Implementation of the findings of a national enquiry into the misdiagnosis of miscarriage in the Republic of Ireland: impact on quality of clinical care

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Objective: To describe the findings of a national inquiry into cases of misdiagnosis of miscarriage in the Republic of Ireland and to report the results of implementation of the findings of the inquiry, including investment in new equipment and training, new national guidelines, and rigorous annual audit of early pregnancy units.
Design: Narrative description of the inquiry and its findings and results of a subsequent audit.
Setting: Not applicable.
Patient(s): Women with problems of bleeding and/or pain in early pregnancy who were erroneously diagnosed as having a nonviable intrauterine pregnancy.
Intervention(s): After two cases of misdiagnosis of miscarriage that were widely reported in the Republic of Ireland in June 2010, a Miscarriage Misdiagnosis Review Team was commissioned by the Irish Health Service Executive (HSE) to undertake a national review of other possible cases of misdiagnosis of miscarriage. The Review Team made a series of recommendations that were subsequently implemented in full. The results of the implementation of the findings of the Review Team have been the subject of three annual audits across the country.
Main Outcome Measure(s): The main outcome measure was the occurrence of misdiagnosis of miscarriage in the Republic of Ireland before and after implementation of the findings of the Review Team.
Result(s): Twenty-four confirmed cases of misdiagnosis of miscarriage were identified, mostly occurring between 2005 and 2010. Analysis led to a series of recommendations by the Review Team, which were implemented in full by the HSE. Over € 3 million was provided to fund implementation; 26 high-quality gynecological ultrasound machines were purchased to reequip 19 units involved in provision of care to women with suspected miscarriage. There was further allocation of resources for new equipment and improvement in the management and staffing of early pregnancy units across Ireland, with each center now having a dedicated and properly staffed Early Pregnancy Assessment Unit. A national training program in the management of early pregnancy problems has been implemented, along with regular national meetings to discuss early pregnancy problems. National clinical guidelines on the diagnosis and management of miscarriage for implementation have been distributed to all hospitals.
Conclusion(s): No cases of miscarriage misdiagnosis were identified in any of the three annual audits, suggesting that implementation of the findings of the review has been successful. We believe that this is the first report of national change in practice leading to improvement in clinical outcomes in the management of suspected miscarriage. (Fertil Steril® 2016;105:417–22. ©2016 by American Society for Reproductive Medicine.)
Key Words: Miscarriage misdiagnosis, early pregnancy problems, early pregnancy ultrasound

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Miscarriage, spontaneous loss of a pregnancy before the fetus reaches viability, is the most common complication of pregnancy (1, 2). Approximately 20% of clinically recognized pregnancies end in miscarriage, with further pregnancies being lost before a clinical diagnosis of pregnancy is made (3, 4). Miscarriage, particularly when recurrent, is a source of considerable distress and grief for women, their partners, and their families (5).

Many women present in the hospital emergency setting with bleeding and/or pain in early pregnancy. Of these, about 50% will miscarry and 5%–10% will have an ectopic pregnancy (6). Many hospitals in the United Kingdom and Ireland have established Early Pregnancy Assessment Units (EPAUs) to allow for specialized assessment and treatment of women with problems in early pregnancy. These provide rapid access to transabdominal and transvaginal ultrasound and measurement of hCG. Early-pregnancy ultrasound, in particular, can often be used to reassure women with threatened miscarriage. A transvaginal scan showing an intrauterine pregnancy with a visible fetal heartbeat in early pregnancy carries a good prognosis. Over 90% of women with sonographic evidence of a fetal heartbeat on transvaginal scan and light vaginal bleeding continue their pregnancy to viability (7). Women can often be discharged quickly without overinvestigation in these circumstances once a viable intrauterine pregnancy has been confirmed.

The corollary to this scenario also occurs frequently, with the demonstration of an empty gestation sac, a fetal pole without apparent heartbeat or an apparently empty uterus (anembryonic pregnancy, missed miscarriage, or pregnancy of unknown location) (8). Despite significant technological advances that have improved the quality of imaging of early pregnancy considerably over the past decade, scans in very early pregnancy continue to fail to identify a viable fetus due to performing the scan at a stage before a heartbeat can be recognised, inadequacy of equipment, or lack of operator expertise. Women with symptoms of threatened miscarriage, particularly those with a history of infertility or pregnancy loss, may apply considerable pressure to clinicians and other hospital staff to perform ultrasound examinations at the earliest stages of pregnancy. While ultrasound can be relied upon to identify a viable intrauterine pregnancy with repeated examinations and in conjunction with serum hCG measurement, first ultrasounds in early pregnancy may not be diagnostic in 8%–31% of examinations, even in specialist hands (9). The correct management of such cases is to repeat the ultrasound scan, with or without measurement of hCG, depending on the level of clinical suspicion of an ectopic pregnancy, and wait until viability or otherwise of the pregnancy is clearly established. Clear clinical guidelines on this topic are now available (10). One of the aims of the review was to determine how frequently these guidelines were followed in cases subsequently shown to be misdiagnosed as miscarriage.

Extensive media coverage was given in the Republic of Ireland during June 2010 to reports of two cases of misdiagnosis of miscarriage. In both cases, a diagnosis of miscarriage had been made in error and surgical or medical treatment to end the presumed nonviable pregnancy was recommended. Subsequent information demonstrated that the pregnancy was viable, and pregnancy continued with the birth of a healthy baby. The publicity led to other women who had had similar experiences coming forward to hospitals, to help lines, or through complaints procedures. In response to these cases, the Irish Health Service Executive (HSE) established a Serious Incident Investigation Team to manage the incidents and a Miscarriage Misdiagnosis Review Team to undertake a national review of cases identified. This was the first national review of miscarriage misdiagnosis, although reports of similar cases from the United States, Australia, and the United Kingdom demonstrate the global nature of this problem (11–13). The Review Team made a series of recommendations that were subsequently implemented in full. This paper reviews the results of implementation of the recommendations in preventing further misdiagnoses.

METHODS

The terms of reference for this review were to consider cases where medical or surgical treatment was recommended after a diagnosis of miscarriage and where subsequent information demonstrated that the pregnancy was viable. The review led to recommendations for service improvement to avoid such misdiagnoses. The review considered cases that occurred from June 2005 until May 2010 inclusive, although cases submitted by women who fell outside the 5-year timeframe were also reviewed where the case was believed to help inform the work of the Review Team. Possible cases were identified from calls by members of the public to the miscarriage misdiagnosis help lines, by direct inquiry to senior medical and management staff at the hospitals that provide care to women with suspected miscarriage in Ireland, and by interrogation of the Starsweb/National Adverse Event Monitoring System (NAEMS) national health care incident reporting system.

Detailed information concerning all clinical and other relevant information was collected for all cases, and a detailed chronology of events was constructed. All responses were anonymized. Available data included information on clinical governance and incident management systems, servicing and maintenance histories for ultrasound scanning machines, copies of formal scan reports, copies of scan images, and copies of hCG blood test results. Systems analysis methodology was then used to examine each case and to allow conclusions to be drawn.

A comprehensive report, the HSE Miscarriage Misdiagnosis Review, containing an analysis of the cases considered in detail, was prepared by the Clinical Review Team and published in April 2011. The report contained a series of recommendations for changes in clinical practice and improvement in equipment and facilities that were believed to be necessary to prevent further misdiagnoses. It attracted considerable media attention at the time of publication.

The recommendations were implemented by the HSE of the Republic of Ireland. One of the recommendations of the report was to conduct an annual audit of possible cases of misdiagnosis. Three such audits have been carried out since 2011, and this paper describes the findings of the report and