

Off-label prescribing of inhaled corticosteroids to children with asthma in primary care

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Introduction: Inhaled steroids (ICS) are commonly prescribed to children in the community. Asthma management guidelines recommend use of ICS at the minimum effective dose, however in paediatric populations' studies have suggested that ICS are commonly used off-label at higher than recommended dose. This practice has been associated with increased risk of adverse drug reactions in children.

Aims: To determine the extent and pattern of off-label ICS prescribing to children in primary care.

Methods: Retrospective observational survey of primary care prescribing data for children aged 0-18 years prescribed at least one asthma medication between September 2001 and August 2006 using the Practice Team Information (PTI) database. Children issued one or more ICS prescriptions were identified and their mean daily dose calculated. The licensed recommendations applicable at the time of ICS prescription issue were obtained from the summary of product characteristics and The British National Formulary. A prescription was considered off-label if it was for a formulation, age group, or dose not licensed for use in children.

Results: During the five-year study period, 48490 ICS prescriptions were issued to 7092 children, 16% (8032) of which were off-label. 14% (980) of all children prescribed an ICS 980 were issued with at least one off-label prescription. Higher than recommended dose was the main reason for an off-label prescription in 65% (638) of children prescribed off-label ICS. Over the 5 year study period there was a significant decrease in off-label prescribing due to dose with a significant increase in off-label prescribing due to age and formulation (Table 1).

Table 1

Reasons for off-label	2001-2	2002-3	2003-4	2004-5	2005-6	2001-6
Age (%)*	(9)	(11)	(15)	(18)	(22)	(16)
Formulation (%)	(20)	(25)	(30)	(37)	(40)	(33)
Dose (%)	(79)	(74)	(67)	(58)	(49)	(65)
Total (%) [†]	(13)	(11)	(13)	(13)	(13)	(14)

As medications in an off-label category can be classified under more than one group, totals may add up to more than a 100%. *Percentage of patients with one or more off-label prescription. [†]Percentage of total children on inhaled corticosteroids.

Conclusions: During the 5 year study period the proportion of children prescribed off-label ICS has remained constant. However the reasons for an ICS prescription being off-label have demonstrated a significant change over time.