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Restoring Confidence in Vaccines by Explaining Vaccine Safety Monitoring

Is a Targeted Approach Needed?

Rachel E. Casiday[1] and *Anthony R. Cox*[2]

1 School for Health, Centre for Integrated Health Care Research, Wolfson Research Institute, Durham University Queen's Campus, University Boulevard, Stockton-on-Tees, UK
2 Aston Pharmacy School, School of Life and Health Sciences, Aston University, Birmingham, UK

Abstract

Public trust in childhood vaccines is crucial to achieving adequate immunisation coverage to ensure population-level immunity. However, in the UK, immunisation uptake has been adversely affected by vaccine safety scares, such as those surrounding whooping cough and measles, mumps and rubella (MMR). It is our belief that greater public awareness of safety surveillance schemes may play a key role in improving trust in vaccine safety.

Many parents of vaccination-age children are unaware of the procedures in place for postmarketing surveillance of vaccines. Thus, we propose specific steps for generating such awareness, such as assisting parents to report suspected adverse reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card scheme, providing information about adverse reaction reporting with vaccination information packs, and displaying posters and leaflets to convey the message that patient concerns and experiences are taken seriously by the MHRA and to generate further awareness about the scheme. In addition, healthcare staff should be encouraged to report suspected adverse reactions relating to vaccine products.

Unresolved issues about the scientific usefulness of data reported by parents and the potential for these steps to increase parental concern and expectations require further investigation.

Public trust in childhood vaccines is a critical public health issue because of the need to preserve herd immunity to vaccine-preventable disease. However, the fact that vaccines are given to healthy individuals, in particular to children, makes the communication of risk and the benefit-risk decision-making by parents particularly difficult. Spontaneous reporting of suspected adverse drug reactions (ADRs), undertaken in the UK through the Yellow Card scheme, performs the vital task of postmarketing surveillance of vaccines and other medicines.[1] However, many parents are unaware of this process and how it works. Greater public awareness of this mechanism for monitoring drug safety may play a key role in improving trust in vaccines. Therefore, we propose specific steps that might be taken to increase parental awareness of, and access to, the Yellow Card scheme for reporting adverse reactions to vaccination in order to improve trust and uptake of childhood vaccines.

1. The Yellow Card Scheme

The UK's Yellow Card scheme, which has been in place since 1964, collates spontaneous reports of suspected ADRs, including those ascribed to vaccines. Doctors are encouraged to report serious suspected reactions (i.e. ones that are fatal, life-threatening, medically significant, disabling, incapacitating or result in hospitalisation) to currently marketed drugs (including vaccines) and all suspected reactions, no matter how trivial, to drugs under intense surveillance (marked in the British National Formulary by an inverted Black Triangle symbol). Additionally, in the case of paediatrics, all reactions should be reported regardless of severity. The scheme is administered by the Medicines and Healthcare products Regulatory Agency (MHRA, previously the Medicines Control Agency), who use the data for postmarketing surveillance and detection of drug safety signals. However, spontaneous reporting schemes commonly suffer from under-reporting, with a median rate of under-reporting of 94%, although there may be an enhanced reporting culture with regard to vaccines.[2]

2. Parental Concerns about Vaccine Safety

ADR reporting is especially important for vaccines, whose efficacy depends on widespread uptake and hence on public confidence in their safety. In the UK, immunisation uptake has been damaged during vaccine safety scares, such as those surrounding whooping cough[3] and, more recently, measles, mumps and rubella (MMR).[4] Although 10 of the 12 authors of the paper that seeded the debate about MMR vaccine[5] retracted any interpretation causally linking MMR vaccine and autism,[6] and the alleged association with autism has been refuted both epidemiologically[7] and in virological studies,[8,9] parental concern, which has been fuelled in many cases by widespread media coverage,[10] has remained.

Public distrust in vaccine safety makes it difficult to attain adequate immunisation coverage in the population.[11,12] Although not a particular concern before the MMR controversy, a number of studies in the wake of the MMR controversy have shown that many parents are concerned that the safety trials and monitoring for vaccines are inadequate.[11,13,14] For instance, 79% of parental respondents to a multiple-choice postal survey in a primary care trust agreed with the statement "More time is needed to be able to fully investigate the effects of the MMR vaccine".[11]

In focus groups and interviews with parents of young children (n = 87) conducted by Dr Casiday[15] between November 2002 and October 2004, parents expressed concern that vaccine adverse reactions might not always be reported to central registries. Several parents (11 of 87) spontaneously described instances in which they, or others they knew, had presented concerns following vaccination to their doctors that were not taken seriously. This concern led to distrust in the large-scale studies and official statistics cited by government and medical authorities to demonstrate the safety of the MMR vaccine.

Most parents at the time of interview were unaware of how vaccines were tested for safety before licensing, and few were familiar with the Yellow Card scheme for postmarketing surveillance. Only 2 of 87 interviewees expressed any knowledge of the scheme, although not all were explicitly asked about this topic. Even parents whose children experienced frightening reactions were often unaware of the scheme. However, nearly all the parents interviewed said that a well publicised mechanism for reporting and investigating parental claims of adverse reactions caused by vaccines would increase their confidence in vaccine safety.

These findings highlight two impediments to reporting vaccine reactions via the Yellow Card scheme: (i) difficulties (real or perceived) in convincing a doctor to report a suspected reaction and (ii) poor public awareness of the scheme. These impediments may have contributed to under-reporting in some cases, and certainly contributed to widespread distrust in the government's surveillance of vaccine safety. Thus, measures to open the scheme to direct parental reporting, publicise the scheme and show how data from ADR reporting are used to evaluate safety, and provide advice to parents on

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when and how to report suspected reactions are a welcome development because these may make a significant contribution to parental confidence and boost vaccine uptake rates.

3. Recent Steps Towards Patient Reporting

Changes in the relationship between patients and providers of healthcare have led to increasing pressure for the introduction of patient reporting. Supporters suggest that patient reporting may discover safety signals earlier than healthcare professional reporting. A small study in The Netherlands found patients reported ADRs 7 months earlier than professionals.[16] Patients may also provide qualitatively different reports. A comparison of emails prompted by the BBC current affairs programme 'Panorama' and Yellow Card reports relating to selective serotonin reuptake inhibitors provided qualitatively rich experiences of adverse reactions,[17] although many details of reactions were missing. At present, only a few countries actively encourage patient reporting of ADRs: Denmark, the US and The Netherlands.

The MHRA's experience of patient reporting is relatively recent. Small pilot studies of patient reporting were launched in the UK with National Health Service (NHS) Direct in April 2003. Patient reports were taken by NHS Direct staff acting as learned intermediaries. Disappointingly, the scheme received a limited number of reports and patient groups argued that professional involvement had prevented patients' qualitative experiences from being collected. The gate-keeping role professionals have held in reporting ADRs can act as a filter, removing ADRs deemed important by the general public. Regulatory authorities are left open to the accusation that genuine public concerns are not reported. In 2004, the Independent Review of Access to the Yellow Card Scheme report recommended that a direct patient reporting system should be introduced.[18]

Re-launched as a pilot scheme in January 2005 and rolled out nationally in October 2005, the revised patient-reporting scheme includes an electronic form for reporting ADRs, a telephone number and a paper form. In the first 6 months of 2005, the MHRA received 407 patient reports, which they considered to be of a similar quality to those from healthcare professionals.[19] The MHRA also plan an evaluation of the patient reporting scheme in 2007, which will investigate patient experience and involvement in the scheme as well as the scientific value of the reports. This is a welcome move by the MHRA. At present, the published evidence for a positive contribution of patient reporting to pharmacovigilance systems is limited.

However, scientific concerns are not the only consideration. As previously noted, under-reporting of ADRs by health professionals is a concern by the public in drug safety controversies. When The Netherlands Pharmacovigilance Centre Lareb started collecting patient reports, half the patients in the first 6 months of the scheme said that the fact their health professional did not listen to their complaint about a possible ADR, or a lack of confidence that a report would be submitted, was a reason for filing their report.[20] Even if the Yellow Card data reported directly by patients are no more useful scientifically than data reported by healthcare staff only, the political advantages of such a system should not be minimised.

4. Childhood Vaccination as a Special Case for Yellow Card Reporting: Proposals

We welcome the steps taken by the MHRA to open the Yellow Card scheme to patient reporting. However, to achieve maximum benefits in terms of public trust and uptake of immunisation, we propose a targeted approach for expanding coverage and awareness of the Yellow Card scheme with respect to vaccines:

1. Encouraging and educating healthcare staff to report suspected ADRs for vaccines. Recent debates about pharmacology training in medical education[21] underline the importance of ADR reporting as a key component of undergraduate education.[22] We do not advocate mandatory reporting; however, we suggest that asking about and reporting reactions

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could be more formally adopted in the vaccination schedules. For example, during the meningitis C vaccination campaign in 2000, nursing staff were extremely effective at reporting ADRs.[17]

2. Providing information to parents about how vaccine surveillance works and how suspected reactions may be reported. Care should be exercised to provide this information in such a way as to minimise anxiety or expectation of adverse reactions. An appropriate way to provide this information may be with vaccination information distributed by health visitors, for example as a section entitled 'How do we monitor and ensure the continued safety of vaccines?'

3. Providing posters and leaflets for display in general practices and other clinics where vaccines are given, conveying the message that patient concerns and experiences are taken seriously by the MHRA and generating awareness about the scheme. The MHRA currently provides such posters to general practices, but special attention is needed to ensure that these materials get displayed.

4. Ensuring healthcare staff are able to advise patients, parents and others on how to fill in Yellow Cards if asked and can direct queries appropriately.

5. Issues Requiring Further Research

The interviews demonstrating a need for greater awareness of ADR reporting for vaccines[15] were conducted prior to the national roll-out of the direct patient reporting initiative, and evaluation is required to determine the extent to which the measures already taken have increased parental awareness of and confidence in vaccine ADR reporting. In addition, we identify two potential drawbacks with the proposals that we have outlined for promoting ADR reporting for childhood vaccines, which will require further investigation:

1. Increasing the visibility of adverse reaction reporting for vaccines might increase, rather than allay, parental concerns about vaccine safety, although careful placement and phrasing of this information should minimise this risk. It may be worthwhile to conduct a randomised controlled trial with a nested qualitative study to assess this possibility before introducing such measures at the policy level.

2. Patient reporting raises an expectation of 'results'; how feedback to the public will be managed will require careful consideration. If patient reports about vaccines reflect biases from media reporting of vaccine scares, regulatory bodies will need to develop effective communication strategies that enable them to explain the scientific basis for why this may not represent a vaccine safety issue. In-depth qualitative investigations of why parents (and other lay people) report ADRs and what they expect to happen when they report should inform these communication strategies.

However, despite these potential drawbacks, we judge that the measures proposed here would likely make important contributions to improved public confidence in the safety monitoring of vaccination.

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Correspondence and offprints: Dr *Rachel E. Casiday*, School for Health, Centre for Integrated Health Care Research, Wolfson Research Institute, Durham University Queen's Campus, University Boulevard, Stockton-on-Tees TS17 6BH, UK.
E-mail: r.e.casiday@durham.ac.uk

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