system has come from, how it developed, and where it is going. The current system began a little over 40 years ago in the wake of the thalidomide disaster. Although it has continued to evolve gradually, the basic principles and powers laid down in the 1960s have not changed, and adverse drug reactions remain an important cause of morbidity and mortality.[9]

Drug usage can be made safer through advances in safety science. A model for excellence in pharmacovigilance has been proposed,[10] and some principles from that have gained widespread acceptance—for example, the development of safety specifications and pharmacovigilance plans for enhanced surveillance and reporting of drug related harms. These principles, which will become legal requirements in the European Union later this year, focus particularly on how knowledge on the safety of new drugs can be extended after marketing.

There is already an international guideline that is based on these principles, produced by the International Conference on Harmonisation,[11] a body that brings together government regulators and drug industry representatives from the United States, the European Union, and Japan to make international drug regulatory processes more efficient and uniform. The International Society for Pharmacoepidemiology, which provides a forum for the open exchange of scientific information and for the development of policy, education, and advocacy in this field, has also considered these issues and proposed ways to increase safety.[12]

The success of these improvements depends on the strategic coordination of such work and the necessary political support to make things happen. Drug safety, however, is a political graveyard. The priority afforded to this issue and the powers available to enforce it have advanced very little in the past few decades, and influential politicians who might have championed the cause have been conspicuously absent from the debate. Political pressures exist to restrain public expenditure and reduce regulation in health care generally, but if the goal is greater safety through more effective regulation then politicians should understand that new powers and resources will be more important than focusing on the effectiveness of regulators, looking for new people to do the job, and proposing yet more organisational change.

In particular, although clear separation is sensible between people responsible for licensing medicines and those responsible for monitoring postmarketing safety, the case for completely separate (and therefore new) agencies has yet to be made. It would be more logical to rethink the regulatory powers underpinning postmarketing safety of drugs: these were enshrined in law in the 1960s and have advanced little since.

Furthermore, policymakers and politicians internationally focus too much on the efficacy and cost effectiveness of medicines at the expense of safety. It is now time to grasp the nettle, improve the evidence base on harms, and focus on regulating safety to at least an equal extent.

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Attempts to prevent postnatal depression

Interventions have not included mental health workers, and have failed

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A systematic review published in this week's *BMJ* concludes that the many psychosocial or psychological interventions tested so far in trials do not effectively prevent postnatal depression.[1] Because this is an important disorder arising from around one in eight births, the authors call for more research on intensive support at home in the postnatal period.[1] As little as 20 years ago, however, there was debate about whether postnatal depression was an important problem at all. It was too often dismissed as only a minor, transient problem with coping. So what happened in the meantime to warrant these trials of possible prevention?

In 1989 the prevalence of depression among women eight months after birth in population based surveys in Victoria, Australia, was 15.4% (95%

P+ *Two additional references (w1 and w2) are on bmj.com*

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confidence interval 12.8% to 18.0%)[2] and two subsequent studies found very similar prevalences and confidence intervals.[3 4 w1] Depression was defined in these studies as a score of ≥13 on the Edinburgh postnatal depression scale: a score of 10-12 out of a possible total score of 30 is sometimes used as the threshold for detecting depression (or possible depression when there is no confirmatory clinical diagnosis.[5])

The response of an anonymous obstetrician to the 1989 findings was highly critical: "Severe postnatal depression occurs in very few women (probably only 5 in every 1000 delivered) but minor problems in psychiatric condition are seen in many women during the first weeks after the birth of a child as they learn to cope with a new baby and all its demands, along with all of the demands of living in the 1980s and 1990s. To imply that the vast majority of these women have postnatal depression is surely a fabrication of the truth."[w1]

A follow-up study of the first survey[2] found that almost a third of the women scoring as depressed (or, strictly speaking, probably depressed) at eight months were still depressed, or were depressed again, 12 to 18 months later.[6] Only 15% of the women defined as depressed had sought help from, or been referred to, any mental health professional. The lack of referral to mental health practitioners was striking.

It is not surprising that many of the women who scored as depressed in that survey but were not referred also rejected the term "postnatal depression," although not on the grounds that problems they had after their babies' births were minor and transient. When interviewed they agreed that they were depressed but saw this as "depression" rather than "postnatal depression." The term postnatal depression implied to them, unacceptably, that their feelings were caused by their babies. One woman said: "The way I have felt has been due to problems with my estranged husband, not the baby." Another wrote: "Answers are not due to postnatal depression. My baby, now 8 months, was operated on at 11 weeks and suffers from asthma and apnoea attacks so I have had a hectic few months." Others rejected the term because they considered postnatal depression to be a severe psychiatric illness that came without warning, out of nowhere.[6] This was the context in which the earliest studies included in the systematic review were designed.

As a coauthor of two of the included trials,[7 8] I can say confidently that the rationale for developing them was not a strong belief that the interventions were likely to be highly effective in reducing maternal depression after birth but a concern that some specific interventions (midwife led postnatal "debriefing" in the United Kingdom and an early postnatal check by the general practitioner in Australia) were already under way or were about to be implemented widely without any evidence of effectiveness. Both interventions seemed feasible, both had support from the relevant practitioners, and neither was seen to require additional staff or major retraining.

The postnatal interventions in the other two UK trials designed at the same time[9 10] clearly required additional resources but the interventions themselves—additional practical support at home for mothers in one[9] and an information package with or without mothers' groups in the other[10]—had been widely discussed in the previous five years and again had substantial support from practitioners, although none were able to reduce maternal depression after birth. The antenatal trials were also ineffective, but their low participation rates suggest that those interventions may have been too time consuming for pregnant women. The trial of MacArthur et al stands alone in terms of effectiveness.[11] It was also firmly located within UK patterns of maternity care although this, unfortunately, makes its findings difficult to extrapolate to other models of postnatal maternity care.

What seems strange, when contemplating these trials 10 years after they were planned, is the apparent lack of involvement by mental health practitioners in the design of the postnatal trials. Could there be a link between the lack of input from the mental health field, inadequate understanding of evidence on mental health, and the lack of effectiveness of the interventions?

Work on reducing other important and common health problems in populations—such as smoking, road deaths, and cardiovascular disease[4 w2]—shows that a shared understanding and belief about the key risks and possibilities for prevention is crucial. The absence of mental health practitioners and researchers from many of the trials of prevention in postnatal depression is a sign that a shared understanding is still some distance away.[12] Closing that gap may be a prerequisite for planning more effective interventions.

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