against what the registry says they have done. They dismiss many registry data as inaccurate. But the quality of the data held by the registry mirrors the quality of data held in the clinical notes. Two large case note studies of breast and colorectal cancer sampled from the Thames cancer registry showed that data on staging were missing for 51% of patients with breast cancer and 46% of those with colorectal cancer.[3,4] The London Implementation Group's review of cancer services was hampered by lack of high quality information on where patients received treatment and the volume of treatment given.

The clinical response to these problems has been to use clinical audit to set up alternative and duplicate data systems. Many of these stand alone systems are not capable of comparisons between clinicians let alone across districts or providers, although more recently there have been signs of more sophisticated developments.[5] Typically, these clinical audit systems do not guarantee the quality of their data and do not link with cancer registries or other routine data systems; their data are not standardised; they are owned and used by clinicians rather than purchasers; and they have no population focus[6]; they also cannot capture patients not receiving care within the NHS acute sector. Population based comparisons of treatment are as important as comparisons of survival. Without these data purchasers will not know how many of their residents clinicians might expect to treat, at what stage they will present, and what treatments they might expect to receive. The purchaser cannot evaluate whether care is reaching all groups within their population or plan for services. Clinicians should be encouraged to pursue clinical audit, but their audits of care should be capable of complementing a population focus and of integrating with cancer registries and routine hospital data systems.

The Expert Advisory Group on Cancer has recently published a policy framework for the commissioning of cancer services.[7] It expects that most district hospitals will become cancer units and that tertiary care will be provided by cancer centres. Its message is clearly that there will be a move towards subspecialisation and more integrated cancer care. But the document fails to quantify the populations to be served and the volume and range of services and support required. Again, cancer registries could help answer these questions. But for them to do so purchasers will need to ensure that registries are properly resourced to develop the population perspective that purchasers need to support them in their task.

ALLYSON POLLOCK
Consultant in public health medicine
Merton, Sutton and Wandsworth Health Authority,
London SW17 7DJ

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Silicone breast implants and connective tissue diseases

No association has been convincingly established

Since 1962 between 1 million and 2·2 million women may have received silicone breast implants in the United States and Canada alone; no figures are available for other countries. In 1964 hypergammaglobulinaemia was reported in two patients who had received silicone and paraffin injections; 18 years later, the first three patients with silicone breast implants and connective tissue diseases were reported on. Since then 293 patients with connective tissue diseases or complaints have been described in papers in English.[1]

In 1992 the United States Food and Drug Administration, after hearings before two independent advisory committees, placed a moratorium on the use of implants other than in research because of inadequate data on their safety.[2] This year certain manufacturers of breast implants and their suppliers set aside funds of $4·225bn to deal with potential legal suits; and, in a unique move, women were given until 17 June this year to decide whether to join a class action suit that guaranteed a settlement of $200 000 to $2 million, to not litigate, or to litigate separately.

Whether silicone implants are associated with connective tissue diseases, therefore, is an important public health issue which is now embroiled in regulatory and legal controversy.[3] Among the first cases reported, scleroderma was seemingly disproportionately common—intriguing, given that, of all connective tissue diseases, scleroderma and scleroderma-like disorders have been most convincingly linked to environmental causes (for example, exposure to silica, polyvinyl chloride, toxic oil, and tryptophan). But, as attention on women with silicone breast implants increased, other connective tissue diseases were also reported, including systemic lupus erythematosus, inflammatory myopathies, Sjögren's syndrome, rheumatoid arthritis, and an ill defined syndrome inappropriately termed "human adjuvant disease,"[4] characterised by malaise, low grade fever, aches, and pains. While the number of anecdotal cases increased, studies that included a control group failed to detect any association.[5-9] Although no single study could definitely rule out such an association, if one existed then it could be only very small. As scientific inquiries continue, the legal debate has shifted from whether silicone breast implants cause connective tissue diseases to whether implants cause a unique rheumatic disease that cannot be defined by existing criteria.[9]

The question of risks to health, particularly the potential risk of connective tissue disease, is difficult to study. No precise data exist on how many women have received silicone breast implants; no systematic follow up data have been collected. Virtually nothing is known about how many women have had repeat implant procedures or how many with silicone breast implants have died. Even the best epidemiological studies are limited by having a relatively small sample size or by potential ascertainment bias, reporting bias, or information bias (which results from systematic differences in the way data on exposure or out-

come are obtained). This is shown by two controlled studies, which found that self reported diagnoses of connective tissue disease and symptoms were more common among women with breast implants but that medical evaluation failed to confirm the diagnosis of connective tissue disease or any difference in objective findings between women with and without breast implants.[6 10]

What should doctors advise women who have silicone breast implants? If they are well and have not had local problems such as hardening or rupture of the implant we recommend that they do nothing. They should be reassured by the epidemiological studies, all of which show no association.[5-9] Patients with connective tissue diseases or rheumatic complaints and silicone breast implants need to be treated on a case by case basis.

Whether removing the silicone breast implants alters the course of a connective tissue disease is unknown. Among 12 reported cases, some improvement was described in seven.[1] Four of nine patients with scleroderma had cutaneous improvement (one of them also had visceral improvement). In two cases of systemic lupus erythematosus both clinical and serological manifestations improved. In one case of "human adjuvant disease" some improvement was noted. No firm conclusion can be drawn from the reports.

Whether silicone breast implants are associated with connective tissue diseases remains controversial. Despite the increased number of cases reported in the literature no association has been convincingly established.

JORGE SÁNCHEZ-GUERRERO
Research fellow
MATTHEW H LIANG
Director, Robert B Brigham Multipurpose Arthritis and Musculoskeletal Diseases Center
Department of Rheumatology and Immunology,
Brigham and Women's Hospital,
Boston, MA 02115,
United States

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Purchasing clinically effective care

National directives cannot be fulfilled without local collaboration

Research findings are often poorly translated into clinical practice. One example is the management of acute myocardial infarction, where the evidence of the effectiveness of aspirin and early thrombolysis is overwhelming.[1 2] Despite this the proportion of patients receiving the treatment may be low.[3 4] Ensuring that patients receive the best possible care should be important for all doctors.

Should purchasers care as well? The NHS Executive thinks so and believes that the issue should be addressed through contracting. Last December all fundholding general practitioners, trusts, and health authorities received a letter from the executive urging them to take clinical effectiveness and clinical guidelines into account in contracting.[5] Seven guidelines were attached for consideration, with the hope that purchasers would include at least one of them in their contracts.

The NHS Executive clearly believes that clinical effectiveness should form part of the NHS's medium term objectives. Planning guidance already issued for 1995-6 has included the objective that the NHS should "invest an increasing proportion of resources in interventions known to be effective and where outcomes can be systematically monitored, and [that it should] reduce investment in interventions shown to be less effective."[6] Purchasing authorities will be expected to increase investment in at least two interventions known to be effective, to reduce investment in at least two interventions that evidence has identified as likely to be ineffective, and to increase the use of clinical outcomes and audits in contracts.

Now a further letter from the executive, issued last week, shows some softening of approach.[7] The complexity of the task is acknowledged, as is the length of time needed to adapt suitable evidence based clinical guidelines for local use. This shift of emphasis is welcome because evidence of the effectiveness of clinical guidelines themselves shows that a top down approach is less likely to change behaviour than the development of guidelines by those who are to use them.[8] Another new approach is the suggested involvement of primary care; family health services authorities are asked to work with medical audit advisory groups, general practice postgraduate tutors, and local practitioners in the development of local documents. Great benefits could accrue from doctors in primary and secondary care working together on clinical policy; it would be wrong to restrict all initiatives regarding clinical effectiveness to hospital providers. Lastly, the letter suggests that patients should be involved in developing guidelines.

Whether any of these initiatives will change doctors' practice—for example, increasing the chances of patients with an acute myocardial infarction receiving aspirin and thrombolysis—is unknown. Haines and Jones have advocated an approach to implementing research findings in clinical practice that incorporates work with opinion leaders, purchasers, and professional organisations; programmes of education and clinical audit; and the use of "patient specific reminders" to support clinical decision making.[9] Most of these approaches have been shown to affect clinical practice, although mostly outside Britain. As systematic reviews of research evidence begin to emerge from the Cochrane Collaboration[10] and the NHS Centre for Reviews and Dissemination we need to establish which methods of implementation work best in the NHS and to