supporting family carers of older people in community pharmacy: a review of guidelines and qualitative study

FINAL REPORT

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Glossary and Abbreviations

Term/ Abbreviation	Meaning
BMA	British Medical Association
Carer	Unpaid for their caring role (except for carers' allowance); usually family carers
CCG	Clinical Commissioning Group
CPPE	Centre for Pharmacy Post Graduate Education
GMC	General Medical Council
GP	General Practitioner
GPhC	General Pharmaceutical Council
LPA	Lasting Power of Attorney
MEP	Medicines, Ethics and Practice guide - published annually by RPS
MUR	Medicines Use Review
NHS	National Health Service
NICE	National Institute of Clinical Excellence– officially linked to England only, but provides guidance and services to all the other UK home countries
NGO	Non-Governmental Organisation
NMS	New Medicines Service - a new advanced pharmacy service, specified and commissioned nationally (England & Wales)
OPG	Office of the Public Guardian
PCO	Primary Care Organisations
PRUK	Pharmacy Research UK
PSNC	Pharmaceutical Services Negotiating Committee
RPS	Royal Pharmaceutical Society– professional body for pharmacists in Great Britain

Background to the project

Little is understood regarding how health professionals interpret or apply their Codes of Ethics in observing their duty of care to patients, including respecting their autonomy, whilst attending to the needs of carers to enable them to be effective in their roles. From both a pharmacist's and carer's perspective, the pharmacist's role in providing advice and guidance for carers, including the context of the need for confidentiality and liaison with other providers, is unclear.

Increase in number of carers

The number of older people in the UK is rising with an increasing reliance on familial and social support. It is estimated that 23% of the UK population will be older than 65 years in 2035 (ONS, 2012). The 2011 census analysis in relation to *2011 Provision of Unpaid Care in England and Wales* report stated that the number of unpaid carers for the sick, disabled and increasingly elderly in England and Wales had grown by 600,000 since 2001 to reach approximately 5.8 million (ONS, 2013). Today the figure stands at 6.5 million, or 1 in 8 people, which saves £119 billion per year¹ (*Valuing Carers: Carers UK, 2011*). This number is predicted to rise to 9 million by 2037 (*Facts about Carers, Carers UK 2014*).

There is a growing recognition from the Government of the valuable role that carers play and the need to provide appropriate information and support to enable them to be effective. The Government's first National Strategy for Carers (*Caring about Carers, Department of Health, 1999*) focused on 3 components: *information* for carers (with regard to health, carer and Government information); *support* for carers (carers should be involved in planning and providing services); and *care* for carers (carers' right to have their own health needs met and to have services provided for them, including having a break).

The national carers' strategy, *Carers at the heart of 21st century families and communities* (Department of Health, 2008), stated that "by 2018 carers will be respected as expert care partners and will have access to the integrated and personalised services they need to support them in their caring role" (pg. 16). The policy paper, *Recognised, Valued and Supported: Next Steps for the Carer's Strategy* (Department of Health, 2010) identifies support and involvement for carers as priority areas. Similar developments are evident within the National Health System. The NHS (2014) *Five Year Forward View* sets out a vision and a direction for the NHS. Its purpose is to consider why change is needed, what success might look like, and how it can be achieved. The document raises a range of issues that are relevant to carers, including: what tangible steps can be taken to support carers and volunteers? It recognises that, with an ageing population, increased long-term conditions, and health funding that is not keeping pace with demand, carers have a crucial role to play in the future of the NHS.

Medication-related roles of carers

Previous studies (Travis et al., 2000; Smith et al., 2003; Francis et al., 2006; Knight et al., 2011) have identified the wide range of medicines-related activities that carers may undertake. These may include monitoring supplies and ordering repeat prescriptions, assisting with administration of many different products, being in attendance for frequent dosing schedules, making clinical judgements and communicating with care recipients and healthcare professionals. Carers may provide support with any stage of the medication management process (Goldstein et al., 1996). Some accept full responsibility for medication management and will provide practical assistance with ordering,

¹ Carers UK website <http://www.carersuk.org/about-us/why-we-re-here>

obtaining, administering and monitoring medication, whilst other care recipients do not require such level of support. Carers may also consider the need for different medicines; they may have concerns and make judgements regarding effectiveness or side-effects and, in this regard, they often have limited access to information and advice. Providing carers with information was one of 3 strategic components of the Government's first National Strategy for Carers (*Caring about Carers*, 1999):

Carers need good information on the health needs and treatment of the person they are caring for – especially on medication: when to take it, and recognising any side effects arising from it... (Chapter 4, para 15).

In a cross-sectional survey in 4 areas of England, 67% of carers reported problems with at least one medication-related activity, such as ordering and collecting prescriptions, administration of medicines, opening containers, noticing side effects etc. Problems were associated with all medication-related activities, and experienced by carers providing different levels of care for older people (Smith et al, 2003). Carers reporting greater numbers of medication-related problems were more likely to experience higher levels of carer strain and poorer mental health status. A narrative review by Gillespie et al. (2014) examined the role of informal caregivers as they manage medications for older adults and/or people living with dementia residing in the community and found that this role is complex and can be made more difficult due to increasing medication regimen complexities, aspects of the relationship between the caregiver and the care recipient, healthcare system practices and a lack of information and/or training available to the informal caregiver.

However, a range of moral and legal tensions arise when health professionals are expected to attend to the needs of carers and to facilitate the important role that they play, while at the same time meeting their duties of care to patients. For example, how can a pharmacist respect patient autonomy and confidentiality in the context of providing medication information to a carer?

Unique role of pharmacists

There are about 12,000 community pharmacies in the UK ranging from small independents to pharmacy chains. Pharmacies are typically based in geographically accessible locations and, unlike GPs and other health professionals, are usually available for consultation without appointment. Therefore, many opportunities exist for pharmacists to interact with carers. Pharmacists are unique amongst health professionals in the extent to which they dispense medicines to and advise patients through carers, especially in the case of older patients. Collection of medicines from a pharmacy by carers, which is commonplace and particular to pharmacy, presents opportunities for both pharmacists and carers to discuss concerns to ensure optimal outcomes for patients. At any one time a community pharmacist is likely to be looking after and providing medicines for 600 carers².

The UK Government is committed to expanding the role of pharmacists to become more patient-centred, promoting the development of services to support medicines optimisation (NICE, 2015). In recent years, pharmacists have been developing more clinical services and having a greater involvement in public health and promotion of healthy lifestyles. This has led to better integration and team working with the rest of the NHS. Policy directions such as the *Pharmacy in the future: implementing the NHS Plan* (Department of Health, 2000) describe roles for community pharmacists in prescribing and the provision of prescribing advice, in assuming accountability for therapeutic outcomes and in contributing to patient care decisions within multidisciplinary healthcare teams. The advent of non-medical prescribing has allowed pharmacists to work more closely with GPs and

² *Understanding and Making the Best Use of Community Pharmacy* South East Local Pharmaceutical Committee Forum in conjunction with PSNC and NPA

other health care professionals. Services such as Medicines Use Review (MUR) and the New Medicines Service (NMS) have been significant developments in providing frameworks for patient-centred support. However, MURs and the NMS cannot be conducted with carers unless the patient is also present; and currently community pharmacists do not have access to patient notes or key information about a patient's overall healthcare.

The expanding role, and commitment to patient care for pharmacists, has resulted in increased independent responsibility and accountability due to increased expectations of the patient, with a resultant exposure to ethical and moral issues (Chaar et al., 2005). Where previously consent/capacity issues were not so prominent, health professionals might now become more aware and perhaps more risk averse.

Changing perception of patient autonomy

Patient autonomy is well established as a central guiding value in medicine. It is an evolving concept that has implications for the relationship between carers and those they care for, as well as for the relationship between health professionals, patients and their carers. The requirement to respect patient autonomy has traditionally been understood to mean adopting a non-interference stance, often operationalised in an informed consent model. Patients make their own decisions, with professionals taking on a largely information-providing role. However, increasingly, it is understood that others, including carers and medical professionals, have a positive role to play in *facilitating* autonomy. The notion of supported decision-making is often understood as a way of enabling autonomy, and it is a central focus of current debates concerning mental capacity (Richardson (2012); Bartlett (2013); Craigie (2015); Cribb & Entwistle (2011)).

Research question, aim and objectives

Research question: In the context of current legal and ethical frameworks how can pharmacy services more clearly and effectively meet the medicines-related needs of carers?

Aim: to improve understanding of the current and potential role of pharmacy services in supporting carers of older people.

Objectives:

1. To review and analyse current legal and ethical guidelines in England and Wales that underpin the practice of pharmacists when supporting older people with carers,
2. To determine perspectives of pharmacists and selected health/social care professionals on interpretation of legal and ethical guidelines in terms of supporting carers,
3. To obtain carers' understanding and experience of the role of pharmacy and other services in assisting them in medication-related activities,
4. To suggest ways in which the ethical and legal responsibilities of pharmacists in relation to carers could be clarified for both carers and pharmacists.
5. To inform policy and guidelines on the role of pharmacists in supporting carers, including identifying gaps in both.

Methods

Overview

The study comprised two stages. The first was a review and analysis of legal and ethical documents and guidelines relevant to the practice of pharmacists when supporting carers of older people, some of whom lack mental capacity, in the use of their medicines (objective 1). It incorporated a review of the literature, including published research, identifying interpretations and application in pharmacy and other settings regarding support for carers who assist older people with medicines. Stage 2 (objectives 2 and 3) was a qualitative research study with carers, pharmacists and other health and social care professionals, in which data were collected in semi-structured, face-to-face, 1:1 interviews. Qualitative analytical procedures were employed. Findings from the two stages were combined to achieve objectives 4 and 5.

Stage 1: Review of relevant legal and ethical guidelines/frameworks and the literature

Search strategies

Papers were identified in a systematic way (see search strategy), summarised and tabulated in the first instance by LJ and these were circulated to FS, JC, RON and SJLE. Papers were included if they informed (directly or indirectly, explicitly and expressly or not) the issue of ethics and the relationship between pharmacists and carers. They were drawn from different disciplines of general law, pharmacy law, bioethics, and social science.

The relevant legal instruments for pharmacists were identified and analysed along with their associated regulations and Codes of Practice.

Guidance from Non Governmental Organisations (NGOs), Alzheimer's Society, Carers' organisations and other professional and stakeholder organisations were also identified and searched. A search was also undertaken for references to 'carers' in key websites of official pharmacy or health bodies (e.g. Royal Pharmaceutical Society, General Pharmaceutical Council, Department of Health).

Relevant case law through BAILII (British and Irish Legal Information Institute) <http://www.bailii.org/> and the Court of Protection, where available, was also identified. Academic legal commentary on these instruments and cases was sought in all the leading health law journals.

Google Scholar and a wide range of legal and health data-bases and medico-legal and ethics journals including Lexis Library (Westlaw UK) and PubMed DARE, CINAHL, EMBASE and Web of Science were searched using English terms such as 'carer' OR 'informal carer' AND 'pharmacy' OR 'pharmacists' AND 'ethics' OR 'supported decision making' OR 'confidentiality'. No time limit in publication type was employed. Studies considered eligible for inclusion were those that reported primary research using qualitative, quantitative and mixed methods published in peer reviewed journals. PhDs were also included. Citations were also followed via reference lists. The majority of the research papers related to work undertaken in Australia, America or the UK.

Process of the review

Organisation of retrieved material was supported by NVivo computer software, which is designed for document analysis. The documents were read by LJ and searched for references to 'carers' and relevant material was extracted. All other members of the team independently reviewed extracted material regarding particular themes according to their expertise: pharmacy (FS and RON), law

(RON), and bioethics (JC and SJLE). Following a discussion of the initial results within the team, documents were analysed regarding the responsibilities of pharmacists in relation to patients, carers and finally within a 'triangle' of care (pharmacist, carer, patient). Findings from published empirical research were incorporated as part of the overall text and included where relevant to the point. This was not a systematic analysis of the findings of empirical research, which would not have been possible given the heterogeneity of research questions, designs and populations involved. However it enabled identification of issues rather than fully generalizable results.

The review includes statutes, case law, documents regarding pharmacists' professional standards and codes of ethics, and qualitative and quantitative research. Thus, a synthesis of material from different sources was achieved across relevant legal and ethical documents and guidelines. The legislation referred to is that of the United Kingdom (UK). The UK consists of three legal jurisdictions made up of four countries: (a) England and Wales, (b) Scotland, (c) Northern Ireland, each having their own court system and legal profession. Since 1997 legislative decision-making for some areas of government has been devolved to the separate jurisdictions creating a national Parliament in Scotland, a national Assembly in Wales and a national Assembly in Northern Ireland. Hence, NHS regulations may vary and this Review does not specifically cover these differences. There are still certain areas which are governed centrally through the main UK Parliament and this review focuses on those areas. However there are some differences in the geographical coverage of the standards issued by the regulating/ professional bodies as below:

- General Pharmaceutical Council /Royal Pharmaceutical Society: Great Britain
- General Medical Council /British Medical Association: United Kingdom
- Nursing & Midwifery Council: United Kingdom
- Health & Care Professions Council: United Kingdom (Social Workers in England from 2012 only)

Stage 2: Interviews with carers, pharmacists and other health/social care professionals

Design

Stage 2 (data for objectives 2 and 3) were obtained from in-depth, semi-structured interviews with carers, pharmacists and other health/social care professionals.

Qualitative interview methods are designed to identify the perspectives, meanings and issues that are important to the people being studied. The aim of the interviews was to obtain carers' understanding and experience of the role of pharmacy and other services in assisting them in medication-related activities and to determine the perspectives of pharmacists (all sectors) and health/social care professionals (e.g. GPs, community nurses, support workers) on interpretation of the legal and ethical guidelines that underpin their practice when supporting older people with carers.

Ethics

The Proportionate Review Sub-committee of the NRES Committee South Central - Oxford C reviewed and approved the study on 06 August 2014 (reference number 14/SC/1172). One substantial amendment was applied for, and granted, in relation to enabling an interview with one health professional to be conducted by telephone (and offered to other participants).

Sampling and recruitment

Geographical locations of the study

The study took place in two broad geographical areas: an inner city London area and a rural/suburban county (Surrey). Whilst it was not intended to be a comparative study, the inclusion of two locations enabled involvement of carers and health/social care professionals from areas where there was potential diversity in service provision (e.g. accessibility of services, types/numbers of pharmacies, pharmacists, staff turnover), setting and socio-economic and/or cultural factors, some or all of which may be relevant to carers' experiences.

Carers

Within each location, carers were initially recruited through carers' support centres and community pharmacies. Carers attending a carers' centre are more likely to be those people who assume fairly extensive caring responsibilities; many other people may provide more limited assistance with medicines for an older person, but not necessarily self-identify as a carer. Such individuals, also deemed important to our study, are likely to be known to community pharmacists. In the latter stages of data collection, to increase participation, we revised our recruitment strategy to include other organisations, e.g. Age UK and Alzheimer's Society. Thus, there was inevitably some self-selection of participants, but in our strategy and process, steps were taken to recruit carers from different locations and settings to promote diversity in the sample.

To enable us to meet the study objective, the eligibility criteria for carers were as follows:

- providing varying degrees of medicines-related assistance for an older person over 60 years old (some of whom will have a cognitive impairment) on regular medicines;
- unpaid (aside from a carers' allowance) for the assistance they provide;
- either living with or having at least weekly face-to-face contact with the person they assist.

Letters of invitation and information leaflets, prepared by the research team, were distributed to carers from the carers' centres (either at support meetings with the researcher present or by the support workers) and community pharmacies (the pharmacist identified and approached potential participants). Carers who indicated their willingness to take part were contacted regarding arrangements for interview.

Health/social care professionals

Health/social care professionals were purposively sampled to include representation of groups who may have some responsibility regarding the use of medicines by older people and/or be in a position to provide information, advice or support to carers regarding the use of medicines. Health/social care professionals in each of the areas were identified and letters of invitation and information leaflets were forwarded. An interview was arranged at the healthcare professional's convenience once they expressed a willingness to take part.

Sample size

As is usual in qualitative studies, our goal was to sample to saturation. Our original plan was to collect data in group interviews with carers, with the option of 1:1 interviews if preferred, and to achieve data saturation. We estimated up to 60 interviews in total. However, at the start of the study, we were advised that carers had been inundated with requests to participate in focus groups and to recruit carers for 1:1 interviews. Whilst the numbers were inevitably smaller (30 interviews)

this enabled more in-depth discussion with each participant, a potentially larger data set and the achievement of data saturation.

Data collection and instruments

Instruments (interview schedules) were developed for both the interviews with carers, and with health/social care professionals. These were refined according to the findings of the review and preliminary discussions with members of the project team, and following early fieldwork. An iterative approach to data collection and analysis was employed in which preliminary analysis of early interviews was undertaken and used to review and refine the instruments so that further data collection could be designed to ensure detailed data were obtained on all issues relevant to participants. In accordance with principles of qualitative enquiry, interview schedules were comprised mainly of open questions to provide an opportunity for respondents to provide their own perspectives and accounts. The researcher was trained in principles of qualitative enquiry and the conduct of such interviews to ensure a robust and scientific approach.

Data collected in the interviews included carers' understanding and experiences of pharmacy services in relation to the medicines-related activities that they undertake, problems they had experienced and how/if these had been resolved or addressed. The interviews examined carers' experiences of pharmacy services, in the context of the length of time in the caring role and whether this role extended to having a full Power of Attorney (which could either relate to property and finances and/or personal care and welfare). Topics included seeking/obtaining information and support, the place of pharmacists in the health care team, particular problems encountered that gave rise to ethical issues (e.g. wellbeing vs. respect for autonomy and where to seek advice), and any approaches or strategies they used when they encountered these difficulties.

The data collection instruments for the semi-structured interview schedules for health/social care professionals was similarly informed by the review and refined after the first few interviews. Whilst the structure and domains of all interview schedules was similar, interview schedules were tailored for each health/social care professional group to ensure relevance. They comprised mainly open questions to enable participants to provide their own experiences and views. A similar thematic framework was employed to examine health/social care professionals' perspectives regarding providing information for, and supporting, carers in their medicines-related roles and potential difficulties which they encountered, which may give rise to ethical issues. Health/social care professionals' experiences were explored, including awareness and use of guidance and its perceived usefulness; interpretation; how capacity and best interests are interpreted; pharmacists' knowledge and understanding of capacity decisions and its assessment and/or reliance on carers.

Interviews were conducted at a location convenient for the respondent (commonly a carer's home, or place of work of a healthcare professional). Written consent was obtained prior to the start of the interview from the carer or health/social care professional. All participants were informed that the information they gave would be treated as confidential; only the research team would have access to individual data. They were assured that any data used would be presented in such a way that individuals were not identifiable. With the permission of respondents, interviews were audio-recorded for later transcription. However, the researcher was prepared to take detailed hand notes should any respondent not wish the interview to be recorded. Field notes were written immediately after the interview, to foster reflection and self-reflection, aid the first stages of analysis and to maximise the comparability between interviews.

It was anticipated that all individual interviews (both of carers and health/social care professionals) would be between 30 and 45 minutes duration. Carers and health and social care professionals were each offered a £10 gift voucher as a 'thank you' and compensation for time given up for this study.

Data processing and analysis

Digital recordings from each interview were transcribed verbatim by a professional transcribing service with participant consent and anonymised by the researcher conducting the interview (LJ) as soon as possible after conducting the interviews. Data was entered into NVivo software (QSR International (UK) Limited, Southport, UK), a data management and analysis programme to enable the application of qualitative analytical procedures which employed a system of coding and memoing developed by Lofland and Lofland (1995). The development of the coding frame was discussed with the study team.

Transcripts and field notes were read and coded independently by LJ. FS read all the transcripts and a sample were also coded by FS to ensure reliability. A themed approach was adopted based on the theoretical frameworks that underpinned the interview schedules and the experiences and perspectives of carers and health/social care professionals from the interviews. First, the key topics and issues that emerged from the data were identified through familiarisation with transcripts. Pertinent excerpts that illustrated emerging themes were coded and memos written to summarise and synthesise these emerging themes and sub-themes. In particular, an iterative approach using constant comparison was employed in the development of coding frames and coding of data. Constant comparison involves the continual appraisal of items in the data set to identify and explain differences and similarities in the experiences and perspectives of different groups or participants. These differing perspectives can also be examined in context to highlight how relevant legal and ethical frameworks underpin practice.

The final stage involved an integration of the results of the review and interview data in order to identify the key findings and implications for pharmacy practice.

Results - Stage 1: Review of relevant legal and ethical guidelines/frameworks and the literature

This section commences with a discussion regarding the variability in the definition of carer that was found across various documents. It then presents an overview of the professional responsibilities and accountability of pharmacists to patients, carers, and in relation to a 'triangle' of care between the pharmacist, patient and carer.

1. How are carers defined?

There is no single definition of 'carer'. The law refers to carers in many contexts (Clements, 2012). However, our review found that 'carer' is commonly used to describe a person who gives significant amounts of help over long periods of time to a relative, friend or neighbour who is ill or disabled; a role which eases the financial burden on health and social care services. What caring involves will vary according to the needs of the care recipient. Caring can mean anything from being someone to talk to, to helping with shopping, collecting prescriptions and other errands, giving medication, and helping with other healthcare tasks and activities (Macmillan Cancer Support). The emphasis, therefore, is on the widespread nature of caring. The term 'informal carer' is used less frequently to describe this kind of role.

Carers UK argue for the term 'carer' to be used only in connection with unpaid carers as opposed to paid workers in health and social services. They argue that people confuse carers with those who are paid employees in social care, so carers fail to recognise themselves as carers. Research by Carers UK (*In the Know, 2006*) found that two thirds of carers take more than a year to identify themselves as a carer and over a quarter took between one and five years. Also, many carers dislike the term 'informal carer'.

Carers' organisations favour inclusive definitions. The NGO definitions are widely used and many primary care organisations (PCOs) and other charities use some form of definition in their documentation. However, in legislation and guidance concerning eligibility for services, the definition is narrowed significantly. The *Carers' Acts* previously defined a carer by reference to caring for someone who may be entitled to services under the community care legislation or the Children Act 1989. The terms 'substantial' and 'regular' were found frequently in policies and each of the previous Carers' Acts (Lloyd, 2006). 'Regular' refers to help provided at fixed intervals (Clements, 2012). Some carers did not recognise that the 'regular and substantial' support they provide (or intend to provide) entitled them to 'carers' rights'. Equally there are service users who do not recognise their carers as such. There was no statutory definition as to what was meant by 'substantial' and the decision rested with individual social services departments which had to take the relevant guidance into account (Clements, 2012).

Carers and Disabled Children Act 2000 and the Carers (Equal Opportunities) Act, 2004

- carers who provide or intend to provide a substantial amount of care on a regular basis for another individual aged 18 or over;
- people with parental responsibility for a disabled child who provide or intend to provide a substantial amount of care on a regular basis for the child.

Carers (Recognition and Services) Act 1995 Act

- an adult who provides or intends to provide a substantial amount of care on a regular basis;
- a child or young person under 18 who provides or intends to provide a substantial amount of care on a regular basis;
- a parent who provides or intends to provide a substantial amount of care on a regular basis for a disabled child.

The **Care Act 2014** came into force in April 2015 and simplified, consolidated and improved existing legislation for *adult* social care in England into a single framework, and introduced reforms to the way care and support is accessed and funded. The Care Act 2014 removed the requirement for the carer to be providing substantial care on a regular basis.

...an adult who provides or intends to provide care for another adult

How carers are defined is of particular importance to this study and has important implications for pharmacists when supporting them in their roles. Many people who provide assistance with medicines for a family member, may not view themselves as a carer. However, even in situations when the help provided appears limited, this may be vital in terms of ensuring an individual has access to their medicines or is able to use them effectively. Thus, this more inclusive definition of the Care Act 2014 is reflective of the circumstances of many people who provide assistance for an older person with their medicines, and for whom the findings of this research will be relevant.

2. Responsibility and accountability of pharmacists

According to the Department of Health (2010) *Responsibility and Accountability Moving on for New Ways of Working to a creative, capable workforce best practice guidance*, responsibility (for

something) can be defined as a set of tasks or functions that an employer, professional body, court of law or some other body can legitimately demand. Accountability (answerability) describes the relationship between practitioner and organisation. It is the mechanism by which failure to exercise responsibility may lead to sanctions such as warnings, disciplining, suspension, criminal prosecution, or deregistration from professional status. Employee responsibilities are defined by a contract of employment, which includes a job description. Professional responsibilities are defined by a duty of care to users and professional codes of conduct. Legal responsibility (defined by statutes and common law) is part of professional responsibility and it is an obligation to comply with the law. The law holds individuals accountable for their actions/omissions through the law of tort, which falls within civil law. This could result in an action or suit for professional negligence which involves three legal principles: the professional owed a duty of care to the client; there was a breach of that duty of care (by an act or a failure to act) and this caused harm to the client. For the individual pharmacist, clinical governance has led to new accountabilities, particularly to NHS employers and also to local public authorities and to patient groups.

Clinical governance is the system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which clinical excellence can flourish. (Sally and Donaldson 1998, p.61)

Ethics can be appealed to as a source of constraints on (or guidance for) behaviour, which is independent of law and policy. Ideally, ethics, law and policy will coincide, but when it does not, ethics can be used to critique law and policy. Ethics in the form of a code of ethics can also be used to shape behaviour in areas where it may not be appropriate to apply legal sanctions.

Codes of professional ethics set out a set of rules and standards of conduct expected within a particular professional setting. The General Pharmaceutical Council (GPhC), which replaced the Royal Pharmaceutical Society of Great Britain in 2010, is the independent regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain. It sets core *regulatory* standards of conduct, ethics and performance that all pharmacy professionals must follow even if a person does not treat, care or interact with patients and the public. The Code of Ethics is public so that health workers and the public (including carers) know what to expect from pharmacists. These regulatory standards must be followed to practise safely and effectively and failure to comply with these standards could put registration at risk. GPhC standards are outcome focussed and are not prescriptive or detailed to enable professionals to make decisions about how best to meet the standards in a particular situation. The guidance acknowledges potential conflicting responsibilities (but does not specifically state that this could be in terms of supporting carers) and advises that pharmacists use their professional judgment when deciding what is in the patient's best interests.

The **GPhC's Standards of conduct, ethics and performance (2012)** sets out seven guiding principles for pharmacists:

1. *Make patients your first concern;*
2. *Use your professional judgement in the interests of patients and the public;*
3. *Show respect for others;*
4. *Encourage patients and the public to participate in decisions about their care;*
5. *Develop your professional knowledge and competence;*
6. *Be honest and trustworthy;*
7. *Take responsibility for your working practices.*

In terms of meeting the standards, the GPhC guidance states (the text in blue is our emphasis of relevant points):

“We do not dictate how you should meet our standards. Each standard can normally be met in more than one way and the way in which you meet our standards may change over time. The standards are of equal importance. You are professionally accountable for your practice. This means that you are responsible for what you do or do not do, no matter what advice or direction your manager or another professional gives you. You must use your professional judgement when deciding on a course of action and you should use our standards as a basis when making those decisions. You may be faced with conflicting professional or legal responsibilities. In these circumstances you must consider all possible courses of action and the risks and benefits associated with each one to decide what is in the best interests of patients and the public”.

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists. Its primary objective is to lead and develop the pharmacy profession. The RPS provides professional standards which are developed and owned by the profession that describe good practice, systems of care or working. Professional standards support pharmacists and their teams as part of the continuous process of professional development. The RPS does not inspect or mandate the use of their professional standards.

Other organisations regulate different professional groups, for example, the General Medical Council (GMC) protects, promotes and maintains the health and safety of the public by making sure that doctors follow proper standards of medical practice and The British Medical Association (BMA) represents and protects the interests of doctors. The Health and Care Professions Council regulates a range of other health and care professions³.

A joint statement by the GPhC and RPS *Using standards and guidance to ensure patient centred professionalism in the delivery of care* (July 2014) states that patient-centred care should be at the heart of everything that pharmacists and pharmacy teams do. Pharmacists have a duty of care to patients, to put them first, and to aid them in their decision-making they should consider what is in the best interests of the patient, be guided by their education and training and CPD, know and use the standards and guidance (both regulatory and professional) that are relevant and understand the legal framework in which they are operating. Depending on the environment that pharmacists work in, there may be additional sources of standards and guidance that pharmacists need to take into account, e.g. from the Medicines and Healthcare Products Regulatory Agency (MHRA), Care Quality Commission (CQC) and other organisations.

Knowledge of Pharmacy Code of Ethics

The research literature shows that the pharmacy Code of Ethics is not referred to by staff nor do they have detailed knowledge of it. Few of the seven community pharmacists interviewed in a study by Hibbert et al. (2000) claimed to consult the Code of Ethics (then under the Royal Pharmaceutical Society of Great Britain) or to know it in any detail. However, the study found that a range of values influenced pharmacists and practical strategies relating to ethical understanding were more common than reference to the Code of Ethics. They showed appreciation of autonomy and beneficence. Chaar et al. (2005) in Australia also found from interviews with pharmacists that they relied on common sense and never referred to their professional Code of Ethics. The majority practised within a theoretical framework of the “best interests of the patient”. Most pharmacists remembered being taught law but little ethics or, for older pharmacists, no ethics whatsoever

³ Arts therapists, biomedical scientists, chiropodists/podiatrists, clinical scientists, dietitians, hearing aid dispensers, occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, practitioner psychologists, prosthetists / orthotists, radiographers, social workers in England and speech and language therapists.

(Cooper et al., 2007a). A French study (Auguste et al., 1997) found from interviews with 15 hospital pharmacists that, in their undergraduate studies, they had received no training in biomedical ethics.

An examination of pharmacists' understanding of some key ethical concepts was undertaken by Deans for a PhD in 2008. This demonstrated the complexity of the ethical problems pharmacists face. Pharmacists understand ethics as being a mixture of personal opinion, peer consensus, cultural influence and institutional rules. Pharmacists take a 'patchwork' approach to ethics, relying on common sense, guidance, strict rules, professional obligations and professional autonomy. One of the strongest themes that emerged was the prominence of institutional rules, and a concern for the interests of the patient. Deans also found barriers that limit pharmacists from discussing ethical issues with patients and this included a lack of knowledge on ethics issues (Deans, 2010).

In a postal survey of ethical issues surrounding supply of information to the public by hospital medicines information pharmacists in the UK (Wills et al, 2002), 54% had neither received nor delivered training on ethical issues and there was a lack of local and national guidelines on dealing with ethical issues. Six factors were identified which pharmacists took into account when attempting to resolve dilemmas. It is the conflict between two or more of these that causes uncertainty for a pharmacist: *freedom of information (that all MI data is in the public domain and should be produced and evaluated on request because patients have a "right" to it: a liberal approach)*, *personal privacy*, *paternalism (to supply information only in the best interests of the patient, which may be via the patient's doctor: a conservative approach)*, *loyalty to the employer*, *professional loyalty and legality*. In terms of a Code of Ethics, Wills et al. (2002) suggest that clinical, moral and legal considerations should be encompassed by a protocol for dealing with public enquiries.

Values of pharmacists

Benson et al. (2009) sought to identify the values drawn on by 38 UK pharmacists (hospital, community and other) through interviews about day-to-day practice activities focused around their conceptions of 'the good pharmacist', good practice and their experiences of ethical issues and dilemmas. Two core values emerged: 'the patient's best interests' and a value labelled as 'respect for medicines'. The law provides constraints on action, but these can compete with core professional values around responsibility for a patient's best interests. Pharmacy practitioners routinely face competing obligations to different parties which can conflict, creating ethical dilemmas and calling on professional judgement and decision making skills. For example, there may be competing obligations to a patient and to the commercial needs of an employer, or between professional and patient values to promote autonomy and ethical concerns such as judging a patient's mental capacity. There was a tendency for practitioners to fall back on their own personal value judgements when addressing these dilemmas. They found little evidence of self-conscious reflection on values or extended deliberation about dilemmas.

3. Legal and ethical responsibilities of pharmacists in relation to patients and carers

Our review has identified responsibilities from three sources, all associated with the community pharmacists' professional role:

- responsibilities flowing from patients' 'rights';
- responsibilities flowing from carers' 'rights'; and
- responsibilities that are not easily explained in terms of either patients' rights or carers' rights, but rather seem to be grounded in the pharmacists' duties of beneficence (to promote well-being) and non-maleficence (to avoid harm) as a health-care professional.

Problems may arise within a triangle of care when a pharmacist finds that these responsibilities are in tension. A patient's carer may ask what a medicine is for, when presenting the patient's prescription. If the principles of patient autonomy and confidentiality are to be respected and maintained, then it seems the pharmacist must refuse to tell the carer. But by so doing they might cause harm to the patient, especially if the carer is in charge of the patient's medicines. Here the principle of non-maleficence competes with a respect for patient autonomy.

The carers themselves also experience ethical dilemmas. A qualitative pilot study with 10 carers in a general medical practice by Hughes et al. (2002) found that dilemmas faced by carers may arise from a personal context and are shaped by long-term relationships. In terms of areas affecting actions and decisions by others (including professionals) these included factors like confidentiality and need for information. Areas affecting actions and decisions of both carers and professionals included consent and safe use of medicines. When talking about 'best interests' two interviewees felt that the best interests of the person with dementia were the concern of the carer. Two spoke of their own best interests and two made the point that their best interests were entwined with those of the person with dementia. These different personal perspectives on the notion of best interests illustrate the complexity of these issues, and they reflect the debates in academic literature (Herring, 2013).

3.1 Pharmacists' responsibilities corresponding to patients' 'rights':

3.1.1 Pharmacists' responsibility to protect patient information and to obtain consent for disclosure of patient information

Confidentiality is an essential requirement for trust between patients and health professionals. It is a legal duty that is derived from case law and supplemented by statute. However, the BMA confidentiality toolkit (1999) notes that the ethical, professional, contractual and legal positions on confidentiality are complex. It states that the legal responsibilities in respect of confidential information cannot be gleaned from common law (based on previous judgments in court) and statute alone, and health professionals must look at the overall effect of the law. The duty to preserve confidentiality can present health professionals with an ethical or legal dilemma, commonly when a third party, such as a carer, requests information about patients or their treatment. Information provided in confidence should not be used or disclosed in a form that might identify a patient without his/her consent as required by common law. Importantly, information does not have to be disclosed or provided in order to be protected; information that is simply observed or discovered also attracts the duty of confidentiality.

Confidentiality of patient information is a requirement of employment under NHS and many independent sector contracts. All staff employed by or contracted to the NHS may be disciplined following a breach of patient confidentiality. The Data Protection Act 1998 regulates the processing of information about living individuals, such as obtaining, use or disclosure of information. Statutory rights of access are contained within the Access to Health Records Act 1990 and Access to Health Records (Northern Ireland) Order 1993. Under the Computer Misuse Act 1990 it is an offence to gain unauthorised access to computer material. The NHS Care Record Guarantee emphasises the commitment of the NHS in England to the confidentiality and security of patient information.

However, the duty of confidence is not absolute. There are situations where it is legal and ethical to breach confidentiality, e.g. if personal information is required by law, the patient consents, or it is justified in the public interest (for example, certain notifiable diseases, national security or as part of a criminal investigation). In England and Wales, Section 251 of the NHS Act 2006 gives the Secretary

of State for Health power to make regulations permitting the disclosure of identifiable information without consent in certain circumstances.

The Data Protection Act 1998 lays out the patient's right to control the processing of (includes third party access to and use of) their personal data. Currently, people are given a period of time within which they are lawfully able to object to processing of their personal data. However, these laws concerning how people can control their personal data are under revision at a European level Directive and it is proposed that the conditions under which data subjects can control their data be restricted to expressed and specific consent.

There is no English statute setting out the general principles of consent to sharing data. In practice, and the professional guidance for pharmacists does not distinguish, consent may be explicit or implied. Hird's (2003) paper discusses how aspects of consent impact on pharmacy practice. The subject of consent is vast and limited with statute, case law, ethical principles and professional guidance. Consent is permission to proceed with a particular course of action and the principle reflects the right of patients to determine what happens to their own bodies. It is an on-going shared decision making process. If we refer to The Department of Health (2001) guidance 12 Key Points on Consent: the Law in England, then technically all pharmacists' patient care activities require consent to be given. For most of these consent is implied, e.g. handing in a prescription or asking for advice over the counter. At present there is little professional guidance for pharmacists on how to obtain consent.

GPhC's Standards of conduct, ethics and performance (2012)

(we have highlighted the relevant part in blue text)

3. Show respect for others

*3.5 Respect and protect people's dignity and privacy. Take all reasonable steps to prevent accidental disclosure or unauthorised access to confidential information. **Never disclose confidential information without consent unless required to do so by the law or in exceptional circumstances***

3.6 Get consent for the professional services you provide and the patient information you use

Consent may be specific to certain information or to certain people (for example, carers). In either case consent should be informed and freely given. Explicit consent is when a patient actively agrees, either orally or in writing, to disclosure of information. Patient agreement can be implied by the behaviour of an informed patient. There are three legal tests for consent: was the patient capable of giving consent ("having capacity"); was the patient under pressure or incentive to give consent and was the patient fully informed before taking the decision to consent? In order for it to be valid it is important that patients are made aware that information about them will be shared, with whom it will be shared, and of their right to refuse. In the majority of cases where a patient has a carer, the patient would be very happy for their carer to know as much as they do. *The Patient's Charter* (Department of Health, 1992) included a standard to ensure that relatives and friends were properly informed in accordance with the patient's wishes. The Government believes that clinicians should proactively offer help and provide information to their patients, and should always explicitly seek the patient's consent for information to be passed to their carer (*Caring about Carers* Chapter 4, para 16, Department of Health, 1999).

Confidentiality is also a professional duty established by the code of conduct. All health care professionals must maintain the standards of confidentiality laid down by their professional body or risk complaint for professional misconduct which may result in a warning, restriction of practice or removal from the register.

The principle of confidentiality has a long history in medical codes of ethics starting with the Hippocratic Oath (5th Century BC):

All that may come to my knowledge in the exercise of my profession or outside of my profession or in my daily commerce with men, which ought not to be spread abroad, I will keep secret and never reveal.

The legal and ethical principles of consent in relation to information disclosure are relatively new to pharmacists (Wingfield & Badcott, 2007). The provision of advice by a pharmacist has to be within the context of the need for confidentiality and liaison with other providers.

Guidance to pharmacy professionals on how to meet the standards on confidentiality and guidance on consent are given in the following documents (the text in blue is our emphasis). As will be apparent, this is somewhat vague guidance:

General Pharmaceutical Council Guidance on Confidentiality–Disclosing confidential information July 2012 and Medicines, Ethics and Practice: The Professional Guide for Pharmacists Edition 39 (2015)

3. Disclosing confidential information

3.3 In the course of your professional practice you may receive requests for confidential patient information from a variety of people (for example a patient’s relative, partner or carer) or organisations (for example the police or a healthcare regulator). You should make decisions about disclosing information on a case-by-case basis and fully consider all relevant factors.

Other professional guidance provides more detail.

Health & Care Professions Council: The standards of conduct, performance and ethics (2012)

2 . You must respect the confidentiality of service users

You must treat information about service users as confidential and use it only for the purposes they have provided it for. You must not knowingly release any personal or confidential information to anyone who is not entitled to it, and you should check that people who ask for information are entitled to it.

You must only use information about a service user:

- to continue to care for that person; or*
- for purposes where that person has given you permission to use the information or the law allows you to do so.*

You must also keep to the conditions of any relevant data-protection laws and always follow best practice for handling confidential information. Best practice is likely to change over time, and you must stay up- to-date.

Nursing & Midwifery Council: The standards of conduct, performance and ethics for nurses and midwives (2008)

Respect People’s confidentiality

5 You must respect people's right to confidentiality

6 You must ensure people are informed about how and why information is shared by those who will be providing their care.

7 You must disclose information if you believe someone may be at risk of harm, in line with the law of the country in which you are practising.

However, this was updated in 2015 to include a person’s right to privacy and to expand on the sharing of information with others (as far as the law allows).

5 Respect people’s right to *privacy* and confidentiality

As a nurse or midwife, you owe a duty of confidentiality to all those who are receiving care. This includes making sure that they are informed about their care and that information about them is shared appropriately. To achieve this, you must:

5.1 Respect a person’s right to privacy in all aspects of their care

- 5.2 *make sure that people are informed about how and why information is used and shared by those who will be providing care*
- 5.3 *respect that a person's right to privacy and confidentiality continues after they have died*
- 5.4 *share necessary information with other healthcare professionals and agencies only when the interests of patient safety and public protection override the need for confidentiality, and*
- 5.5 *share with people, their families and their carers, as far as the law allows, the information they want or need to know about their health, care and ongoing treatment sensitively and in a way they can understand.*

There is guidance from the GMC about fundamental ethical principles that most registered doctors will use every day, like consent and confidentiality. The guidance is more detailed in terms of what information is shared and with whom.

General Medical Council Guidance for doctors: Confidentiality (2009)

Sharing information with a patient's partner, carers, relatives or friends

64. *You should establish with the patient what information they want you to share, who with, and in what circumstances. This will be particularly important if the patient has fluctuating or diminished capacity or is likely to lose capacity, even temporarily. Early discussions of this nature can help to avoid disclosures that patients would object to. They can also help to avoid misunderstandings with, or causing offence to, anyone the patient would want information to be shared with.*

65. *....Unless they indicate otherwise, it is reasonable to assume that patients would want those closest to them to be kept informed of their general condition and prognosis.*

The GMC guidance is somewhat contradictory to some of the other advice. Most guidance focuses on the protection of patient information. In the GMC guidance, the carer's right to information seems to be assumed, with the presumption for disclosure rather than against. This uncertainty must surely cause practical difficulties for pharmacists and health professionals. There are two powerful demands on practitioners: to provide carers with information regarding patients; and not to disclose information unless the patient consents. There is very little discussion of the interaction between these principles – how are they to be balanced or reconciled when they conflict.

A wide range of other policies and standards exist which provide guidance for health professionals in terms of confidentiality and consent. This includes the **Caldicott Guardian Manual 2006** and the **Department of Health Confidentiality: NHS Code of Practice, 2003**, which is a guide to required practice for those who work within or under contract to NHS organisations concerning confidentiality and patients' consent to the use of their health records. It is circumspect about carer involvement.

Examples of confidentiality decisions in practice: Model B1 Healthcare Purposes (pg 40)

5) To carers without parental responsibility

Carers often provide valuable healthcare and, subject to complying with the best practice outlined, every effort should be made to support and facilitate their work. Only information essential to a patient's care should be disclosed and patients should be made aware of this. However, the explicit consent of a competent patient is needed before disclosing information to a carer. The best interests of a patient who is not competent to consent may warrant disclosure.

The NICE (2012) guidelines acknowledge that carers need to be appropriately informed and just warns staff to be mindful of the duty of confidentiality.

NICE Patient experience in adult NHS services: improving the experience of care for people using adult NHS services (clinical guideline 138) (2012)

Involvement of family members and carers

1.3.11 *If the patient cannot indicate their agreement to share information, ensure that family members and/or carers are kept involved and appropriately informed, but be mindful of any potentially sensitive issues and the duty of confidentiality.*

There are also references to supporting and providing information to carers in a range of other health and social care policies, for example:

Department of Health: National Service Frameworks for Mental Health (1999)

Service models and examples of good practice- Checklist for GPs and primary care teams to help carers (p 71)

- *Do you always ask patients who have carers whether they are happy for health information about them to be told to their carer?*

However, a professional is not prevented from talking to carers about facts they already know; a breach of confidentiality only occurs when confidential information is newly disclosed and the BMA extract below gives clear advice on this (the relevant points are in blue text).

BMA document: Confidentiality & Disclosure of Health Information (1999):

3.1 Confidentiality

...Patients have a right to expect that identifiable information about themselves provided or discovered in the course of their health care will not be shared with other people without their knowledge, and the disclosure of identifiable information without subject consent to someone who did not previously know it breaches confidentiality.

3.1.1 Breach of confidentiality

Logically, confidentiality can only be breached when the recipient of the information learns something that was previously unknown to him or her. It is not a breach of confidentiality to discuss the medical implications of general information which is already known to the recipient. Where relatives, for example, are already aware of an individual's condition or diagnosis, an explanation of the possible options for that patient does not breach confidentiality, but revealing the person's views of those choices would do so.

The Supplementary Guidance: Public Interest Disclosures Department of Health (2010) expands on the Department of Health's key guidance, **Confidentiality: NHS Code of Practice 2003**, and is aimed at aiding staff making difficult decisions about when disclosures of confidential information may be justified in the public interest. In such cases, the patient's consent should still be sought unless it is not practicable to do so, for example because the patient is not competent, in which case the patient's welfare attorney, court-appointed deputy, guardian, or relatives/friends or carers should be consulted.

Literature on pharmacists, ethics and patients' rights

The most frequently cited issue in pharmacy ethics is confidentiality (Wingfield et al., 2004), and the concept of consent to use and disclose patient information. Three themes emerged:

Lack of professional and patient understanding of confidentiality and privacy laws

Hattingh et al. (2015) obtained the views of mental health users in pharmacy settings in Australia in relation to confidentiality and privacy. Carers experienced obstacles in communication of timely and accurate information. From the carer's perspective there was a reported requirement to balance therapeutic needs with privacy constraints. The authors concluded that the difficulties that carers faced may reflect knowledge gaps in the application and understanding of privacy laws, and signifies a need for education for community pharmacy staff.

A review of literature in respect of medical confidentiality between 1966 and 2000 (Sankar et al., 2003) found that there needs to be a greater understanding of how patients understand medical confidentiality. While there is some familiarity with medical confidentiality, the term itself may not be that familiar. They conclude many patients are unaware of, or misunderstand, their legal or ethical right to confidentiality. The possibility that information may be revealed to acquaintances in

a clinic or elsewhere worries them as much as information release to insurers or employers. However, research has also shown that many patients with memory problems acknowledge their dependence on carers and believe that they should be informed – and do not have concerns in this regard (Smith et al., 2015).

Rights of carers secondary to those of patients

Some research has suggested that professionals use ‘confidentiality smokescreens’ to withhold information from carers of people with mental health problems (Gray et al., 2008). Goodwin & Happell (2006) [Australia] found that mental health nurses were sympathetic to carers but felt that the rights of carers to information and involvement can be viewed as secondary to those of the service user, particularly when an issue of conflict arises, such as the carers’ right to information versus the service user’s right to confidentiality. A focus group which examined perspectives of carers on medication management in dementia (Poland et al., 2014) found that confidentiality issues could be caused by professional codes which focused on the person with dementia and prevented sharing of knowledge with carers, leaving carers uninformed and unsupported.

Information sharing

Machin (2004) outlines two principles for sharing of information: (1) professional sharing of information based on user consent which they are entitled to withhold or withdraw and, (2) justification for sharing confidential information in “need to know” cases in the public interest. Guidance from regulatory bodies confirms the need for consent to disclosure and recognises the practical necessity to share confidential information within professional teams; treat that as based on the patient’s implied consent; recognise the right of a competent patient to withhold consent; seek to minimise patient objection by encouraging service staff to explain the need for information sharing to patients without drawing undue attention to their right to object; but advise that the patient’s actual consent be sought before disclosing confidential information to non-professionals, including informal carers. Machin would prefer to see sharing amongst professionals justified on the basis of public interest irrespective of consent, subject to the limits of relevance and necessity. Machin believes disclosure to carers should be subject to consent, express or genuinely implied. He believes it is important to protect the autonomy of competent users and disclosure of sensitive information to family/friends is likely to be more problematic for a user than disclosure within a professional team.

3.1.2 Pharmacists’ responsibility to understand law concerning mental capacity and knowledge of and to action arrangements when the patient has lost or has fluctuating mental capacity

In law, every adult has the right to make his/her own decisions and is assumed to be competent (in legal terms, to have the mental capacity to make their own decisions) unless it is established otherwise. Mental capacity is a decision-specific concept, such that a person may be judged to have the capacity to make some decisions and not others, for example, decisions about medicines but not finances. Decision-making abilities are spread along a continuum, making the point at which a person lacks the mental capacity to make a particular decision difficult to judge. Whether a person has the mental capacity to make a particular decision may also fluctuate over time, just as their mental abilities do. All healthcare professionals, including pharmacists, need to understand the Mental Capacity Act [MCA] (2005) which sets out the legal framework in England (and in Scotland by the Adults with Incapacity (Scotland) Act 2000), for deciding when someone is unable to make a decision for themselves; as well as acting for and making decisions on behalf of people aged 16 years and over who lack the mental capacity to make decisions for themselves.

A person is unable to make a decision for himself/herself if s/he is unable (a) to understand the information; (b) to retain that information; (c) to use or weigh that information as part of the process of making the decision; or to (d) to communicate his decision. The MCA requires that all practicable steps are taken to assist a person to make a decision, before a judgement is made about their mental capacity. If a person does not have capacity to make a particular decision for themselves, then others must decide in their best interests, as defined in sections 4.1 – 4.11 of the statute. The MCA gives anyone who has been appointed as a lasting power of attorney (LPA), powers to make decisions about the patient's finances and welfare⁴. A new Office of the Public Guardian (OPG) is responsible for the register of LPAs, pre-MCA enduring powers of attorney (EPA) and deputies (court appointed). The MCA Code of Practice (2007) explains how the Act operates and offers examples of best practice. Anyone who is an attorney under a LPA, or is being paid to act for or make decisions for a person who lacks capacity, is legally required to have regard to the Code of Practice. The MCA also now puts advance decisions on a statutory basis. These are a method of supporting values-based information sharing practices between professionals, patients and carers but pharmacists have no particular need to be aware of this provision.

The **GPhC Guidance on Consent (2012)** has a section outlining how pharmacists should assess capacity of patients.

2.1.1 *In England and Wales, under the MCA (2005), a person lacks capacity if at the time the decision needs to be made, they are unable to make or communicate the decision, because of an 'impairment or disturbance' that affects the way their mind or brain works.*

2.2 Assessing Capacity

2.2.1 *You must base an assessment of capacity on the patient's ability to make a specific decision at the time it needs to be made. A patient may be capable of making some decisions but not others.*

2.2.2 *In general, to make an informed decision the patient should be able to:*

- understand the information provided*
- remember the information provided*
- use and weigh up the information provided, and*
- communicate their decision to you (by any means).*

2.2.3 *You must not assume that because a patient lacks capacity on one occasion, or in relation to one type of service, that they lack capacity to make all decisions.*

2.2.4 *A patient's capacity to consent may be temporarily affected by other factors, for example fatigue, panic, or the effects of drugs or alcohol. The existence of these factors should not lead to an automatic assumption that the patient does not have the capacity to consent. Instead you should use your professional judgement to make a decision based on the individual circumstances.*

2.2.5 *You must not assume that a patient lacks capacity based just upon their age, disability, beliefs, condition, or behaviour, or because they make a decision you disagree with.*

2.2.6 *You must take all reasonable steps to help and support patients to make their own decisions or to be as involved as they can be in a decision...*

The GMC guidance also refers to the MCA in its Guidance on consent and gives further guidance on disclosure of information about patients who lack capacity to consent.

General Medical Council Consent: patients and doctors making decisions together (2008)

62. The legal framework

Making decisions about treatment and care for patients who lack capacity is governed in England and Wales by the Mental Capacity Act 2005. The legislation sets out the criteria and procedures to be followed in making decisions when patients lack capacity to make these decisions for themselves. It also grants legal authority to certain people to make decisions on behalf of patients who lack capacity.

⁴ Making decisions: 'A guide for family, friends and other unpaid carers' and 'A guide for people who work in health and social care' Helping people who are unable to make some decisions for themselves OPG602/603 Office of the Public Guardian.

Making decisions when a patient lacks capacity

76. You must also consider:...

- e. *the views of anyone the patient asks you to consult, or who has legal authority to make a decision on their behalf, or has been appointed to represent them*
- f. *the views of people close to the patient on the patient's preferences, feelings, beliefs and values, and whether they consider the proposed treatment to be in the patient's best interests*
- g. *what you and the rest of the healthcare team know about the patient's wishes, feelings, beliefs and values.*

General Medical Council Guidance for Doctors: Confidentiality (2009)

Disclosure about patients who lack capacity to consent

61. *If a patient who lacks capacity asks you not to disclose personal information about their condition or treatment, you should try to persuade them to allow an appropriate person to be involved in the consultation. If they refuse, and you are convinced that it is essential in their best interests, you may disclose relevant information to an appropriate person or authority. In such a case you should tell the patient before disclosing the information and, if appropriate, seek and carefully consider the views of an advocate or carer. You should document in the patient's record your discussions and the reasons for deciding to disclose the information.*

One particular difficulty for a pharmacist is that they often only deal with an intermediary, the carer, so it is difficult to assess capacity of the patient. However, as pharmacists become fully integrated partners in care teams, they are increasingly likely to be involved in the care of, or come into contact with, adults who lack or who are losing capacity. They should, therefore, have an understanding of the principles of consent where capacity exists but also of what the law requires when it does not (Wingfield, 2003). This observation was recently underlined by a House of Lords select committee, which found that understanding and implementation of the MCA was lacking within medical practice:

Select Committee on the Mental Capacity Act 2005 - Report Mental Capacity Act 2005: post- legislative scrutiny House of Lords (2014)

Conclusion 5 The general lack of awareness of the provisions of the Act has allowed prevailing professional practices to continue unchallenged, and allowed decision-making to be dominated by professionals, without the required input from families and carers about P's wishes and feelings (paragraph 107)

Patient autonomy and partnerships with carers

In the care of older people, the traditional perspective on autonomy (making independent choices without interference from others) is an ethical issue and can be a source of ethical conflict between older people and carers (Collopy, 1988). Many older people with cognitive impairment will have the ability to make their own decisions about the use of medicines, and will want to do so for as long as possible (Wahlich et al., 2013). Francis et al. (2006) focused on the *partnerships* between carers and patients in decisions regarding medicines, and provided some insights into different ways in which carers may operate in partnership with their care-recipient and other carers (professional and informal). It highlighted difficulties that can arise, e.g. conflicting views and perspectives of carers and patients regarding the need for medicines and differing practices regarding the sharing of information. Thus, it cannot be assumed that the perspectives of patients and carers regarding the use of medicines will necessarily coincide. A study of formal 'substituted judgements' in the US also suggests they often do not (Shalowitz et al., 2006). Carers need support both in the form of information and in the form of emotional and social care to make substituted judgements on behalf of relatives who lack mental capacity (Edwards et al., 2011).

3.1.3 Pharmacists' responsibilities to disclose information in relation to the pharmacist–carer relationship so that this is transparent to the patient

A patient has no right to prohibit a professional from engaging with the carer, or from providing information and support, or from talking to the carer about the care recipient, providing that no confidential information is divulged. Whilst information provided by a carer about the care recipient is not considered to be information confidential to the carer, the service provider has to exercise judgment about whether, when or to what extent that information should be shared with the care recipient (Machin, 2004).

The GMC guidance below indicates that a professional should warn a carer that they might tell the patient about such a conversation and it could be construed as a breach of trust by the patient if they have requested a health professional not to listen to a carer's views as emphasised by the text in blue below. The GPhC does not give any guidance in this area.

General Medical Council Guidance for Doctors: Confidentiality (2009)

Sharing information with a patient's partner, carers, relatives or friends

66. If anyone close to the patient wants to discuss their concerns about the patient's health, you should make it clear to them that, while it is not a breach of confidentiality to listen to their concerns, you cannot guarantee that you will not tell the patient about the conversation. You might need to share with a patient information you have received from others, for example, if it has influenced your assessment and treatment of the patient. You should not refuse to listen to a patient's partner, carers or others on the basis of confidentiality. Their views or the information they provide might be helpful in your care of the patient. You will, though, need to consider whether your patient would consider you listening to the concerns of others about your patient's health or care to be a breach of trust, particularly if they have asked you not to listen to particular people.

A carer also has his/her own right to confidentiality: "The relationship between a carer and a member of the user's professional care team is itself one which attracts confidentiality and so gives rise to a duty not to disclose confidential information about the carer without consent, or pursuant to an overriding public interest" (Machin 2004, pg 13).

Department of Health's Practitioner's Guide to Carers' Assessments under the Carers and Disabled Children Act (2001)

53. The carer may wish to discuss information they have not revealed to the person they care for. Such information can only be shared with the service-user with the carer's consent.

Patient rights are often taken to be immutable. However, a pharmacist also has certain responsibilities to ensure that carers' rights are taken into account even when they involve potentially conflicting obligations.

3.2 Pharmacists' responsibilities corresponding to carers' 'rights' :

3.2.1 Pharmacists' responsibility to provide information to carers

Our review found evidence for the view that carers have a right to information and that carers need information to fulfil their duties. Carers need general information (in the public domain) as well as personal information (relating to the care of the person, such as medicines information). They may also need confidential information about the person cared for.

The relevant parts of the Guidance given by various organisations in relation to carers being given information about medication issues are extracted below (in blue text).

The Royal Pharmaceutical Society Professional Standards and Guidance for the Sale and Supply of Medicines [section 3 Supply of Prescribed Medicines]

This gives guidance which states that carers must be informed about outstanding medication –
you must ensure that:...3.5 patients or their carers are informed if you are unable to dispense their prescription in its entirety and given the opportunity to take their prescription to another pharmacy. 3.6 when medication is outstanding, the patient, carer or their representative is provided with a legible note detailing the name and quantity of medicine outstanding and, where possible, informed when the balance will be available for collection....

Care Quality Commission Outcome 9 (Management of Medicines) of the Essential Standards of Quality and Safety (2010)

People who use services:

Wherever possible will have information about the medicine being prescribed made available to them or others acting on their behalf.

Department of Health: The National Service Framework for Older People (2001)

NHS Plan: Principles (page 6)

...Information should be provided to older people and their carers about the services which are available and the options they have [Standard 2]

Royal Pharmaceutical Society Professional Standards for Homecare Services (2013)

1.2 Information about homecare services

Patients (and/or carers) have access to information and support in order to make informed choices and consent to the use of homecare services.

7.5 Distribution and storage

7.5.4 Patients and/or carers are informed of the correct storage conditions for their medicines and where appropriate additional storage facilities/equipment is provided to patients as part of the service.

The important point from these examples is that whether the pharmacist is dealing with the patient directly or the carer, their responsibilities are the same.

Information needs of carers

The need for carers to have information on medication and treatments has been identified in an integrative review by Silva et al. (2013).

The NHS plans to give carers access to patient's digital health records to become more in line with the Scottish system. This might have implications for pharmacists, as carers will already have the information, so pharmacists are not likely to breach confidentiality. A *Framework for Action (Department of Health, National Information Board, 2014) entitled Personalised Health and Care 2020 Using Data and Technology to Transform Outcomes for Patients and Citizens* will 'give care professionals and carers access to all the data, information and knowledge they need' – real-time digital information on a person's health and care by 2020 for all NHS-funded services, and comprehensive data on the outcomes and value of services to support improvement and sustainability'. Currently one in three individuals provide substantial levels of unpaid care every week with no support from the technology and data services that underpin the formal care system. As carers are vital to the sustainability of health and care services they should also share, and have access to, digital tools to support those they look after, with appropriate consents.

3.2.2 Pharmacists' responsibility to recognise carers as partners and co-experts and to include carers in decision-making

The relevant parts of the Guidance given by various organisations in relation to carers being treated as partners and co-experts are extracted below (in blue text).

GPhC's Standards of conduct, ethics and performance (2012)

4. Encourage patients and the public to participate in decisions about their care

4.2 Work in partnership with patients and the public, their carers and other professionals to manage their treatment and care. ..

Medicines, Ethics and Practice The Professional Guide for Pharmacists Edn 39 (2015)

(Medicines optimisation and pharmaceutical care – principles for medicines optimisation p3)

Principle 1: Aim to understand the patient's experience

To ensure the best possible outcomes from medicines, there is an ongoing, open dialogue with the patient and/or their carer about the patient's choice and experience of using medicines to manage their condition; recognising that the patient's experience may change over time even if the medicines do not.

GPhC's Standards of conduct, ethics and performance (2012)

Principle 4: Encourage patients and the public to participate in decisions about their care

This is worded as something that should be encouraged rather than something that is "required".

Royal Pharmaceutical Society Professional Standards for Homecare Services (2013)

Standard 1 Patient Engagement

Patients (and/or carers) are supported in their decision-making about homecare medicines

1.1.5 The views of patients and carers are actively sought to inform the development and delivery of homecare services.

NICE clinical guideline 76 Medicines adherence Involving patients in decisions about prescribed medicines and supporting adherence (2009)

Increasing patient involvement

1.1.18 Encourage and support patients, families and carers to keep an up-to-date list of all medicines the patient is taking...

However, this guidance also states in the Introduction (pg.4) "*with the patient's consent, carers should have access to appropriate levels of information and support.*"

It calls into question the idea that carers have "rights" to information or support or in decision-making: "*if the patient agrees, families and carers should also have the opportunity to be involved in decisions about treatment and care. Families and carers should be given the information and support they need (pg 5)*"

General Medical Council Guidance for Doctors: Confidentiality (2009)

Sharing information with a patient's partner, carers, relatives or friends

66. ...You should not refuse to listen to a patient's partner, carers or others on the basis of confidentiality. Their views or the information they provide might be helpful in your care of the patient.

In the Good Medical Practice (2013), the term 'you must' is used for an overriding duty or principle. 'You should' is used when the guidance provides an explanation of how a person will meet the overriding duty. 'You should' is also used where the duty or principle will not apply in all situations or circumstances, or where there are factors outside a person's control.

GMC Guidance for doctors: Consent: patient and doctors making decisions together (2008)

Involving families, carers and advocates

22. You should accommodate a patient's wishes if they want another person, such as a relative, partner, friend, carer or advocate, to be involved in discussions or to help them make decisions...

The NHS Constitution for England (2015)

4. The patient will be at the heart of everything the NHS does.

It should support individuals to promote and manage their own health. NHS services must reflect, and should be coordinated around and tailored to, the needs and preferences of patients, their families and

their carers... *Patients, with their families and carers, where appropriate, will be involved in and consulted on all decisions about their care and treatment.*

Report on Modernising Pharmacy Careers Programme: Smith & Darracott (2011)

“there is a need to develop Day 1 pharmacists who can respond to a diagnosis, usually developed by a medical practitioner, formulate a plan for initial and ongoing treatment in partnership with the patient, carers and other health professionals as appropriate, applying prescribing skills where appropriate” (p7)

Department of Health: Developing Services for Carers and Families of People with Mental Illness (2002) states that services should be:

- *positive and inclusive: carers should be involved in decision-making and recognised as partners and co-experts*

NICE clinical guideline 138: Patient experience in adult NHS services: improving the experience of care for people using adult NHS services (2012)

Quality statement 13

Patients' preferences for sharing information with their partner, family members and/or carers are established, respected and reviewed throughout their care.

Involvement of family members and carers

1.3.10 Clarify with the patient at the first point of contact whether and how they would like their partner, family members and/or carers to be involved in key decisions about the management of their condition. Review this regularly. If the patient agrees, share information with their partner, family members and/or carers.

This guidance, again, seems to question the supposed ‘rights’ of carers. It suggests that it is first and foremost up to the patient how much involvement carers have in decisions regarding their medical care. There is no presumptive ‘right’ for carers to be involved as ‘co-experts’ or to be included in decisions about a patient’s medicines. It is likely that patients’ rights trump carers’ rights in reality.

3.2.3 Pharmacists’ responsibility to provide support/advice for carers

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (No. 349)

PART 2 Essential services Support for self-care

21. An NHS pharmacist must, to the extent paragraph 22 requires and in the manner set out in that paragraph, provide advice and support to people caring for themselves or their families.

PART 2 Essential services Service outline in respect of support for self-care

22. (1) Where it appears to an NHS pharmacist (P), having regard to the need to minimise the inappropriate use of health and social care services, that a person (X) using P’s pharmacy would benefit from advice from P to help X manage a medical condition (including, in the case of a carer, to help X in assisting in the management of another person’s medical condition), P must provide advice to X as regards managing the medical condition, including, as appropriate, advice—(a) on treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines; and (b) on changes to the patient’s lifestyle.

Medicines, Ethics and Practice The Professional Guide for Pharmacists Edn 39 (2015)

(Medicines optimisation and pharmaceutical care – principles for medicines optimisation p3)

Principle 1: Aim to understand the patient experience

To ensure the best possible outcomes from medicines, there is an ongoing, open dialogue with the patient and/or their carer about the patient’s choice and experience of using medicines to manage their condition; recognising that the patient’s experience may change over time even if the medicines do not.

Principle 4: Make Medicines optimisation part of routine practice

Health professionals routinely discuss with each other and with patients and/or their carers how to get the best outcomes from medicines throughout the patient’s care.

Therefore a feature of professional guidance for pharmacists is that they are required to provide information and support for carers. Emergency Supply of medicines (at the request of the patient or

carer) could be a dilemma for a pharmacist. The pharmacist may provide an emergency supply of up to 30 days for most prescription medicines, with some exceptions e.g. controlled drugs. Whether to supply, and the amount of medication the pharmacist supplies, is entirely at the pharmacist's discretion. Regulation 225 Human Medicines Regulations 2012 requires a pharmacist to interview the patient. The RPS recognises that in some circumstances this might not be possible, for example if the patient is being cared for. In these circumstances the RPS advises pharmacists to use their professional judgement and consider the best interests of the patient.

Royal Pharmaceutical Society: Emergency Supply A Guidance on Professional Practice (2011)

As a pharmacist, you can supply prescription only medicines (POMs) to a patient without a prescription in an emergency at the request of a prescriber or a patient. You should consider each request on a case by case basis, using your professional judgement to decide which course of action you believe will be in the best interest of the patient.

3.3 Pharmacists' responsibilities within a pharmacist–carer–patient triangle of care

Three further responsibilities identified by our review could not be straightforwardly or exclusively understood as arising from the rights of patients or carers.

3.3.1 Pharmacists' responsibility to be sure that people claiming to be carers are genuinely carers

Health & Care Professions Council: The standards of conduct, performance and ethics (2012)

2. You must respect the confidentiality of service users

.....you must not knowingly release any personal or confidential information to anyone who is not entitled to it, and you should check that people who ask for information are entitled to it.

The single reference to this responsibility in terms of pharmacy practice was found in guidance from the **Consultation skills for pharmacy practice (Centre for Pharmacy Postgraduate Education, 2014)**.

In the context of physical learning disabilities and adherence:

Carers may play a key role in the adherence process for these patients. However you need to be sure of the role of a carer before making any assumptions (p.17)

Although the guidance does not elaborate, this would be to protect the patient and also to recognise genuine carers as valid partners. Bona fide carers have a right to be recognised as partners and co-experts and patients have a right to be protected from people representing themselves inappropriately as their carer. However, evidence shows that carer identification in community pharmacies and elsewhere is not good. Carers come into contact with a number of health and social care professionals who could potentially advise about local support and services. A survey of 2,000 carers found that over 70% of carers come into contact with health professionals over time but health professionals only identify 11% of carers and GPs only 7% (*Prepared to Care? Exploring the impact of caring on people's lives – Carers Week 2013*).

The importance of the role of general practice in recognising carers resulted in the inclusion of voluntary quality indicator points in the 2002 GP General Medical Services Contract Quality and Outcomes Framework (QOF). This provides a financial incentive for practices to have a protocol for the identification of carers and to develop mechanisms for the referral of carers for social services assessment. Primary care IT systems have Read Codes for recording carer status. However, not all local authorities operate carers' registration schemes. Priority 5 of NHS England's *Commitment to Carers* (2014) stated that "NHS England will work with NICE and other partners to develop measurement and best practice guidance in order to increase identification of carers".

3.3.2 Pharmacists' responsibility to be satisfied that medication information is understood by carers

Once a carer has been recognised as such, a pharmacist must ensure that information about medicines is both provided to and understood by the carer, thus both satisfying the need for a carer to have information and the need to protect the patient from inappropriate or non-optimum use of medicines. A pharmacist may have to use their own judgment as to the likelihood that the carer is able to understand the information and is administering the medicine appropriately.

GPhC's Standards of conduct, ethics and performance (2012)

1 Make patients your first concern

1.7 Be satisfied that *patients or their carers know how to use their medicines.*

Medicines, Ethics and Practice The Professional Guide for Pharmacists Edn 39 (2015)

(Medicines optimisation and pharmaceutical care – principles for medicines optimisation p3)

Principle 3: Ensure Medicines use is as safe as possible

The safe use of medicines is the responsibility of all professionals, healthcare organisations and patients, and should be discussed with patients and/or their carer.

Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities)

Regulations 2010 Management of Medicines states:

The registered person [service provider] must protect service users against the risks associated with the unsafe use and management of medicines, by means of making appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity.

NICE Patient experience in adult NHS services: improving the experience of care for people using adult NHS services (clinical guideline 138) (2012)

Information

1.5.17 *Give the patient (and/or their family members and carers) information to enable them to use any medicines and equipment correctly. Ensure that the patient and their family members and carers feel adequately informed, prepared and supported to use medicines and equipment and to carry out self-care and self management.*

NICE guideline 5 Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes (2015)

1.1.2 *Health and social care practitioners should explain to patients, and their family members or carers where appropriate, how to identify and report medicines-related patient safety incidents.*

1.2 *Medicines-related communication systems when patients move from one care setting to another Relevant information about medicines should be shared with patients, and their family members or carers, where appropriate, and between health and social care practitioners when a person moves from one care setting to another, to support high-quality care.*

1.2.4 *Health and social care practitioners should discuss relevant information about medicines with the person, and their family members or carers where appropriate, at the time of transfer. They should give the person, and their family members or carers where appropriate, a complete and accurate list of their medicines in a format that is suitable for them. This should include all current medicines and any changes to medicines made during their stay.*

1.3.6 *Involve patients and their family members or carers, where appropriate, in the medicines reconciliation process.*

1.4.3 *During a structured medication review, take into account: the person's, and their family members or carers where appropriate, views and understanding about their medicines; the person's, and their family members' or carers' where appropriate, concerns, questions or problems with the medicines.*

Nursing & Midwifery Council Standards for medicines management (2010)

Standard 17: Delegation *A registrant [nurses, midwives and specialist community public health nurses] is responsible for the delegation of any aspects of the administration of medicinal products and they are accountable to ensure that the patient, carer or care assistant is competent to carry out the task.*

Royal Pharmaceutical Society Professional Standards for Homecare Services (2013)

1.3 Adherence to medicines pathways

1.3.3. Patients and/or carers are trained and assessed by a healthcare professional as being competent to self-administer their medication including use of any equipment or ancillaries provided as part of the homecare service unless suitable alternative arrangements have been made to support delivery of the medicine pathway to the patient in their home or other appropriate community setting.

3.3.3 Pharmacists' responsibility to report potential issues re the carer-patient relationship

Pharmacists also have a duty of candour to ensure that the patient is not being disadvantaged in terms of their care by issues within the carer-patient relationship. The Guidance below implies that a pharmacist has a duty to report on cases where s/he suspects negligence by a carer.

General Pharmaceutical Council (GPhC) Guidance on raising concerns (2012)

1 The importance of raising concerns

1.1 This includes raising and reporting any concerns you have about the people you come into contact with during the course of your work, including pharmacists, pharmacy technicians, pharmacy owners, managers and employers, other healthcare professionals or people responsible for the care of a patient, such as carers, care home staff or key workers. It includes concerns about behaviours, competency, the working environment and any actions that may compromise patient safety.

The GPhC imposes its own standards on the administration of medication to protect the public. A person may be guilty of professional misconduct even though they have not caused harm necessary to find them liable in negligence. Again, could a pharmacist themselves be "negligent" because they failed to notice or report negligence or other misconduct by a carer in administering medications?

Carers' duty of care

Stone and Dobinson, R v (1977) 1 QB 354 and R v Hood (2004) 1 Cr App R (S) 73

It is established in case law that a person who undertakes to look after another, but then fails to do so, can face a manslaughter conviction. In the cases above the victim lacked capacity so the defendants were responsible for acting in the victim's best interests and failed to do so. So there is an assumption of a duty of care from voluntarily assuming responsibility for looking after someone, knowing that the person is relying on them. While the responsibilities and legal liabilities of professional carers are understood, untrained carers assuming responsibilities may find themselves exposed to unexpected liability. The law of tort imposes a duty of care on a person who looks after someone else. However professionals have guidance informing them of their obligations and informal care can be provided without a person being *aware* that they are taking on legal obligations.

Results: Stage 2 - Interviews with carers, pharmacists and other health/social care professionals

Recruitment and characteristics of participants

Recruitment of carers was via carers' support groups in London and Surrey (Camden Carers, Surrey Heath Carers, East Surrey Carers' Support Association), voluntary organisations (Age UK, London and

Alzheimer's Society, Surrey) and community pharmacies in both London and Surrey/Hampshire border area.

The lead researcher (LJ) attended carers' support meetings run by Camden carers and Surrey Heath Carers and the Alzheimer's Society to briefly talk about the study. Information about the study with contact details was also placed in newsletters and/or websites of these organisations. Information packs were left with or forwarded to these organisations to pass on to potential participants.

Community pharmacies were identified through our collaborators and the carers' centres. LJ visited all who agreed to participate to meet the pharmacists and their teams and to brief them on the study and what was required in terms of handing out information packs to people known to the pharmacy to be a carer for someone over 60 taking regular medicines. LJ usually left 15 packs per pharmacy to distribute.

UCL School of Pharmacy (together with Age UK) had previously run a successful public engagement day on Medicines for Older People. Some attendees gave their permission to be contacted to take part in future studies: *Age UK Engage network*. These participants were contacted by email by our contact at Age UK giving details of the study and passing on the researcher details.

Achieving the required sample size was challenging. In general, information in newsletters or on websites resulted in no response. Because of the slow response, the period of recruitment for the study was extended to enable additional organisations and pharmacies to take part. Saturation point (the point at which no new information emerged) was reached after 18 interviews with carers and 12 interviews with health/social care professionals. 7 carers were recruited from carers' centres, 4 via community pharmacies, 5 from Alzheimer's Society and 2 from Age UK.

Face-to-face interviews were conducted by one qualitative researcher (LJ) experienced in interviewing. All carer interviews were performed in the participant's own home with the exception of two carers who came to UCL School of Pharmacy. Interviews took place between October 2014 and May 2015 and lasted between 25 minutes and 1 hour. The carer and patient were sometimes present together and, if this were the case, LJ tried to include the patient if and where appropriate. At times carers had to break off the interview to attend to the care recipient (e.g. to turn them in bed, attend to personal needs etc.) or answer the doorbell or phone.

Interviews with family carers

Carers were aged between 51 and 90 years old. Nearly two thirds (11/18) of the carers were female and two thirds of the care recipients were suffering from dementia. Six carers were the wife of the care-recipient, six were a husband, one a sister, five were daughters and one a son. See Table A (Appendix 6.)

Many family carers were full-time carers and had a high caring load as several care recipients were bed bound or were suffering from dementia, particularly those recruited from carers' support groups. Other carers were in a transition phase where the care was gradually being transferred to them as the care recipient became less able to do things for themselves. A few carers managed to work part-time with support from paid carers. Some younger carers had to reduce their working hours or give up work, whereas most of the other older carers were retired. So, the range of activities and amount of support provided was very varied; however, all carers had a role in terms of medicines activities. The length of time the carer had been in a caring role was variable. For most

carers, taking on this role had been a gradual process. People used the care recipient's year of diagnosis or when they became ill as a benchmark to determine the point at which they became a carer, with a caveat that they had probably started helping out prior to that. Some referred to the year they were officially registered as a carer with the council.

Carers were also concerned about what was going to happen in the future should their own health deteriorate. Another issue that caused anxiety was the worry over what would happen if the carer had to go into hospital.

So do you think, I mean what would happen if, you know, you were not able to do that, if you were in hospital yourself?

That is the thing I ask to Social Worker, that is always worrying me. (Carer 9)

Carers worried about medications for their care recipients even when in hospital.

It's happened before with these patches, yes, it's happened before and then my constant phone calls, my you know, chasing, chasing all over again even sometimes from the hospital, I've been in hospital and chased. (Carer 3)

Many carers were suffering from conditions such as diabetes, arthritis, heart problems, themselves and thus had to manage two lots of medicines. These carers ordered the medicines from the same pharmacy and organised both medicines at the same time.

Medication role

Carers were managing between 3 and 12 medicines a day plus inhalers and patches, all to be given at different times. Some of the medicines the care recipients had been taking for years; others were newly prescribed as a result of a diagnosis (e.g. Aricept for Alzheimer's) or a symptom (e.g. laxatives for constipation). See Table B (Appendix 7) for details of medicines and regimens.

Most carers were responsible for ordering the medicines, collecting the prescription, overseeing the administration and disposal of unused medicines, although most carers said they did not have any unused medicines. Carers spent a lot of their time checking: supplies, deliveries, daily doses. Some carers admitted to preferring to be in control of the medicines rather than rely on someone else. Some carers simply had to remind the care recipient to take the medicines, otherwise he/she would forget. Others put the medicines in little pots, ranging from home containers to dosette boxes. They, or a paid carer, would then either observe, or give the medicines to the care recipient, in one case a family carer physically putting a medicine in the care recipient's mouth. Some carers had to administer a range of formulations.

Some family carers mentioned trying to involve the care recipient in the organisation process.

once a day, he helps me press them out, he likes that job, I try to find him little jobs to do because he doesn't really want to do much at all, I suggest things, keep his brain going a bit, and so we do that on a Saturday morning, that's our job, he likes it, I don't like that job, and then I put them on the table for him with some water every time, whenever they're due. (Carer 14)

Some carers had the medicines supplied in blister packs; others preferred to sort the pills themselves. The reasons for not wanting a blister pack ranged from fear of dropping one with no spare, to being a creature of habit or to not having information leaflets with blister packs. One care recipient felt it was a loss of control over her medicines.

... the Chemist did say to me, she said "If you like", because she knew mum used to be on a lot more tablets and she said "Now she's only on three or whatever", she said "I could put them in a blister pack for you", and I think I did it for the first month and then I said to her "Do you know what, I think I'd rather have them in the boxes because if we lose one or whatever..." (Carer 5)

Carers' strategies and problems with medicines activities

Running out of medicines was one issue, although this was not a common problem. However, phrases like "supply problems" are confusing for carers as they have no idea what it means. Being provided with half a prescription was quite stressful for them as it is another thing to remember and they do not understand how a pharmacist cannot have enough of certain medicines when the care recipient has been taking the same medicine for some time.

Most carers followed the instructions with medicines carefully. But sometimes carers organised dosing of medicines to make things easier for themselves without referring to a health professional or understanding potential consequences.

Well he's on Loperamide because of the cancer thing so, um... So he would have a sort of constant diarrhoea if he didn't. And that's supposed to be four, one, you know, one pill four times a day, I actually do it twice, two a day twice.

Okay. Did you make that decision yourself?

Yes. I thought there's no way I'm going to give him medication four times a day.

Why did you feel that?

Because I wouldn't remember, I wouldn't know when to do, you know...

So is it to make it easier for yourself?

Yes.

Did you discuss that decision with anybody? I mean, you know...

I probably told the doctor, yeah. And it might be, I mean it might be illogical but it seemed to me it worked well.

Works for you, yes, but I just wondered if, you know... Whether it works for him? [Laughs]

Or whether you had discussed with anybody, you know, whether that was the right thing to be doing, maybe it was too large a dose to be giving at one time or whether you'd actually had the opportunity to talk that through? I mean it works for you but I just wondered if you got any support making that decision?

It might not work for him. I mean he does go more often during the day than, you know, than anybody else would, um... Yeah. (Carer 1)

A few carers said that they made decisions in regard to giving the care recipient vitamins and other supplements.

I was on Adcal because you know, I've had a bone scan and anyway, she said after 3 years I think, or 2 years, she said it was, she'll try me without but wanted me to try, take Vitamin D, so I give it to him too, we're not in the sun anymore.

So you made that decision.

I made that decision, and B12 the nurse thought was supposed to help with your memory so I give him B12 and a multivitamin, and a folic acid because every time he had a blood test it was low. (Carer 14)

Carer strategies for dealing with medicines

Some commented that the pharmacist had suggested administration aids; again, other carers had been more proactive and bought pill crushers or dosing cups themselves. Buying an organiser was a common way for carers to manage the medications.

Carers also devised ways to have access to the care recipient's information:

So you always went to the same pharmacy did you?

Yes, I always went there to get her meds and I always, you know, used to do the repeat and it was much easier when the doctor changed it so you could do the repeats on the computer.

Online.

So I just used to, I had log in for her and I logged in for her, you know I basically, because they said you can get your log in, because I've got my own log in obviously for the doctors and I went and got one for her so I used to just log in as her.

.....So I think I just sort of said, oh, when they started their online system for ordering repeat prescriptions, I obviously got myself one and then I got her one and I don't even think I'd mentioned it to them, I think I just took it, the form that you had to fill out and filled it out and dropped it back in and

they give you like a password or a login thing and you set up the account and I think I just did it because my mum wasn't computer literate at all. (Carer 5)

One carer admitted that she kept emergency supplies of medicines as the possibility of running out would cause her too much stress.

Our method is now is ridiculous to say but on a deceitful manner we've hid a week's supply so that like god forbid if it ever got to the stage...

You've got an emergency?

...we would be left on that we have an emergency, yeah.

So you're devising strategies to cope?

Exactly. A case of having to because of what we've experienced, d'you know what I'm saying? And it's just to alleviate the stress. (Carers 7 and 8)

A few carers expressed concern about side effects. One or two wondered whether the medicines were working and a couple of carers felt that the amount of medicines being taken was too many, one was concerned about interactions of medicines and another commented that it had occurred to her *what would happen if we stopped them all (Carer 17)*.

Choice and frequency of visits to a community pharmacy

Accessibility of the pharmacy is very important to carers and most family carers tend to use the community pharmacy that is most local to them, although they may also use others (multiple pharmacy use) on occasions such as when there are supply issues or the carer requires some non-prescribed items e.g. dressings, personal hygiene products or meal replacement drinks. Carers visit the pharmacy mainly to drop off and collect prescriptions. The number of visits per month was variable with some carers not going at all if the pharmacy provided a delivery service. The delivery service was variable both in terms of being offered and being taken up by the carers, with some carers keen to continue dropping off and collecting prescriptions whilst they could. Some carers co-ordinated visits to the pharmacy with their shopping routine. Often supply issues or syncing medications necessitated further visits.

But just in terms of your actual pharmacy, how often do you visit the pharmacy in terms of the medicines for your husband?

Quite often because it's quite hard to get them all to coordinate. (Carer 1)

Reasons for switching pharmacies included pharmacies providing a different brand of medicines, not providing a personal service and failure to deliver all (especially more expensive) items on a prescription.

Why did you choose to go to the pharmacy, you know, this one that you've given...

We were registered at [high street chemist] and there was a constant turnover of staff there, they're a chain, there's no... There's never the same pharmacist, they seem to have loads of part-time pharmacists, you couldn't get any continuity, even though they held six months prescriptions they were never done and you were always waiting, it was just, just a nightmare and when this new one opened because it's relatively new...(Carer 15)

Attitude of staff and relationship of pharmacist with carer

The relationship with the pharmacist is very important to carers. Often the pharmacist has known the carer/care recipient for years, and usually since the onset of any illness. To some extent this relationship feeds into the carer experience of pharmacy services, which was very variable, with some praising their pharmacy and others saying they have never been offered any help. There was a sense that what carers really need in terms of support is reassurance and someone to listen to them. Here the attitude of the pharmacist and staff is key, with some going the extra mile to pop things around to a carer's house and, at the other end of the spectrum, a carer going into a pharmacy with a patient suffering from dementia and coming out feeling that her loved one was being a nuisance.

For most carers, being acknowledged and feeling supported was really appreciated.

....but it's just the feeling and you know, we're not made of wood, we can sense when someone is... And this is the difference between x pharmacy and the y pharmacy and y pharmacy is busy, it's a tiny pharmacy, tiny, ... and there are always people waiting for medication and yet they will come and speak to you in a friendly supportive way, which I cannot say for the x pharmacy so I'm thinking actually, even though it's further away, I'd almost rather just go back to them, just because of the way we're treated. (Carer 4)

Perceived roles of pharmacist and the GP

Several carers had no real understanding of the role or scope of pharmacy services. Some family carers commented that they had seen the adverts encouraging people to use their pharmacy, but when discussing the training and knowledge of medicines that pharmacists have to undergo, most admitted this was something they had not really thought about.

No. No, this has been really good. One of the reasons that I agreed to do this [take part in this study] was because I was hoping to learn something about the role of pharmacies and I feel that I have and so now I also have a better idea about how I can be more proactive with our pharmacist and more proactive with the doctor...(Carer 4)

Times when pharmacy has been helpful

Examples given when a pharmacist had been helpful included advice on medicines or side effects, providing emergency supplies or help with syncing medicines. Carers also appreciated discussions with the pharmacist in the form of a medicine use review.

I presume it's a thing that the Government have said 'look after the patients' and they actually do, you know. (Carer 6)

So it was a bit of a medicines review was it?

Yes.

Yes, and again, was your wife present for that?

She was, yes.

Right, OK, yes, was that when there was a change of medicines at all?

No.

No, they just were doing it to see how you were coping.

Absolutely.

And as a result of that did anything change?

No. (Carer 13)

Times when pharmacy could have been more helpful

In terms of being given the information they need to help them in their medication role, most family carers say they have been given information, but they had had to ask for it. By their own admission, these are often the more assertive carers and some carers felt that there could be a lot of people struggling out there who would not ask for help. There was a feeling that pharmacists need to be more proactive in terms of offering information and support. It was suggested that pharmacists could use clues such as someone running out of a medicine or having trouble syncing prescriptions as a warning sign that they may not be coping.

..having run out of something, I kind of feel it's a symptom of this is too much. (Carer 1)

Other suggestions included having someone on hand specifically to answer queries and provide support.

I know this again, this is a problem of funding, of money, but it would be great if there were more than one person in a pharmacy who had that knowledge, so that there's one person left back there doing the, you know, and they're always busy, they are always busy but if there could be one person who can then just step out and talk to customers and there's a primary pill filler, you know, prescription filler back there who can just do that all day long or they can take turns but having two people or three or

whatever they can afford so that there is one person, a knowledgeable person who's available to discuss these issues with customers and clients. So that would be nice. (Carer 4)

In terms of services provided by a community pharmacist, home delivery was said to be very useful but it was also very variable, with some pharmacies providing a better service than others. Some things could improve this, such as advance warning of delivery times.

Better liaison between the GP surgery and the pharmacy was also recommended as often this caused problems when prescriptions were not available.

Many carers were positive regarding a pharmacist having access to the patient's healthcare record as they feel it can only be a good thing for the pharmacist to know what other medicines and conditions the patient is suffering from as pharmacists are professionals and part of the healthcare team. However, confidentiality should be assured. Some had concerns regarding who would have access to it (e.g. pharmacy assistants) as they felt that the more people who have access to the data, the greater the chance of breach of confidentiality.

I suppose if you're looking at increasing the role of the pharmacist in care then of course they should have access to this. If you're not going to increase their role in care, if they're going to just remain dispensers of medication and you leave it up to the patient or the client to ask the questions which you can't rely on, you know, then they should have more information, I think it's the job of the professionals to lead the question asking, how are we to know what questions to ask. (Carer 4)

I don't see any problems with this you know, I mean they'd be covered by confidentiality anyway wouldn't they? (Carer 18)

Support from GPs and other healthcare professionals

Many of the carers were happy with the support and information they received from healthcare professionals in general.

The eye clinic is the only one he goes to very regularly at the moment and they're happy for me to sit in with him, to listen to what is said... (Carer 15)

Most carers spoke about trusting their GP and feeling able to ask him/her anything. This relationship was clearly valued by carers. However, some carers felt that GPs only paid lip service to their requests or that a locum did not listen to the care recipient.

When carers spoke about not feeling supported by or receiving help from healthcare professionals, it was often the case that they did not feel listened to or treated as expert care partners.

There was a time when I asked our contact at the Memory Clinic, I said please, I need to speak to you alone. And what happened, he was short on time so he just saw us together because he just didn't have the time and so where was my chance to speak to him privately? None. And again, nothing that I wanted to discuss was discussed so I just, I... It's a problem, I'm not blaming him because the case load is obviously...(Carer 4)

On the Monday the Registrar came round and I said to her "I think she's reacted badly to that Memantine because obviously she was agitated and she threw up" and she said to me, we had this weird conversation, because she said to me "Well no because she's not been on it long enough for there to be side-effects but we've seen some positive improvements". So I said "Well you're arguing two sides of the same coin here because how can you say someone has been on a drug long enough for there to be improvements but not long enough for there to be side-effects?" And she was going "Oh because", I said "I'm here all the time", I said "Not being funny", I said "But you see my mum in the morning on your ward rounds for like five minutes, I see her eight hours a day and I know what she was like before, you know I'm here every day". And then she said "Oh well you're too close to the, to the situation. (Carer 5)

Hospital admissions are a particularly tense time for carers. Often there was a lack of information, either as a result of lack of communication, or as a result of continuity of information flow. A change of medication on discharge was also a potential time for medication difficulties causing anxiety for carers. Experience of hospital pharmacy was variable; this was often caused by shifts and constant staff change-overs.

Was it though you didn't feel you had sufficient information that...?

Not enough information.

About the medicine changes that were going on?

Yeah. And it's not all them, I mean it is doctors that have to prescribe in the first place but when you even, what's the word I'm looking for?

Communication?

There's no, yeah, there's no communication from doctor to pharmacy and...

Right. And then down to you?

Yeah. You know, to put it across of how and whys and when's, kind of situations, which when she went in there for just a hip operation and then they started mucking around with her heart tablets, her water tablets.

No, they just done, they had the attitude they could do, "this is our patient, we'll do this, this is this team, this is that team, this is that team, do, do, do, do, do" and I'm there and I'm confused. Nobody has said "look, this is this, this is" and then because of the frustration I would then say "look excuse me, I need to see a doctor, I need to know what's happening here, I need to know what is this?" "Oh we'll just go down and see" and you just got brushed off aside literally. (Carers 7 and 8)

Did you meet the hospital pharmacist at any time during this period?

Yeah, there was loads of them. Loads of them every day, different ones entirely.

Different pharmacist every day?

Every day. Every day. And one says one, one says another, one says something else, one says something else and...(Carers 7 and 8)

Limitations

The carers recruited via community pharmacies were known to the pharmacist (hence selection by the pharmacist for possible recruitment). This could be a bias in terms of recruitment as these carers seem to have a good relationship with their pharmacist. This contrasts with some of the carers recruited from carers' centres who did not have the same relationship with their pharmacist.

Interviews with health and social care professionals

Health/social care professionals interviewed included four community pharmacists, two hospital pharmacists, one primary care (CCG) pharmacist, two Care of the Elderly consultant physicians, one hospital ward sister, one GP and one Care agency supervisor. (For further details of participants, please see Table C in Appendix 8). Two thirds of the professionals interviewed were female. One had only recently graduated in 2012, two graduated in 2008 and the remainder graduated over ten years ago (2005 or earlier).

Triangle of care: health professionals, patients and carers

In a hospital setting, the presence of the carer and the patient enables health professionals to identify carers and also to establish roles in caring for the patient.

... it can be quite difficult I think sometimes because again, it depends on the level of like, of what they want to know, so I think it's, it is helpful if the carer is present on, in the ward and then you can actually talk to them face-to-face, 'cos again, sharing information over telephone we don't, well you know obviously we're bound not to do that because we don't know who the other person on the telephone, on the end of the telephone is.

So you would never do that?

I guess it depends on the situation and if we call them at least we know, and once we've met them face-to-face as well and got all the details and everything...

I see, you've got the relationship.

...then it's kind of confirmation that you know that it's them so, but if say a relative just, or a carer just rang up over the phone to ask something, again that would be another, another case where we'd either get the family member to actually speak to them, or the patient to speak to them directly, or ask for their consent verbally if that's alright.. (Staff 10, Nurse)

From the perspective of a GP, they may have records and permissions regarding the roles of a carer: *if the patient's confused, if I go and see a patient and they're home alone and their daughter's the main carer but they're at work I might phone the carer and say 'this is'...*

Oh you would?

Yeah, this is, if I've got permission to do so and I know that they're very involved with their care then I might phone them and say, you know, 'I've just seen your mum or your dad and this is what I've done, this is what's gonna happen', so I might follow through with that, and again, we're better at documenting phone numbers and things for carers so that makes it easier. (Staff 2, GP)

Community pharmacists would usually rely on the carer identifying themselves. This often occurs when people collect prescriptions on behalf of someone else.

How would you know though if somebody is a carer when they come in?

That's a difficult one, I think like we were discussing earlier about the fact that some people don't consider themselves as carers and there isn't really like a universal definition, and I guess when people do go into the doctor's surgery to collect medications either on behalf or with a patient perhaps the doctor doesn't term them as a carer either, so they feel either that that's just their obligation as a family member or a relative or a friend or they feel slightly embarrassed sometimes to call themselves a carer because they don't feel that they're doing enough, so it's difficult at times. I think often when I'm handing out prescriptions that's when it'll come to my attention so I'll confirm, 'can I just confirm this medication is for you' or 'can I just take your name' and then it won't be the same as the person on the prescription, and that will bring to my attention 'OK, so this person is collecting on behalf' so in that way it might give me a way in, but it's still quite a tenuous way of doing it I guess, it's not that this person's coming in and introducing themselves as the carer for that patient...

(Staff 6, community pharmacist)

Sometimes a record will be made:

There's a, we have a system called ProScript which we use so basically each patient has all his details on the system along with all the medicines that are dispensed so there would be a section which is notes so we could put any notes there, for example... 'medicine always picked up by husband' or 'medicine always picked up by carer'. (Staff 3)

Supporting carers with medication

Community and hospital pharmacists make real efforts to support carers with their medicines and this can be help with formulations or organising medicines.

We try and make their life easier so say if they're in trouble crushing tablets because the patient is being fed by a tube then we would try and give liquids so if they came in with tablets we'll swap it over for a liquid and tell the GP "For ease of administration we have given this, upon discharge will you please continue supply", so yeah. (Staff 1, hospital pharmacist)

What, if anything, do you ask a carer about their medication role?

We do, there's a lot of discussions that go on regarding dosette boxes, pill boxes, so for example for the elderly a lot of them we have to do these pill boxes so we, we would have a lot of interaction with the carers regarding that because they would, for instance, call and say that they were not sure which one of the medicines, if for example, they changed the colour of the pills, or the shape or something so they would like confirm with us, 'what's in the dosette box' and a lot of carers would come in and actually pick up the dosette box for the patient so that's a lot of interactions with the carers regarding the dosette boxes for elderly. (Staff 3, community pharmacist)

However, on discharge from hospital, policies are in place that medication and discharge summaries have to be handed to the patient. Due to staffing issues, nurses go through this with them. If the patient has a carer, it was not hospital policy to wait for the carer to be present to go through any changes of medicines.

Well hospital policy at the moment, we document everything in their discharge letter so they have written information of all the changes that have happened so that's one way of informing them. The other way the hospital policy is that every patient before they go home we, pharmacy discharge,

pharmacy dispense the medication, they put the discharge letter with the medication and send it off to the ward and the Nurses go through each and every medication with the patients and the carers so they tell them they need to take this, that, so the Nurses do that.

Do you know if they wait for the carer to be present?

Ah, it's not a policy.

Okay.

But if a patient, but if the carer is there then they give it to them. (Staff 3, hospital pharmacist)

GPs tended to rely on pharmacy services to provide the support.

I think we're probably not so good at that, I think we rely on our pharmacy colleagues and I don't know how well they do it and I suspect it's very variable... I'm sure it's very variable, I mean occasionally I'll help someone to draw out, you know, a table of what they take when they take it. (Staff 2, GP)

Training in ethics

For many participants training in ethics was "just the normal pharmacy law and ethics at university (Staff 12)" and was often a long time ago, with no training since that time.

Again a chunk of our pre-registration year was to do with the ethics, law and practice MEP Guide, there is a section of the pre-registration that is solely dedicated to that. (Staff 11, community pharmacist)

In terms of top-up training since pre-registration, CPPE (Centre for Post Graduate Pharmacy Education) was found to be especially helpful. One pharmacist reported that ethical issues and confidentiality had been addressed in prescriber training. GPs also had training as an undergraduate with limited further top-up training. Hospital staff agreed that they were more familiar with informed consent, but capacity was still a difficult area for them.

What training have you had personally in ethics?

In ethics? Not an awful lot!

Not a lot! [Laughter]

I think you kind of pick up bits here and there, like you know about, obviously you know about consent and informed consent and things like that, 'cos obviously we're a surgical unit so you should know about what is informed consent and how to get that, and I guess in terms of capacity as well, knowing whether a patient's got capacity and can they, have they got the capacity to make these decisions is, yeah, I think that is more of a grey area, I think most people like consent, informed consent would probably, would know what that is and what that looks like, whereas with the Mental Health Act and capacity and things like that, that's more like a, people are like 'ooh, I'm not really sure' and 'I don't know how to do that capacity assessment' and sometimes, and again, capacity's such a big issue because it can sometimes it can be fluctuating as well...(Staff 10, Nurse)

Some participants mentioned completing in-house, mandatory, on-line courses which included coverage of the Data Protection Act, confidentiality and general ethical issues. Although they were all familiar with the term 'confidentiality' they admitted they had not given much thought to the issue, particularly in regard to carers.

Ethical situations and considerations

Staff admitted that carers now want to know more information and that litigation cases were on the increase and staff were becoming more aware. However, a hospital pharmacist admitted she did not feel confident about where she might stand legally.

Do you think your clinical practice is influenced by legal or ethical considerations at all?

I will be very silly if I say it's not, yes in a way more and more so now, yes.

....is that because you're more aware of it or you're more risk averse or why do you think that is or you think there's more carers?

I think a bit of all really, the relatives nowadays want to know more about what's going on, they also want to be better informed compared to previous rather than leaving it all to the doctors and more so we have, in recent times, there's been

And how are your practices influenced by any legal considerations or ethical considerations, does that ever affect your practice at all?

Legal, I don't even think about it.

You really don't?

Ethical, yeah, I mean like I don't want to get into trouble and I don't want to say stuff to carers or next of kin without getting consent from the actual patient so those are the things that come into my mind, saying "Okay, can I speak to the patient, can I take as much information out of them rather than go to someone else and if not, than is it okay, can I speak your wife about your medication, will she know?" And then they'll like "Okay, yeah", so it's, because it's part of a conversation but legally I wouldn't even think about it so if there's a problem than... I would have no clue where I stand legally.

No, but you, so the thing that's up in your mind is consent...

That's, from what we've been taught right, patient confidentiality, so you don't want to leak that out without taking consent from a patient so that will certainly then legally that will be a problem but that's where my thinking stops and then it turns into more of a clinical thing. (Staff 1, hospital pharmacist)

Familiarity with Pharmacy Code of Ethics or GMC Guidelines

Professionals admitted to being "vaguely" or "quite familiar" with their Code of Ethics/Guidance (e.g. hospital pharmacist, Staff 1 and hospital pharmacist, staff 5) and no one had had cause to refer to it in terms of dealing with a carer or confidentiality issues or found the guidance confusing. The same was true of the GMC guidelines. When asked how familiar healthcare professionals were with their discipline's guidelines, responses were typically as follows-

Probably vaguely familiar.

That's terrible isn't it? (Staff 7, consultant geriatrician)

Some had vague recollections of consent in terms of sharing information with third parties.

Yeah, I mean I don't remember a lot of it, but again, we would usually in the pharmacy, I mean it's usually about the patient themselves and if there is a third party involved you, they would have to provide consent for anything to be given out regarding anything. (Staff 3, community pharmacist)

Vaguely... I mean I suppose from my community pharmacy days I am familiar with the, um, whether there are bits within there in terms of how you would share that patient's information or who you're able to share that patient's information with. I wouldn't be able to recite that off the top of my head but I know that there are, there's a section in there in terms of who you are able to share that information with. (Staff 8, integrated care pharmacist)

One pharmacist had re-visited ethics as part of a leadership course, but still suggested this was not sufficient:

From your recollection of [leadership course] do you think it covers this issue of dealing with carers in terms of consent and confidentiality sufficiently?

Not sufficiently but obviously when it comes to the issue of consent it allows, provided the patient involved is able to give consent, yeah, that kind of covers it. But if the patient cannot give consent then there's like, it's like a grey area whereby it's obviously you have to use your professional judgement.

Do you feel confident using your professional judgement in ethical situations?

Not all the time.

Why? In what way?

Because sometimes you don't know if you're doing the right thing at the time

(Staff 12, community pharmacist)

In terms of interpreting the guidelines, only one person had any comment

No, I think it's pretty clear, I mean obviously you need to make sure that before you give any information to anybody else that you, that you make sure that the patient is happy with that, and that they give their consent for you to do so, and also I think in terms of information sharing within the hospital, within perhaps medical teams, Social Services, other professionals that district nurses, that kind of, who are also health professionals, again, I think there is an implied consent in there that you share information as much as people need to know that information..., 'have you gained consent from the patient' seems to be coming up more and more... I think it's definitely things are becoming more that way to make sure that patients are more involved but also that they're aware of what we're doing on their behalf as well. (Staff 10, nurse)

Some participants spoke about discussing difficult issues with a colleague if they were unsure what to do. This was easier for hospital based staff who work within clinical teams. Others spoke about referring to an indemnity provider or a legal team, but they did not refer to any other guidelines.

Requirement for more training

Almost all participants agreed that they would benefit from further training. Most participants preferred to have scenario based training and most admitted that further Guidelines might not be read. Capacity was highlighted as one area that most participants felt they would benefit from having further training.

Themes cutting across both carer and healthcare professional interviews⁵

Triangulation of carers and healthcare professionals’ data sets enabled the identification and analysis of themes from across these perspectives.

CARERS	HEALTHCARE PROFESSIONALS
Theme 1a Identification and recording of carer/ carers	
<p>Most carers took the initiative and registered themselves as a carer at their GP’s surgery. Other people had been advised to do so by the Alzheimer’s Society. However, many family carers felt that GPs had a lack of knowledge about carer rights and entitlements. None of the carers were aware of a carers’ register at their local pharmacy and most had not been asked if they were a carer by the pharmacist. Often they were known to the pharmacist, having an established relationship with the pharmacy over many years, making formal identification of their role unnecessary.</p> <p>Part of the problem about identifying themselves as a carer was that many people did not understand the term or see themselves as a carer initially. When asked how they felt about being a carer, many people referred simply to being a husband and wife or doing what needed to be done for family. Often a carers’ assessment form was a starting point for a person accepting the role. One carer felt it was assumed that she was a carer and she felt thrust into and unprepared for the role; this was particularly the case if the caring role came about as a result of an accident or hospitalisation.</p>	<p>Community pharmacists did not have protocols for identifying carers in place. The pharmacist usually relies on the carer identifying him or herself. This often occurs when people collect prescriptions on behalf of someone else and the pharmacist confirms the identity of the person and may sometimes, but not always, ask if he/she was a carer. People take time to see themselves as a carer which makes identification by healthcare professionals particularly difficult.</p> <p>In terms of logging carer information, community pharmacists made handwritten notes or put information on the patient record, e.g. ProScript. However, <i>“it’s not something that we put down as like a standard operating procedure that we must keep a log of carers.”</i> (Staff 6). Community pharmacists did not have computerised carer information for all patients. Some healthcare professionals in hospitals referred to the social history of the patient done by the junior doctors which documents carer and capacity issues. These professionals said that within 24 hours they had to find out who the patient lives with and whether they care for anyone or have formal or informal carers themselves. As the notes may not be accurate they check with the patient where possible. A hospital pharmacist would do a full medication reconciliation and required at least two sources of information. One would be the medication the patient bought in and the GP’s</p>

⁵ We have supporting quotes for these statements; for the sake of brevity in this report they have been omitted but will appear in subsequent publications

	<p>list but another source would be the patient or the carer, whoever was helping. Staff kept the question simple by asking ‘who helps with medicines at home?’ (hospital pharmacist) or ‘who helps generally at home?’ (nurse).</p> <p>Carer identification training was provided for all staff at one healthcare centre by a carers’ support centre (having obtained a grant) which meant that healthcare professionals became more proactive. Notices were in the surgery waiting room asking carers to come forward. Prior to this it was a matter of GPs getting to know patients and who was looking after them, but documentation of this was poor. However, when preparing care plans for over 75s it was routine to ask about, and document, carer roles. GP surgeries use Read Codes to record the information on the computer system and also log it on the patient notes.</p>
<p>Theme 1b Multiple carers</p>	
<p>Some care recipients had both family and paid carers. Paid carers would sometimes deal with personal care or give the family carer a break and provide company for the care recipient. Some family carers said that they “<i>had not had to go down the paid caring route yet</i>” but were aware that this may become a reality for them. Other carers were managing on their own as they had no family living nearby. Some had relatives or friends who gave them a break. However, one main person (or siblings) tends to assume overall responsibility for ordering and preparing the medicines. Yet both paid and informal carers might collect prescriptions from the pharmacy and administer medicines.</p>	<p>It was apparent from the interviews with healthcare professionals that multiple carers can cause confusion, both in terms of identifying who-is-who, but also in terms of sharing information. People have complex lives with different partners and children from various marriages. Healthcare staff in hospitals have had situations when they had to go to the legal team for an opinion and they go by what is documented in the notes as ‘next of kin’. If the patient is <i>compos mentis</i> we ask the patient <i>really who they want us to talk to (Staff 4, consultant)</i></p> <p>Some healthcare professionals mentioned an increase in the number of paid carers.</p>
<p>Theme 2 Recognition of carer as expert care partner</p>	
<p>Family carers feel they know the care recipient better than anybody yet felt they were sometimes not listened to in terms of knowing what their loved one would want or needs, particularly in a care home or hospital. Carers were not always considered to be expert care partners. e.g. one said her mother would not like to be given so many painkillers in hospital as she hates taking pills, particularly painkillers, and she can tell the way she holds her head when something is not agreeing with her. This was ignored and she could not wait to get her mother home. Carers referred to having a familiarity with the care recipient. “<i>We know her reactions, we know her contentments, we know her body language</i>”... (Carers 7 and 8). Staff might say “<i>Oh Mrs Y, it’s time to take your</i></p>	<p>Most healthcare professionals said they very much took carers’ knowledge of the care recipient and their preferences into account. Staff recognised that carers would notice if patients deteriorated after starting medication and would be aware if a patient did not like a particular medication and said they would take this into account.</p>

<p><i>medication”, whereas I never said medication, I just used to be like “It’s time for your pills mum”, because she always called them pills (Carer 5).</i></p> <p>However, other carers did feel listened to.</p>	
<p>Theme 4: Obtaining consent from care recipient to share information with carer</p>	
<p>Often consent is implied when carers go with the care recipient to GP appointments. This is not the case when carers interact with pharmacists as the care recipient is usually not present. Sometimes the GP will talk freely if the carer is present; at times in consultations with GPs/consultants, the care recipient is asked if they are happy for the carer to be present.</p> <p>A diagnosis of Alzheimer’s may mean the health care professional makes an effort to include the carer. <i>I think to be honest, ever since the Alzheimer’s diagnosis they’ve been pretty accepting of what that entails, what that actually means in terms of someone’s ability to make decisions for themselves and the importance of including the carer (Carer 4).</i> A formal carer status meant GPs were more willing to talk privately about a carer’s concerns.</p> <p>However, some carers found they were not able to deal with the care recipient’s medicines until the care recipient had signed a form agreeing to this. This could be a standard form or a letter that the carer drafted for the care recipient to sign to agree that s/he was happy for the carer to talk to the GP about their medicines.</p>	<p>Healthcare professionals said they use implied consent when patients and carers present together or the carer is sitting in the same room on a home visit. <i>I think it’s usually implicit unless something very sensitive came up or I got a funny vibe (Staff 2).</i> Some professionals said they do check with the patient if it is okay to discuss certain matters in front of a carer and obtain verbal consent. The care recipient’s wishes take precedence. Paid carers had their own care plans with a consent form to sign.</p> <p>One community pharmacist spoke about using her professional judgment in the best interests of the patient if she could not obtain consent and this would depend on the severity of the situation. If a patient refused to give consent or expressed a wish that information should not be shared with a carer, all professionals respected this, even if this meant the carer became angry. This was more the case with younger people than with the elderly who were generally happy for relatives to be involved. It could also be as a result of a family feud or having several partners (or children). If there is a safeguarding concern around a patient in hospital, then a hospital pharmacist said she would not discuss anything with a carer.</p>
<p>Theme 5: Confidentiality</p>	
<p>Most carers did not feel there was a lack of information being provided due to confidentiality. <i>“The only time when I had to ask for her information, personal or medical, health information is when she was admitted in the hospital after the stroke and because they know that I’m her husband or next of kin then they would not hesitate to give me any information ...” (Carer 10)</i></p> <p>However, test results were one area where confidentiality was highlighted and carers were unable to phone the GP surgery to obtain these.</p>	<p>Health and social care professionals recognised confidentiality more than capacity. They had more training in confidentiality, e.g. Data Protection Act so there is a balance to be achieved.</p> <p>One strategy to preserve confidentiality was to use open questions such as ‘what medicines does x take?’ (hospital pharmacist)</p>
<p>Theme 6: Assessment of Capacity and Power of Attorney</p>	
<p>Some carers had obtained a full Power of Attorney, having been advised to do so by Age UK or Alzheimer’s Society. <i>“Really you should get Power of Attorney, Court of Protection</i></p>	<p>Pharmacists and other healthcare professionals did not take capacity into account and admitted they would not be confident in terms of assessing it. Some community pharmacists</p>

<p><i>because technically people can adjust her care without consulting you because even though you're next of kin they could if they thought it was in her best interests, you know, adjust stuff or do stuff without your consent. (Carer 5)</i></p>	<p>adapted the Fraser/Gillick guidelines for younger people to make a crude assessment of capacity for older people. Another had experience of the MMSE. One or two community pharmacists were proactive and informed the GP if they felt the care recipient did not understand information. Several healthcare professionals admitted they were only just getting to grips with the Mental Capacity Act and 'best interests' of a patient. Some people referred to the social history of the patient which would document capacity issues. If the patient is not able to understand information, hospital staff would inform the next of kin.</p>
<p>Other carers only referred to having the one covering financial decisions not recognising that there were two types. A couple of interviewees commented that it was costly and time consuming to obtain. Few carers had been asked whether they had power of attorney.</p>	

Discussion: Integration of findings from the review and interviews

Unique role of pharmacists

This study has identified that pharmacists, more so than other healthcare professionals, need guidance on how to support carers; in particular as community pharmacists often see the carer alone (unlike other healthcare professionals) and they commonly work in isolation without a multi-disciplinary team with whom to discuss dilemmas.

- Community pharmacies do not have formal procedures for identifying carers or access to any systems maintained by healthcare professionals;
- Pharmacies may employ locum staff and healthcare assistants who may interact with carers;
- Carers may use several pharmacies;
- Patients may have multiple carers, ranging from family members to paid carers, causing particular difficulties for pharmacists;
- Hospital pharmacy is different from community pharmacy in that the hospital pharmacist may see patients and carers together on admission or discharge, facilitating the triangle of care. Also, admission to and discharge from hospital may often require new medicines and/or adjustments to existing medicines, potentially causing uncertainty and a need for support for the carer.

No consistent definition of 'carer'

Our study has shown that people who help others with medicines do not always see themselves as carers and pharmacists are not always aware of who might help a patient with their medicines. Various definitions of carer are in use. The term 'Informal carer' was not widely liked by carers, and there are difficulties regarding the distinction between paid and unpaid carers. Potentially anyone can assume the role of carer and people move in and out of caring roles. Often the role is shared between family members and/or paid carers. The study also found that carers take time to identify themselves as such. Carers are more likely to come forward if a description of what is meant by the term is given, and some practical help is offered.

With respect to pharmacy services an inclusive definition of 'a person who assists someone else with their medicines in any way' may be most relevant. The spectrum of care provided by a carer can be very wide (e.g. collecting prescriptions may be a minor but important role) and may make identification of a carer, or self-recognition as a carer, very difficult. A broad definition will include both those who do self-identify, as well as others who provide more limited assistance, but who,

along with the people they care for, may benefit from the information and support that comes with being identified as a carer.

Lack of protocols to identify carers

Our study found that identification protocols for carers were often not in place in healthcare systems. The review found more guidance for GP surgeries than pharmacies in terms of identifying and recording carer status. *Supporting Carers: An action guide for general practitioners and their teams: 2nd edition (The Princess Royal Trust for Carers & The Royal College of General Practitioners)* suggests possible ways to identify carers (although the focus was not on people who help with medicines): at registration; self-identification, using posters, newsletters; opportunistically, e.g. flu vaccination, when carers make appointments for patients and manage repeat prescription requests, when they bring patients to appointments or are present during home visits; list searches, e.g. patients with certain conditions often have carers; at diagnosis or on hospital admission or discharge or via carer's organisations. A suggested example of good practice in Triangle of Care⁶ included having a discussion with the service user to establish if anyone was providing significant care. This is recorded and shared. There have been examples of community pharmacies working with carers' centres to identify carers (e.g. information in prescription bags) but these have been to advertise the support of carers' centres rather than for pharmacy services (e.g. Moray Carers' Centre).

Similar approaches may be effective in community pharmacy (e.g. PSNC, 2015, is exploring possible approaches to identify informal carers and provide support). However, due to the informality of the setting and the fact that the pharmacist will commonly see the carer (but not the patient) and the need to identify people who assist with medicines who may not self-identify as carers, specific and tailored systems may be required. For example, simple triage questions to identify people who assist someone else with medicines and to establish their roles could be developed and employed. Also, triggers, such as new prescription items, or running out of medicines, may provide opportunities for pharmacists to be proactive in identifying where support may be needed and offering services.

Recording of carer status

Some medical centres have 'Is carer' added to their problem list on their medical records. This a read code which then makes carers eligible for additional support and allows them to be sign-posted to services. Pharmacists, however, admitted that they did not have a systematic method of recording carer/people who help with medicine status, although at times this was noted on the PMR. In many situations carers may be well known to local pharmacists. Our interviews with pharmacists and carers indicate that this relationship is valued and provides a framework for pharmacy support. However, a lack of systematic recording could potentially lead to difficulties in ensuring that issues of confidentiality and consent are observed by all pharmacy staff. Recording and regular updating is necessary to take account of changing roles and situations of patients and carers (e.g. as disease progresses). This could become a formal part of pharmacy IT systems for patient medication records and the Summary Care Record. Assuming confidentiality would be assured, our study found that most carers were in favour of the pharmacist having access to a summary care record, recognising that this may be beneficial for pharmacy services. If pharmacists' access to patients' medical records becomes more routine, then pharmacists will need to be even more mindful of the risk of breaching patient confidentiality by disclosing information to the carer. However, the record could also provide an opportunity for details of carers' roles and patient consent for disclosure.

⁶ A Guide to Best Practice in Mental Health Care in England Second Edition- a joint publication by the National Mental Health Development Unit and the Carers Trust.

Lack of policy guidance for pharmacists in relation to carers

Our study found that policy guidance is vague and does not address the range of ethical issues that supporting carers, or consultations with any third party, can present to pharmacists who rely on professional judgment. The legislation makes reference to a need for carer involvement in healthcare and for information and support to be provided to carers as part of their “rights” but our review found a lack of policy guidance on how to involve carers, especially for pharmacists, and particularly when there might be conflicting responsibilities to patient and carer. The Guidance on patient confidentiality from GPhC (2012) recommends that pharmacists exercise their professional judgment and make decisions about disclosing information on a “case-by-case basis”, without further direction. Hence there is a gap between the complexities of the ‘triangle of care’ and policy guidance. Guidance indicates that patients should come first, for example, a joint statement by the GPhC and RPS *Using standards and guidance to ensure patient centred professionalism in the delivery of care* (July 2014) states that patient-centred care should be at the heart of everything that pharmacists and pharmacy teams do. It was unclear how this responsibility to patients is to be reconciled with the pharmacist’s responsibility to, and putative rights of, carers, when the two conflict.

This lack of guidance was also identified in the *Positive and Inclusive report* (Pinfold et al., 2005), which focused on mental health and highlighted a lack of a robust carer focus and conflicting statements on information sharing with carers. Policy guidance was inconsistent and scattered in a range of documentation (as in our review). The report found that: “Current professional codes neither explore nor develop the moral ground that lies between carers’ needs for information to enable them to care and the service user’s need for privacy. Professionals are uncertain about what they may share and carers are often unaware of their rights. “The need to balance rights with responsibilities deriving from advances in case law and the Human Rights Act 1998 is an imperative for constructing an ethical basis to enable professionals and carers to share appropriate information for the benefit of service users and patients.”(pg 31).

The literature found that, in the absence of explicit and specific guidance, pharmacists draw on more general principles. If pharmacists use a common sense approach rather than a code of ethics, this could mean that different pharmacists, faced with the same facts and circumstances, may be responding to the same ethical dilemma in different ways. In the absence of detailed guidance, it would seem that at least in some contexts, a range of responses could be justifiable and therefore legitimate (Hibbert et al., 2000). While the law is generally more explicit, interpretation is sometimes required and ethical issues may conflict with the law. Situations arise in pharmacy practice whereby strict adherence to the law may not be in the patient’s best interests and their treatment.

Obtaining service user consent by pharmacists

Our study found that consent was not obtained routinely from patients in order to share information with carers in community practice. Everyday pharmacy practice is often not conducive to the consent process as the pharmacist may not be able to see the patient. Dilemmas may therefore be faced by pharmacists, who are expected to simultaneously maintain legal and duty of care responsibilities in the patient consent process (Roche & Kellier, 2009).

The *Positive and Inclusive report* (Pinfold et al., 2005) recommended that consent should be collected *before* information is shared with carers. A suggested example of good practice in Triangle of Care was that professionals should establish what level of information the service user agrees may be shared with the carer. This may be full, partial or no disclosure and the decision should be

recorded. The Royal College of Psychiatrists and the Princess Royal Trust for Carers (The Carers' Trust) compiled checklists for carers, service users and professionals to aid communication (Partners in Care, 2004) and to provide carers with the support they need from their GP or health centre. They suggest that (where appropriate) the person they care for gives their consent. They advise carers that often consent will be implied if carers accompany patients to see their GP. They provide a patient confidentiality form at the back of a leaflet which patients and carers can sign in the presence of a healthcare professional giving consent to information about their health to be discussed with their carer and agreeing to carers having information about diagnosis and treatment.

At a medical centre in London, a warning comes up on the computerised medical records which states whether there are specific people who the patient has agreed can have access to their records (a scanned document with a consent form is kept in the records).

Procedures must also be in place for when consent is not given. Slade et al. (2007) devised a framework for best clinical practice when consent is not given to share information with carers (see Appendix 9). If the service user wishes no disclosure, these wishes must be respected, but staff should regularly revisit this decision. Careful consideration is needed on how the carer(s) can still be offered support and general information.

These examples focus on medical practice rather than pharmacy practice, but may be helpful in informing any initiatives in community pharmacy. One difference is that the health professional in medical practice will see both patient and carer. An approach is required that enables observance of the law and ethical principles, and is feasible in a pharmacy setting

Knowledge of guidance

Most healthcare professionals, including pharmacists, said they were only vaguely or quite familiar with their professional guidance. Pharmacists work in isolation and often call a colleague for advice rather than refer to guidance. There have been calls for research to update ethical competence guidelines for practising pharmacists (Wingfield et al., 2004). Wingfield & Badcott (2007) discuss the drawbacks of having a code of ethics, claiming that these documents frequently need interpretation and rarely apply to all situations. Given the complexity of the issues around carers, this seems an important point in the current context. If it is too detailed such a document is unlikely to be read, and takes away professional judgement. If it is too general, it is unlikely to be useful.

Ethics knowledge

Our review found that pharmacists are not very familiar with ethics, with most not having had any training since their degree. Patient confidentiality and capacity were not well understood, although the former was reported as being addressed in pharmacist prescriber training and this may provide a model which could be adapted for further training which should focus on the triangle of care. Most pharmacists support people who help others with medicines ad hoc, generally unaware of patient capacity or consent or confidentiality issues and information is provided in the patients' best interests. Health professionals tend to believe in the right of an individual to privacy and are trained more in patient confidentiality than information sharing (Leggatt, 2001). In contrast to medicine and nursing, Cooper et al. (2007b) highlighted the paucity of studies concerning ethical practice in community pharmacy. Only a small number were undertaken in the UK, and none focused on the needs of carers. Little has been published in journals on the core values that might underpin pharmacy ethics, particularly in this area.

Wingfield et al. (2003) question whether current pharmacy ethics and law teaching equips pharmacists for the accountabilities now expected in practice, given the heightened prospect of litigation and the ever expanding regulatory challenges of a risk averse society. They also question whether it creates "value literate" practitioners who can identify and address the ethical issues that arise in practice. Support for carers presents an additional dimension. Professionals should receive training in the application of confidentiality and information sharing which should be ongoing. Where the research literature does examine ethical issues, the most common method is to employ the "scenario approach" (Wingfield et al., 2004) for example, the study by Wills et al. (2002) (pg 17).

Lack of awareness of the role of pharmacy services / pharmacist

Our study found that there is a general lack of awareness among patients and carers of the expanded role of pharmacy services. Carers therefore may not be aware of the information and support that could be provided, which places an onus on the pharmacist to be proactive in offering advice. However, there is much that is unclear from the perspectives of pharmacists and carers regarding how their needs should be met in the context of existing legal and ethical frameworks.

Professionals now run the risk of carer litigation if carers are not provided with information. The RPS is proud of the fact that there has never been a case before the Statutory Committee (or, since 2010, the Fitness of Practice Committee) for unlawful disclosure of information (Mullan, 2003) and no case law has been found in relation to pharmacists and carers. However, as pharmacists take more proactive roles to support patients in achieving optimal outcomes from their medicines, robust systems and practices regarding support for carers must be in place. This research can provide a basis for informing guidelines, training and systematic procedures regarding identifying people who help others with medicines, recording this information, and obtaining consent, including in cases where capacity may be limited.

Key recommendations

1. Who is a carer ?
<ul style="list-style-type: none"> • A definition is required that works for pharmacy services, so a starting point might be to identify "a person who assists someone else with their medicines in any way". This broad definition will include both those who do self-identify as carers, but also others who provide more limited assistance, but who, along with the people they care for, may also benefit from information and support.
Further research could be undertaken to assess the application of this definition for pharmacy services and carers.
2. Identification of carers
<ul style="list-style-type: none"> • A pharmacy agreed method of identifying carers is required and one method might be to formulate triage questions. Possible triggers could be new prescription items, which could indicate a new diagnosis, or a patient running out of medicines. Carers are more likely to come forward if a description of what is meant by the term is given and some help is offered. • Pharmacies to collaborate with GP practices, where systems and approaches to identify carers are also being developed. This could be at CCG level.
Further research could test this triage question.
3. Raising awareness of how pharmacy teams could help those who help others with medicines
<ul style="list-style-type: none"> • Self-identification of people who help with medicines could be supported by local and national campaigns and voluntary organisations using posters and advertising, e.g. via the library, local council website or social media: <i>'do you help someone with their medicines?' If so, your pharmacy could.....</i> • Pharmacists could be more proactive in offering advice and services. Carers or people who help

with medicines could be involved more explicitly – e.g. in MURs or NMS.
4. Pharmacists’ obtaining patient consent to share information
<ul style="list-style-type: none"> Pharmacists need guidance on how to obtain consent when the patient is not present.
Further research is needed to develop feasible methods and a suitable tool to obtain consent.
5. IT systems and recording of carer status
<ul style="list-style-type: none"> Community and hospital pharmacy system suppliers could add a field for carers which would include one which recognises any carer with medicines responsibility. This could also be recorded on the e-discharge and paper discharge forms. The system could also record consent information and be regularly updated. This information needs to be shared with healthcare professionals in primary and secondary care.
Further research could consider how this information can be recorded, maintained and accessed by community pharmacists
6. Supporting pharmacy teams to develop their role in terms of carer support
Policy guidance
<ul style="list-style-type: none"> The Pharmacy Code of Ethics is currently under review (2014-5). Our work suggests that pharmacists would benefit from guidance as part of the code of ethics as to how they could support people who help with medicines on an informal basis and this would include identification of such people, recording their details, the ethics of working with them to support patients and recognition of them as an expert partner in patient care. Stakeholders could inform guidance which could be endorsed by carers’ organisations. General Pharmaceutical Council could include the pharmacist/pharmacy working with relevant carers within their assessment tools.
Work with the RPS and GPhC to develop guidance and professional standards for inclusion in ‘Medicines Ethics and Practice’.
Training
<ul style="list-style-type: none"> Bespoke training programmes for pharmacists could be developed to upskill the workforce drawing on components from other courses that are available and adding in components which are not covered, such as capacity assessment. Subjects could include consent, confidentiality, information sharing and capacity (cognitive functioning, dementia). Training could be online, face to face or run as a CPPE workshop, in the form of case studies or scenario-based. Develop peer mentoring and support groups to embed and strengthen pharmacy role.
Further research could consider how pharmacist prescriber training may inform a model; and assess the feasibility and value of training to support carers in pharmacy settings.

REFERENCES

- Auguste, V., Guerin, C. & Hazebroucq (1997) Opinions and practices with regard to confidentiality in French hospital pharmacies. *International Journal of Pharmacy Practice* 5: 122-127.
- Bartlett, P. (2013) The United Nations Convention on the Rights of Persons with Disabilities and Mental Health Law. *Modern Law Review* 75(5): 752-778.
- Benson, A., Cribb, A. & Barber, N. (2009) Understanding pharmacists' values: A qualitative study of ideals and dilemmas in UK pharmacy practice. *Social Science & Medicine* 68: 2223–2230.
- British Medical Association (1999) Confidentiality and disclosure of health information toolkit. London: BMA.
- Carers UK (2011) Valuing Carers. London: Carers UK.
- Carers UK (2014) Facts about Carers. London: Carers UK.
- Carers UK (2006) In the Know. London: Carers UK.
- Carers week (2013) Prepared to Care? Exploring the impact of caring on people's lives.
- Centre for Pharmacy Postgraduate Education (2014) Consultation Skills for Pharmacy Practice: practice standards for England
<http://www.consultationskillsforpharmacy.com/docs/docb.pdf>
- Chaar, B., Brien, J. & Krass, I. (2005) Professional Ethics in Pharmacy: the Australian experience. *International Journal of Pharmacy Practice* 13: 195-204.
- Clements, L. (2012). Carers and their rights: the law relating to carers (5th Edition). Carers UK: Cargo Publishing.
- Collopy, B.J. (1988) Autonomy in long term care: some crucial distinctions. *Gerontologist* 28 (Suppl): 10-17.
- Cooper, R.J., Bissell, P. & Wingfield, J. (2007a) Dilemma in dispensing, problems in practice? Ethical issues and law in UK community pharmacy. *Clinical Ethics* 2: 103-108.
- Cooper, R.J., Bissell, P. & Wingfield, J. (2007b) A new prescription for empirical ethics research in pharmacy: a critical review of the literature. *Journal of Medical Ethics* 33: 82–86.
- Craigie, Jillian (2015) A fine balance: reconsidering patient autonomy in light of the UN Convention on the Rights of Persons with Disabilities. *Bioethics*:
<http://onlinelibrary.wiley.com/doi/10.1111/bioe.12133/abstract>
- Cribb, A. & Entwistle, V. (2011) Shared decision making: trade-offs between narrower and broader conceptions. *Health Expectations* 14(2): 210–19.
- Deans, Z. (2008) PhD The ethics of pharmacy practice: an empirical and philosophical study. Keele University.
- Deans, Z. (2010) Ethics in Pharmacy Practice. London: Pharmacy Practice Research Trust.
- Department of Health (1992) The Patient's Charter. London: Department of Health.

- Department of Health (1999) *Caring about Carers: A National Strategy for Carers*. London: Department of Health.
- Department of Health (2000) *Pharmacy in the future: implementing the NHS Plan*. London: Department of Health.
- Department of Health (2001) *Guidance 12 Key Points on Consent: the Law in England*. London: Department of Health.
- Department of Health (2010) *Responsibility and Accountability- Moving on for New Ways of Working to a creative, capable workforce*. Best Practice Guidance. London: Department of Health.
- Department of Health and National Information Board (2014) *Personalised Health and Care 2020 Using Data and Technology to Transform Outcomes for Patients and Citizens: A Framework for Action*. London: Department of Health.
- Edwards S.J.L., Brown, P., Twyman, M.A. Christie, D. & Rakow, T. (2011) A qualitative investigation of electing surrogate decision-makers. *Journal of Medical Ethics* 37: 601-605.
- Francis, S.A., Smith, F., Gray, N. & Denham, M. (2006) Partnerships between older people and their carers in the management of medication. *International Journal for Older People Nursing* 1: 201-7.
- Gillespie, R., Mullan, J. & Harrison, L. (2014) Managing medications: the role of informal caregivers of older adults and people living with dementia: a review of the literature. *Journal of Clinical Nursing* 23: 3296-3308.
- Goldstein, R. & Rivers, P. (1996) The medication role of informal carers. *Health and Social Care in the Community* 4(3), 150-158.
- Goodwin, V. & Happell, B (2006) Conflicting agendas between consumers and carers: The perspectives of carers and nurses. *International Journal of Mental Health Nursing* 15: 135–143.
- Gray, B., Robinson, C., Seddon, D. & Roberts, A. (2008) Confidentiality smokescreens and carers for people with mental health problems: the perspectives of professionals. *Health and Social Care in the Community* 16(4): 378-387.
- HM Government (2008) *Carers at the heart of 21st century families and communities*. London: HM Government.
- HM Government (2010) *Recognised valued and supported: Next Steps for the Carers' Strategy*. London: HM Government.
- Hattingh, H. L., Knox, K., Fejzic, J., McConnell, D., Fowler, J. L., Mey, A., Kelly, F. and Wheeler, A. J. (2015) Privacy and confidentiality: perspectives of mental health consumers and carers in pharmacy settings. *International Journal of Pharmacy Practice* 23: 52-60.
- Herring, J. (2013) Forging a relational approach: best interests or human rights? *Medical Law International* 13: 32-54.
- Hibbert, D., Rees, J. A. & Smith, I. (2000) Ethical awareness of community pharmacists. *International Journal of Pharmacy Practice* 8: 82–87.
- Hird, M. (2003) Aspects of consent and how it impacts on pharmacy practice. *The Pharmaceutical Journal* 271: 240-242.

- Hughes, J.C., Hope, T., Reader, S. & Rice, D. (2002) Dementia and ethics: the views of informal carers. *Journal of the Royal Society of Medicine* 95: 242-246.
- Knight, D.A., Thompson, D, Mathie, E. & Dickinson, A. (2011) Seamless care? Just a list would have helped! Older people and their carers' experiences of support with medication on discharge home from hospital. *Health Expectations* 16: 277–291.
- Leggatt, M. (2001) 'Carers and carer organisations' in Thornicroft, G. and Szmulker, G. (eds) *Textbook of Community Psychiatry*, pp.475-486. Oxford: Oxford University Press.
- Lloyd, L. (2006) Call us carers: Limitations and risks in campaigning for recognition and exclusivity. *Critical Social Policy* 26: 945-960.
- Machin, G. (2004/ postscript 2012) Carers and Confidentiality: Law and Good Practice. Conference paper.
- Mullan, K. (2003) What prescribing pharmacists need to know. *The Pharmaceutical Journal* 271: 152-155.
- NHS England (2014) NHS England's Commitment to Carers.
- NHS England (2014) The NHS 5 Year Forward View.
- Office for National Statistics (2012) Population Ageing in the United Kingdom, its Constituent Countries and the European Union. London: Office for National Statistics.
- Office for National Statistics (2013) Census Analysis: Unpaid care in England and Wales, 2011 and comparison with 2001. London: Office for National Statistics.
- Pinfold, V., Farmer, P., Rapaport, J., Bellringer, S., Huxly, P., Murray, J., Banerjee, S., Slade, M., Kuipers, E., Bhugra, D. & Waitere, S. (2005) Positive and Inclusive? Effective ways for professionals to involve carers information sharing. Report to the National Co-ordinating Centre for NHS Service Delivery and Organisation R & D (NCCSDO).
- Poland, F., Mapes, S., Pinnock, H., Katona, C., Sorensen, S., Fox, C. & Maidment, I. (2014) Perspectives of carers on medication management in dementia: lessons from collaboratively developing a research proposal. *BMC Research Notes* 7: 463.
- Pharmaceutical Services Negotiating Committee (PSNC) Briefing 001/15 (2015) Support for carers – how community pharmacy teams can help.
- Richardson, G. (2012) Mental disabilities and the law: from substituted to supported decision-making? *Current Legal Problems* 65(1): 333–351.
- Roche, C. & Kelliher, F. (2009) Exploring the patient consent process in community pharmacy practice. *Journal of Business Ethics* 86: 91-99.
- Sankar, P., Moran, S., Merz, J.F. & Jonrdx, N.L. (2003) Patient perspectives of medical confidentiality: a review of the literature. *Journal of General Internal Medicine* 18: 659-669.
- Sally, G. & Donaldson, L.J. (1998) Clinical governance and the drive for quality improvement in the new NHS in England. *British Medical Journal* 317(7150) 4 July pp.61-65.
- Shalowitz, D.I., Garrett-Mayer, E., & Wendler, D. (2006) The Accuracy of Surrogate Decision Makers: A Systematic Review. *Archives of Internal Medicine* 166(5):493-497.

Silva, A.L., Teixeira, H.J., Teixeira, M.J.C. & Freitas, S. (2013) The needs of informal caregivers of elderly people living at home: an integrative review. *Scandinavian Journal of Caring Sciences* 27: 792-803.

Slade, M., Pinfold, V., Rapaport, J., Bellringer, S., Banerjee, S., Kuipers, E. & Huxley, P. (2007) Best practice when service users do not consent to sharing information with carers. National multimethod study. *The British Journal of Psychiatry* 190: 148-155.

Smith, F.J., Francis, S-A., Gray, N.J., Denham, M. & Graffy, J.P. (2003) A multi-centre survey among informal carers who manage medication for older care-recipients: problems experienced and development of services. *Health and Social Care in the Community* 11(2): 138-145.

Smith, F.J. (2007) Patient safety and patient error: the carer's perspective. *The Lancet* 369: 823.

Smith, A & Darracott, R. (2011) *Modernising Pharmacy Careers Programme Review of pharmacist undergraduate education and pre-registration training and proposals for reform Report to Medical Education England Board.*

Smith, F.J., Grijseels M.S., Ryan, P. & Tobiansky, R. (2015) Assisting people with dementia with their medicines: experiences of family carers. *International Journal of Pharmacy Practice* 23: 44–51.

The Royal College of General Practitioners and the Princess Royal Trust for Carers *Supporting Carers: An action guide for general practitioners and their teams (2nd Edition).*

Travis, S.S., Bethea, L.S. & Winn, P. (2000) Medication hassles reported by family caregivers of dependent elders. *Journals of Gerontology: Medical Sciences* 55A:M412–M417.

Wahlich, J., Stegemann, S. & Orlu-Gul., M. (2013) Medicines for Older Adults: Learning from Practice to Develop Patient-Centric Drug Products. *International Journal of Pharmaceutics* 456: 251-257.

Wills, S., Brown, D. & Astbury, S. (2002) A survey of ethical issues surrounding supply of information to members of the public by hospital pharmacy medicines information centres. *Pharmacy World Science* 24(2): 55-60.

Wingfield, J., Wilson, K. & Hall, S. (APPLET) (2003) What should we be teaching students about pharmacy law and ethics? *The Pharmaceutical Journal*. 270 No 7244: 515-516.

Wingfield, J. (2003) Consent and Decision Making for patients who lack capacity: what should pharmacists know? *The Pharmaceutical Journal* 271: 463-464.

Wingfield, J., Bissell, P. & Anderson, C. (2004) The scope of pharmacy ethics – an evaluation of the international research literature 1990-2002. *Social Science and Medicine* 58: 2383-2396.

Wingfield, J. & Badcott, D. (2007) *Pharmacy Ethics and Decision Making.* London: Pharmaceutical Press.

General Pharmaceutical Council

Standards of Conduct, Ethics and Performance (2012)
Guidance on Patient Confidentiality (2012)
Guidance on Consent (2012)
Guidance on Raising Concerns (2012)

Medicines, Ethics and Practice

The Professional Guide for Pharmacists Edition 39 (2015)

Royal Pharmaceutical Society

Professional Standards and Guidance for the Sale and Supply of Medicines
Emergency Supply: A Guidance on Professional Practice (2011)
Professional Standards for Homecare Services (2013)

General Medical Council

Confidentiality: Protecting and providing information (2000)
Guidance for Doctors - Consent: Patients and doctors making decisions together (2008)
Guidance for Doctors: Confidentiality (2009)
Good medical practice Consent guidance: Involving families, carers and advocates (2013)

British Medical Association

Confidentiality & Disclosure of Health Information (1999)

Health & Care Professions Council

The standards of conduct, performance and ethics (2012)

Nursing & Midwifery Council

Standards for medicines management (2010)
The Standards of conduct, performance and ethics for nurses and midwives (2015)

Caldicott Guardian Manual (2006)

Department of Health

Practitioner's Guide to Carers' Assessments under the Carers and Disabled Children Act 2000(2001)
Developing Services for Carers and Families of People with Mental Illness (2002)
Confidentiality: NHS Code of Practice (2003)

National Service Frameworks

For Mental Health (1999)
For Older People (2001)

NICE

Clinical guideline 76 (2009) Medicines adherence Involving patients in decisions about prescribed medicines and supporting adherence
Clinical guideline 138 (2012): Patient experience in adult NHS services: improving the experience of care for people using adult NHS services
Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes (2015)

Care Quality Commission Outcome 9

(Management of Medicines) of the Essential Standards of Quality and Safety (2010)

The NHS Constitution for England (2015)

Statute Law - Medicines	Legislation type
Medicines Act 1968 (Primary legislation)	UK Public General Acts
Human Medicines Regulations 2012 (SI 2012/1916) (Secondary legislation)	UK Statutory Instruments
Regulation 214 Human Medicines Regulations 2012	UK Statutory Instruments
Regulation 238 and Schedule 19 of the Human Medicines Regulations 2012	UK Statutory Instruments
The National Health Service (Pharmaceutical Services) Regulations 2005	UK Statutory Instruments
The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (2013 No. 349)	UK Statutory Instruments
Miscellaneous Legislation	
Data Protection Act 1998	UK Public General Acts
Access to Health Records 1990	UK Public General Acts
Health and Social Care Act 2008 (Regulated Activities) Regulations 2010	UK Statutory Instruments
Mental Health Act 1959	UK Public General Acts
Mental Health Act 1983	UK Public General Acts
Mental Health Bill 2004	
The Mental Capacity Act 2005	UK Public General Acts
Human Rights Act 1998	UK Public General Acts
Equality Act 2010	UK Public General Acts
Carers (Recognition and Services) Act 1995 Act	UK Public General Acts
Carers and Disabled Children Act 2000	UK Public General Acts
Carers (Equal Opportunities) Act 2004	UK Public General Acts
NHS & Community Care Act 1990	UK Public General Acts
Care Act 2014	UK Public General Acts

List of Appendices (available from the author upon request)

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