

**Homely Remedy Protocols: A solution to the supply and administration of
non prescription medicinal products and dietary supplements by nurses to
research participants in non NHS settings**

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Summary

Patient Group Directions, although widely used since their introduction in the late 1990s, are not widely reported in the literature. However, when described it is recognised that their use are inappropriate for non prescription medicinal products or for use outside NHS settings. This paper thus describes a suitable alternative to Patient Group Directions, for use in research participants requiring non-prescription medicinal products in their own homes, the Homely Remedy Protocol.

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Introduction

The National Centre for Social Research (NatCen), including the Scottish Centre for Social Research, is the largest independent social research institute in Britain, designing, conducting and analysing research studies in social and public policy, informing policy and public debate (www.natcen.ac.uk). NatCen has a dedicated Health and Lifestyles research department responsible for implementing large scale complex studies such as the *Health Survey for England* and the *National Diet and Nutrition Survey*. These studies require survey nurses to visit research participants of all ages, including young children, in their own homes, to obtain objective information from a range of measurements (such as blood pressure) and frequently includes blood sampling from some respondents. To undertake these studies, survey nurses are employed on a freelance basis and are overseen by ten regional nurse supervisors who are similarly employed. Certain measurements within the studies conducted by NatCen require nurses to provide respondents with a vitamin supplement and also to offer a topical anaesthetic gel to facilitate venepuncture. However, how the survey nurses are legitimated in the distribution and use of such products has hitherto been problematic.

This paper sets out to discuss the position of Patient Group Directions (PGDs) and a rationale for implementing Homely Remedy Protocols (HRPs) as an alternative to PGDs, to facilitate the distribution and use of over the counter (OTC) supplements and Pharmacy (P) listed medicines within NatCen. OTC supplements are those which can be bought openly within health food shops, supermarkets and other stores and include some dietary supplements and herbal remedies. P listed medicines may only be acquired under the supervision of a pharmacist (National Prescribing Centre (NPC) 2004) and may include certain antihistamine preparations, including sleep remedies, and tetracaine (Ametop[®]). Neither OTC supplements nor P listed medicines require a prescription. Those medicines which do require a prescription are known as

Prescription Only Medicines (POMs) and within the remit of this paper are discussed only to provide a backdrop for HRP development within NatCen.

Current studies co-ordinated by NatCen indicate that nurses may be required to distribute and/or use medicinal products and dietary supplements which fall into both OTC and P listed categories. These include: tetracaine (Ametop[®]), a P listed medicinal product and Para-Aminobenzoic Acid (PABA), a non-essential nutrient derivative of folic acid (www.naturaldatabase.com) and an OTC dietary supplement. Consequently the current provision and use of these two products provide the rationale for this paper. A medicinal product is defined as any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals (Nursing and Midwifery Council (NMC) 2007). Consequently, both Ametop[®] and PABA may be seen as 'medicinal products' since they could be deemed to modify physiological functions.

Patient Group Directions

Patient group protocols were introduced in the 1990s following the publication of the first Crown Report (Department of Health (DH) 1989) in which recommendations were made that community nurses, after appropriate training, should be enabled to prescribe specified medications (Dimond 2003). The supply and administration of medicines under group protocols by hospital-based nurses followed this initiative in 2000 (Dimond 2003, Home Office Circular 049/2003, NPC 2004). Group protocols later became known as Patient Group Directions (PGDs) (Dimond 2003, Baird 2005) and provide a legal framework to certain health care professionals to supply and administer medicines to groups of patients (NPC 2004). PGDs apply to groups of patients who might not otherwise be individually identified (Miles 2001), are designed to promote speedy and effective responses to their needs (Miles 2001, Gibson et al. 2003) and to legitimise hitherto 'unofficial' prescribing, particularly by

Clinical Nurse Specialists (CNSs) (Gibson et al 2003). They: *'have also been advocated for use in those situations where it is impractical to obtain a prescription for a named patient'* (Jones 2002:371). The aims of a PGD should be to enhance the patient/client experience, compliance and outcome and to make effective use of healthcare professionals' time (Anon 2006, Siriwardena 2006). Along with many nurses, patients and medical practitioners have generally welcomed the introduction of PGDs (Siriwardena 2006).

A PGD is: *'a written direction relating to the supply and administration ... of a prescription only medicine... which.. is signed by a doctor .. and a pharmacist and relates to the supply and administration, or to the administration, to persons generally'* (Statutory Instrument 2000 cited in Royal College of Nursing (RCN) 2004a). A PGD is not a form of prescribing (NPC 2004). Excluded within PGDs are: new drugs falling within the black triangle scheme (Box 1), unlicensed medicines, medicines used outside their licensed indications and medicines used in clinical trails (Jones 2002, Dimond 2003). However, revisions to these exclusions are constant, legislation concerning exclusion criteria alters frequently and there are exceptional circumstances when PGD use for medicines falling within these excluded groups is legitimate (RCN 2004a). Further exclusions concern their use by staff extrinsic to the NHS, independent hospitals, agencies and clinics registered under the Care Standards Act (2000), the prison health care services, police services or defence medical services, and include those working in care homes and the independent sector (NPC 2004, Griffiths 2007). This legislation suggests that NatGen falls within the exclusion criteria for PGD usage.

To be lawful, a PGD must be authorised by a Health Authority, an NHS Trust, a Primary Care Trust (Dimond 2003), or by an organisation registered with the Healthcare Commission (Griffiths 2007) or Care Standards Act 2000 (NPC 2004). Directions within a PGD must be compiled by a senior doctor and senior pharmacist giving registered nurses, pharmacists and other specified healthcare

professionals authority to supply and administer POMs (Home Office Circular 049/2003). They are devised through interprofessional collaboration (Dimond 2003, NPC 2004, Anon 2006). PGDs are now widely used in NHS community and hospital-based settings (Miles 2001, Jones 2002, Deave et al. 2003, Gibson et al. 2003, Baird 2005, Siriwardena 2006, Baileff 2007). Where they should not be used is within the independent sector and arenas external to the NHS (RCN 2004b). Consequently, it is becoming increasingly recognised that the provision and use of medicinal products, outside NHS settings, other than through a doctor's prescription, is problematic (e.g. Jones 2002). Thus, the provision and use of medicinal products, other than POMs, outside these settings is currently under debate.

How PGDs are used

In practice, a PGD, signed by a doctor, agreed by a pharmacist and authorised by the organisation in which it is used (NPC 2004), enables nurses, midwives and affiliated health care professionals, such as occupational therapists, to supply and/or administer POMs to patients. The application of a PGD follows assessment of patient need, without necessarily referring back to the prescribing doctor (RCN 2004a, Baird 2005). Despite their frequent use, PGDs have not been widely reported in the literature since their introduction in the late 1990s (Baileff 2007, Miles 2001, Gibson et al. 2003). Nurses working under the guidance of PGDs are often experienced clinical nurses in senior positions, such as clinical nurse specialists (Miles 2001, Gibson et al. 2003), where PGDs have been approved by the relevant health authority (Miles 2001, RCN 2004a). PGDs are frequently used in specialist areas where drugs appropriate to the speciality are regularly required (Gibson et al. 2003) and the impetus to develop a PGD commonly arises from the health care professional who will most commonly use it (Baird 2005).

The law is clear that PGD use should be reserved for situations advantageous to patient care which are consistent with appropriate professional relationships

and accountability and which do not compromise patient safety or identity (NPC 2004, RCN 2004a). The RCN interprets this to mean that PGDs should only be used to supply and/or administer POMs to homogenous patient groups where presenting characteristics and requirements are sufficiently consistent for them to be included in a PGD (RCN 2004). Examples of such homogenous patient groups reported in the literature include: women with sexual health needs requiring anti-biotic creams and pessaries (Miles 2001), those attending NHS walk-in centres where anti-biotics are provided (Deave et al. 2003, Baileff 2007), children receiving immunisations and adults requiring travel vaccines (Jones 2002, Jordan 2004, RCN 2004a, Anon 2006), people requiring treatment for anaphylaxis (Jones 2002); people, particularly women, requesting contraception (Jones 2002, RCN 2004a) and where children with a variety of chronic illnesses are treated homogeneously (Gibson et al. 2003). Specific to the needs of NatGen, another key homogenous group of patients for whom PGDs are considered are those requiring local anaesthesia (Jones 2002). Key guidance in PGD use is currently provided through the Pharmacy Community Liaison Group (Taylor and Machell 2004) and the National Prescribing Centre (2004) and requirements for inclusion within a PGD are also documented (Jordan 2004, NPC 2004, RCN 2004a).

The benefits of PGDs

Clear benefit to patients has been derived from using PGDs. For example, an audit of PGD use, by CNSs, in a sexual health clinic, demonstrated that the number of prescriptions required from a doctor reduced from 35.4% to 16.9% of a CNS caseload (Miles 2001). One consequence of this reduction in doctors' prescriptions was to decrease the waiting time for hospital attendees (Miles 2001). Others have considered that PGD use similarly enhances patient/client experiences and makes effective use of health care professionals' time (Anon 2006). To ensure benefits of PGDs are maintained and to comply with the principles of clinical governance, a prerequisite in their use concerns annual auditing (Jones 2002, Dimond 2003, NPC 2004, Baileff 2007). Ways in which

audits into PGD use are undertaken are a matter for local debate (Jones 2002). However, audits of PGDs are described in the literature and include meticulous inspection of notes maintained by nurses (Miles 2001, Baileff 2007). To examine the auditing process more closely, it has been suggested that at the very least audits should comprise: *'which practitioner treated which patient, with which medicine, at what dose, by what route and on what date'* (Jones 2002:372). They should also include annotations of whether the PGD is followed in practice, whether patients have been involved in any adverse incidents and benefits to patients (Jones 2002). Benefits for staff of PGD use may arise from the multidisciplinary collaboration required to compile a PGD (Anon 2006).

The disadvantages of PGDs

PGD audit can also reveal some disadvantages in their use. For example, an audit on the provision of anti-biotics through PGD use, by CNSs, to women in a sexual health clinic, revealed that PGDs were probably used inappropriately due to *candidiasis* management not being defined according to locally accepted practice (Miles 2001). These findings are consistent with research undertaken across a number of Walk-in Centres which demonstrated low compliance levels with PGD requirements (Deave et al. 2003).

A further perceived disadvantage concerns a lack of national guidance on PGD compilation. Although advice is proffered nationally on when PGDs might be required (NPC 2004, Taylor & Machell 2004) and what should be included within a PGD (NPC 2004, RCN 2004a), recommendations urge PGDs to be drawn up at a local level (RCN 2004a). One consequence of this guidance has resulted in an inconsistent approach to PGD formulation which, in turn, may result in poor compliance, as outlined above (Deave et al. 2003).

Additional disadvantages of PGD use are associated with what has been termed 'non-medical prescribing' and include a lack of experience in assessment and diagnosis by those other than doctors (Sirwardena 2006). In addition, no

systems currently exist to monitor reporting of drug errors. It has also been suggested that in the current political climate, there may be a reluctance to report drug errors or perverse disincentives to reporting (Sirwardena 2006). Consequently, whilst a number of benefits to PGD use are documented, perceived disadvantages to their use are given almost even measure.

Training in PGD use

Authors writing on PGDs provide a united consensus that training in PGD use is not essential (Jordan 2004, NPC 2004, Anon 2006, Baird 2005). Further, whilst a PGD competency framework exists to aid organisations in training and development programmes (NPC 2004), there is no standardised education provided to nurses in their use (Anon 2006). Nonetheless, previous research has identified a need by nurses who regularly 'prescribed' on an informal basis, for education into this area of role expansion (Gibson et al. 2003) and it is incumbent upon employing organisations to ensure that users of PGDs are competent in their use (NPC 2004).

One solution to education regarding PGDs has been to provide local, in-house training (Baird 2005). However, in Gibson et al.'s study (2003) nurses who valued education into this expanded role were not specific about who they perceived appropriate to provide such education or what their educational needs comprised. These findings are compounded by Dimond (2003) who suggests that nurses should receive appropriate training and supervision without stipulating what 'appropriate' entails.

More recent literature has been clearer about education required by nurses who undertake PGD training (Baileff 2007). This includes: educational preparation in basic pharmacology, history taking and physical assessment, management of minor illness, exacerbations of chronic disease and emergency presentation. The recognition for education in PGD use and in prescribing more generally has resulted in some hospital environments expanding nurse prescribing (Gibson et al. 2003).

Assessing the competent use of PGDs

Whilst it has been suggested above that training is not viewed as essential, PGD training has been viewed as good practice towards attaining competent practitioners (NPC 2004). Competence in PGD use has previously been determined using frameworks comparable to those outlined by the NMC, as central to the role of the advanced nurse practitioner, and those developed by the NPC (NPC 2004, Baileff 2007). For nurses using PGDs within an NHS walk-in centre, competency in PGD use has been assessed to determine knowledge and skills. These skills and knowledge have, in turn, been determined through participation in a multiple choice pharmacology exam paper, an assessed physical examination, an observation of practice and a professional conversation (Baileff 2007).

Nurse Prescribing

Nurse prescribing was first highlighted in the Cumberledge Report during the late 1980s (DHSS 1989). However, the initiative was not implemented until pilot studies were undertaken during 1994 with district nurses (Gibson et al. 2003). Later, in April 2002, the nurse prescribing initiative was expanded to allow for a wider range of nurses to prescribe from an extended formulary and in April 2003 supplementary prescribing was introduced (NPC 2004). More recently, confusion has existed between prescribing and PGD usage and which is the most appropriate for what circumstances (NPC 2004).

Due to the slow implementation of the nurse prescribing initiative, it is unsurprising that that one natural consequence of PGD use has been to increase nurse prescribers in some NHS Trusts (e.g. Gibson et al. 2003). Thus, nurse prescribing has been enhanced through PGD implementation and a number of NHS Trusts now view PGDs as a stepping stone towards nurse prescribing (Gibson et al. 2003). However, not all nurses, particularly those in junior positions, are eligible to become prescribers and so there are still many who

could usefully benefit from PGDs (Jones 2002). Even when nurses are eligible to become prescribers, the education required to take on this extended role may be resource intensive, both in terms of time and cost. For example, education programmes usually prepare nurses with at least three years experience, at degree level (Jones 2002, Baird 2005). This education may be of at least three months duration within a higher education institute (Jones 2002, Jordan 2004) and be followed by an element of supervised practice (Jordan 2004). Not all nurses may wish to undertake such education (Jones 2002), have attained the required experience or be provided with the financial resources to do so.

Homely Remedy Protocols

Despite a number of NHS organisations building on PGDs to enhance nurse prescribing, such initiatives are not, as outlined earlier, appropriate or legal for those working outside those areas earlier identified or in arenas where small numbers of medicinal products are used. Neither do they apply to medicinal products other than POMs. Therefore, one alternative to both nurse prescribing and PGD use, in organisations such as NatCen, extrinsic to the NHS and not registered with the Healthcare Commission or Care Standards Act 2000, and to the dispensing and use of medicinal products other than POMs, lay in Homely Remedy Protocols (HRPs).

HRPs are poorly reported in the literature and to date no definition of HRPs has been elicited. However, it can be said that HRPs are not prescriptions or directives but protocols to facilitate the supply and use of OTC or P listed products in homes or within the independent sector, where health care professionals are required to facilitate this process. Thus, HRPs may be applied to Ametop[®] and PABA and are appropriate for use by NatCen.

To date, HRPs have had little publicity and their use has been limited to settings including care homes, children's homes and some educational

institutions (NMC 2007). Some guidance in HRP use is provided to school nurses working in the independent sector, by the RCN (RCN 2004b). Within this guidance, it is recognised that the Medicines and Healthcare products Regulatory Agency (MHRA) restricts the use of PGDs within independent schools where P or POM medicines are required, whilst acknowledging instances when such medicines might need to be administered. Under such circumstances, it is advised that patient specific directions (Box 2) are required or that nurses are contracted by local primary care organisations. Thus, it acknowledges difficulties for nurses working outside the NHS and outside the MHRA restrictions in administering P listed medicines.

HRPs have no legal standing yet they are recommended for liability purposes. Paralleling PGD use, any registered nurse using a HRP must ensure there is a written instruction that has been drawn up and agreed in consultation with other relevant qualified professionals (NMC 2007). Where possible this should be a medical practitioner or pharmacist. The protocol should clarify what product may be administered and for what indication it may be administered, the dose, frequency and time limitation before referral to a medical practitioner. Examples of a HRP for an OTC product could be those prepared for St. John's Wort or Vitamin C supplementation. All registrants using the protocol should be named and they should sign to confirm they are competent to administer the medicinal product, acknowledging they will be accountable for their actions. The NMC consider it good practice that the employing organisation signs off all protocols (NMC 2007).

Conclusion

This paper has outlined the evolution and increasing use of PGDs within community and hospital based services within the NHS. It has further suggested that PGD use is increasingly and currently leaning towards further advancement of nurse prescribing. In setting the scene for HRPs, it has highlighted the

inappropriate and unlawful use of PGDs outside NHS settings and those organisations not registered with the Healthcare Commission or the Care Standards Act 2000. It has also highlighted the importance of audit and for education of nurses working according to PGDs.

Consultation with key players in the field of nurse prescribing and PGD use and a review of available literature shed light on an alternative to PGDs and nurse prescribing which suits the needs of nurses working in settings extrinsic to the NHS - the Homely Remedy Protocol. The HRP is thus currently viewed by NatCen as a potential means of addressing the hitherto problematic difficulties in the supply and use of two medicinal products, PABA and Ametop[®]. Whilst Ametop may not traditionally be viewed as a 'homely remedy' in the truest sense, it can be argued that combating pain associated with venepuncture, in a research participants own home, could 'remedy' this pain, and thus be deemed a 'homely remedy'. To this end, a policy to introduce HRP use as a safeguard to both nurses working within NatCen and to the organisation, from litigation has recently been introduced and two HRPs developed, adopting a multidisciplinary approach.

It is recognised that whilst much medication administration by nurses occurs within NHS settings or within recognised research units, the situation encountered by NatCen can by no means be unique. It is thus anticipated that this paper sheds light on this little documented issue and facilitates others who may grapple with providing and using medicinal products with healthy persons away from NHS health and conventional clinical trials research settings.

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Box 1

The black triangle scheme refers to the prescription of new drugs which are subject to monitoring for potential side effects by the MCA (Dimond 2003)

Box 2

Patient Specific Directions refers to administration of medicine specified for a particular recipient, by a medical doctor