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EDITORIALS

Safety of medicines delivered by homecare companies

Inadequate surveillance threatens patient safety and public health

Anthony Matthews *research fellow in statistical epidemiology*, Liam J Donaldson *professor of public health*, Stephen J Evans *professor of pharmacoepidemiology*, Sinéad M Langan *associate professor*

Department of Non-Communicable Disease Epidemiology, London School of Hygiene and Tropical Medicine, London, UK

Delivery of specialised medicines through homecare companies can help transform the lives of those with conditions requiring regular treatment and monitoring.[1] However, the scope and quality of surveillance of medicines delivered in this way in the UK are currently not good enough to provide the protection that patients should expect.

The two routes through which NHS patients have traditionally received medicines are hospital based specialist services and primary care. In the mid-1990s, the UK government opened up a third route, homecare services, to supply medicines directly to patients with long term conditions such as multiple sclerosis, or those requiring complex treatments such as peritoneal renal replacement therapy. NHS hospital doctors prescribe these medications, but they are delivered and sometimes administered directly to patients at home by commercial homecare providers rather than the patient making regular trips to the hospital or collecting them from a pharmacy.

Homecare services have become an increasing priority for the NHS. They improve accessibility for patients but also save money as drugs delivered directly to patients are free of sales tax.[2] The cost savings means that the route is used for many new, expensive, and specialised drugs. Although such drugs are fully licensed by the UK Medicines and Healthcare Products Regulatory Agency (MHRA), the knowledge base supporting them is often limited. Prescribing through homecare is rapidly expanding, with a market value exceeding £1.5bn (€1.7bn; $2bn) in 2016.[3]

Two reviews for the Department of Health[1 4] recommended that all drugs prescribed through the homecare route should be recorded in hospital pharmacy systems. However, among 47 respondents to a questionnaire we distributed to 126 acute hospital trusts in England (37% response rate), only 28 claimed that all of their homecare medications were processed through the hospital pharmacy. Capture of homecare medications in hospital pharmacy systems may be even lower in the 63% of trusts that did not respond. This situation seriously compromises the validity of large scale pharmacovigilance studies in the post-licensing phases of these medications. The lack of linkage of hospital prescribing systems to longitudinal patient data with clinical outcomes exacerbates the problem.

Safety of medications prescribed by general practitioners can be monitored using databases such as the Clinical Practice Research Datalink.[5] However, drugs prescribed through the homecare route are not regularly captured in general practitioner records, so our ability to use these databases to explore safety is limited. The innovative nature of many homecare prescribed drugs makes it vital that all prescriptions are recorded fully in hospital pharmacy systems. Linkage of these systems to other electronic health records is also essential. The NHS must at least have knowledge of the benefits and harms of new and expensive medicines.

Researchers have been unable to explore serious safety signals from homecare medications. For example, several case reports have pointed to a potential causal association between interferon beta, a treatment for multiple sclerosis, and thrombotic microangiopathy.[6] Interferon beta is regularly delivered to patients' homes, so use may be under-reported in hospital prescribing systems. Researchers also have little opportunity to link any existing hospital prescription records to patients' clinical records. The true incidence of interferon beta induced thrombotic microangiopathy in the UK therefore remains unknown, and large scale epidemiological studies to investigate this possible causal link are currently impossible.

Commercial homecare providers, like all NHS providers, are expected to report suspected adverse drug reactions to the MHRA through the yellow card scheme.[7] Employees of homecare providers delivering these drugs may not be fully aware of the importance of reporting adverse reactions, a cornerstone of drug safety in the UK. Since the MHRA does not record the employers of people making a yellow card report, evidence on reporting behaviour among homecare providers is unattainable. It is imperative for patient safety that all homecare providers fully report any suspected adverse reactions to the MHRA and that the source of reports is recorded, so any under-reporting can be identified.

The current surveillance system for drugs delivered through homecare is so weak that it is a ticking time bomb. The inability of researchers to accurately investigate adverse event signals from the many drugs prescribed through this route has the potential to compromise patient safety and public health through

Correspondence to: A Matthews anthony.matthews@lshtm.ac.uk

a serious safety failure. Urgent action is needed to protect both, and to fully understand the benefit-risk profile of new and innovative medications.

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