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Is there clinical evidence of the efficacy of medicinal products extemporaneously dispensed in community pharmacies?

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Focal points

- The aim of the project was to search for evidence of clinical effectiveness for extemporaneously dispensed medicinal products
- Data was collected on 1,146 medicinal products dispensed in 97 community pharmacies in a two-month period in 2001
- Many of the products with clinical evidence of their effectiveness were those provided by specials manufacturers, whereas most prepared in the community pharmacies investigated had little or no evidence to support their use
- Pharmacists will find it difficult to ensure that prescriptions for extemporaneous products are sage and appropriate, satisfy clinical guidelines and represent evidence-based practice

Introduction

Since July 2001, a requirement of the service specification for the dispensing of extemporaneous preparations has been that "pharmacists must be satisfied as to the safety and appropriateness of the formula for the [extemporaneous] product".[1] An aspect of the dispensing process covered by a standard operating procedure, mandatory form January 2005, is that "the pharmacist's professional input into the assessment of the safety and appropriateness of a prescription . . . should be explicit". Additionally, the Royal Pharmaceutical Society of Great Britain (RPSGB) policy document on clinical governance in pharmacy[2] states that quality improvement activities should include "clinical guidelines/evidence-based practice".

In order to fulfil these requirements, pharmacists need evidence of the clinical effectiveness of extemporaneously prepared medicinal products. This project aimed to search for that evidence.

Method

Data collectors in 97 community pharmacies gathered information relating to all extemporaneously dispensed products and specials dispensed during a two-month period during 2001. Clinical evidence of effectiveness was sought initially in the British National Formulary, then in Martindale, with other sources used if necessary. Each medicinal product was categorised from 1 to 5 (Table 1).

Results

Two hundred and twelve stores were recruited and information was returned from 97, representing a 45.75 per cent response rate. The number of extemporaneous items dispensed was 1,146 (range 2 to 54 per store), comprising 404 different medicinal products. These were grouped as shown in Table 2.

As no evidence of improved effectiveness of corticosteroids as a result of dilution or mixing with other ingredients could be found, all such topical products were categorised as 3. Most other topical products were categorised as 1,2 or 3, notable exceptions being menthol in aqueous cream and glyceryl trinitrate 0.2 per cent ointment. All the liquid formulations, which were provided by Rosemont or specials manufacturers were categorised as 5 and the other products included all categories.

Table 1 Categorisation of medicinal products

Number allocated	Meaning	Percentage of total items (n = 1,146)
1	Obsolete/not recommended/no evidence of efficacy	14.0
2	Similar/alternative licensed product(s) available	9.3
3	Not known – insufficient information found	41.8
4	Some justification for prescription of product	15.3
5	Fully justified – no alternative found	19.6

Table 2 Grouping of extemporaneous items dispensed

Type of medicinal product	Number of dispensed items	Percentage of total (n = 1,146)
Topical products containing corticosteroids	338	29.5
Other topical products	356	31.0
Upper respiratory tract (URT) medicines	51	4.5
Gastro-intestinal (GI) medicines	46	4.0
Liquids (BNF drugs not formulated as liquids)	128	11.2
Others (includes injections, drops, unusual forms or strengths	227	19.8

Discussion

Many of the products with clinical evidence of their effectiveness were those provided by specials manufacturers, whereas most prepared in the community pharmacies investigated had little or no evidence to support their use. Given these circumstances, community pharmacists will find it difficult to ensure that prescriptions for extemporaneous products are safe and appropriate, satisfy clinical guidelines and represent evidence-based practice.

References

1 Royal Pharmaceutical Society of Great Britain. Medicines, ethics and practice: a guide for pharmacists. London: RPSGB; 2001.
2 Royal Pharmaceutical Society of Great Britain. Achieving excellence in pharmacy through clinical governance. London: RPSGB; 1999.