unobtainable and potentially dangerous. Regional variation in technique is something that can be dealt with only by regional transfusion centres, but not by any central laboratory.

Variations in technique have also led to difficulty of scoring results. Suggestions have been made for allocating scores for correct findings and for deductions to be made in the case of errors, the final scores to be explained as percentages. Nevertheless, problems of scoring where extra or different techniques are used have created difficulties which cannot be dealt with on a national basis. Indeed, while scoring of results can be helpful in giving hospital pathologists some indication of the efficiency of their own units compared with others in their Region, consultation which has developed between hospital laboratories and the transfusion centres has often been of greater value.

By testing all samples from regional transfusion centres 'blind', the Blood Group Reference Laboratory is now controlled. In addition, the Blood Group Reference Laboratory sends to all regional transfusion centres samples of sera known to contain antibody mixtures, directors being invited to test the material and report their findings back to the Blood Group Reference Laboratory. The results are examined at the Blood Group Reference Laboratory and directors of regional transfusion centres are told of the overall findings of other regions, anonymity being maintained. In this way, most regional transfusion centres, hospital laboratories and the Blood Group Reference Laboratory are now being controlled. During 1974 more than twenty-five exercises were organized throughout the country, and there were more than five hundred participants.

Reagent Control

The reliability of the reagents used has a considerable influence on the standard of serology reached in any laboratory. In some proficiency testing schemes participants are asked to state the names of the manufacturers and the batches of reagents used, so that any errors appearing in the results of a group of individuals may be shown to be dependent on some shortcoming of one or more of the reagents.

The Blood Group Reference Laboratory undertakes large-scale quality control of the reagents that it distributes but, equally, it provides an independent check on many grouping sera issued by regional transfusion centres or by overseas laboratories. Large numbers of tests are performed at all stages to ensure adequate potency and specificity of all sera issued. Specifications are laid down in Appendix XV of the British Pharmacopœia for ABO- typing and Rh-grouping sera as well as for anti-IgG. Care is taken at the Blood Group Reference Laboratory to see that reagents always reach, if not exceed, these standards. As an example, the antibodies that are excluded in anti-A grouping sera issued by the Blood Group Reference Laboratory are:

Anti-B, -M, -N, -S, -s, -Mi^a, -V^w, -P, -P_1, -C, -C^w, -c, -D, -E, -e, -Le^a, -$Le,^b$ -Lu^a, -Lu^b, -K, -k, -Fy^a, -Fy^b, -Jk^a, -Jk^b, -Xg^a and -Wr^a.
Anti-Gm (1), (2), (4), (5), (10), (11), (14) and (17).
Anti-Inv (1) and (2).

Several members of staff of the Blood Group Reference Laboratory, directors of some of the regional blood transfusion centres and some hospital pathologists are members of the British Committee for Standards in Hæmatology's working party on the control and certification of blood grouping reagents. This working party has considered specifications, production of and standardization of rapid-typing Rh antisera, antiglobulin sera and various other reagents. It has also considered the possible need for and disadvantages of colouring blood grouping sera. Many of its findings have been made available to directors of regional blood transfusion centres and to the British Committee for Standards in Hæmatology in order that the quality of serological reagents can be kept at the highest possible level.

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Audit and the Pathologist

From time to time I have made some remarks about audit, and in consequence I have been asked to speak – largely from ignorance let it be admitted – on this subject as it affects the pathologist. I shall limit my use of the term to studies of professional behaviour that may have a bearing on the proper delivery of care to patients. I am not directly concerned with the internal quality control of the pathological laboratory; rather I am trying, against the background of what the clinician in general and the surgeon in particular does or should do to make a good job of looking after patients, to ascertain how the pathologist is involved, what information, and in what form, he is committed to supply and how he may add to the richness of clinical surveillance.

Audit for the clinician is in general that process of self-assessment in quantitative or qualitative terms which permits him to say 'I have handled this patient or group of patients in an appropriate way'. There are many definitions of 'appropriate': initially, and still to a great extent, it is death or survival; more recently (and particularly in surgery) it is the incidence and severity of complications; in the United States, perhaps because of its association with money, it may be concerned with processes – what has been done and why, judged usually against a series of norms for the condition from which the patient is alleged to be suffering. Finally, it can be based on such measurable factors as length of hospital stay; or on less easily quantified ones – for example, emotional or social satisfaction of the patient with his management.

The morality of self-assessment is without question; indeed it is such an implicit part of professional conduct that when it is discussed we tend in this country to feel embarrassed. Nevertheless, technical skills are becoming so much more complex, factual knowledge so much greater, that it would be arrogant to feel that we are totally able to scrutinize ourselves or that alternatively a qualifying examination such as a College Fellowship gives once and for all the right to practise professionally without anything more than the most nugatory supervision. I take it as axiomatic, though others may disagree, that we should none of us be averse to some form of feedback of performance that permits an external critique. As a surgeon I am also conscious that one can think one is doing well only to learn by the behaviour of patients, or chance comments not meant for one's ears, that in fact performance has been disastrous, inappropriate or irrelevant.

For all the purposes I have mentioned information is required. The form this takes must be geared to need. It is to this problem that I would now like to address myself and to do so I shall take some specific areas. In our hands the proper management of patients with breast cancer rests on a number of premises: recognition of patients with distant dissemination that precludes cure; the establishment of involvement of the juxta-axillary or pectoral node as a marker for involvement of the axilla; and the certainty of adequate surgical clearance in the patient who has either mastectomy or wide local excision.

To study our clinical performance we plot the track of a patient through a system of decisions. To do so requires pathological information of a type and in a detail that must be related to the clinical decision making. In turn this requires submission of material that permits the appropriate statements from the morbid anatomist. He must be familiar with what is wanted and be prepared to organize his reporting system along appropriate lines. If he does so in consultation with the clinician a form of report emerges which is quite different from the conventional. It is created as a check list which leads to the pathologist auditing himself in the sense that he must reach the standard we have agreed to. It may well be that detailed examination of this form would expose areas of controversy or disagreement by others. But *we* have agreed it for now; we may well change later but for now it is our audit standard. It contains the critical factors for decision that I have mentioned above and a good deal more besides. By providing this the pathologist is contributing to the clinical audit process. Furthermore, he is creating a framework for debate of his own performance because if he departs from this agreed form he must justify it at, in our practice, a weekly histopathological conference. Equally the clinician is committed to the same process because if he fails to supply specimens of high quality to an appropriate time schedule he will not get a good report in *his* terms and so be able to benefit the patient. Marking of the apex of an axillary dissection with a stitch, pinning out a resected specimen from the gastrointestinal tract and properly orientating mucosal biopsies becomes a *sine qua non* of good reporting. These phenomena are of the nature of boot straps: the clinician helps the pathologist to help the clinician to help the pathologist, the common aim being to reach, to measure and to maintain a certain standard of care.

Here then is ongoing quality control of clinicopathological interaction, not by bickering or argument but by useful colloquy in relation to agreed objectives. We have found the same process useful in gastric and colonic disorders, such matters as the margin of resection, the involvement of lymph nodes and the orientation of a specimen being amenable to a reasonably objective description. If I may reiterate what seems to have been a long and complicated chain of reasoning, provided the clinician and pathologist can identify the information required to make clinical management decisions, then clinicopathological audit takes the form of ascertaining if these standards have been reached. I submit that in many fields much remains to be done to generate such rationality.

These then are methods by which an audit framework can be established and sustained. Let me turn now to a more controversial field, in which I am less sure that we have the means to audit in a meaningful way what the pathologist is doing. Here audit means finding out how, if at all, the result produced contributes to the welfare of the patient. As such we are now dealing with an earlier stage of the process of clinicopathological

cooperation – a stage where audit merges imperceptibly into operational research. A subsidiary question would be 'Can the pathological information help, but is it currently in a form which makes it less than satisfactory as a message of the patient's state?' I refer in both instances to the data which emanate principally from chemical pathology laboratories, but also are common in the field of hæmatology.

The clinician orders (the word is inappropriate and should in fact be 'requests') tests for three reasons: their discriminatory power, their value as base lines, and the possibility of detecting abnormalities on the basis of a risk group. I am specifically excluding multiphasic nondirected screening from this description. In all instances he will be fed back an item of data which he then must relate to a statistical expectation about the population from which that patient is drawn. How this expectation is computed is a complex matter. First, the population must be defined; second, the mathematical technique for prediction must be agreed; and third, the inferential mechanism used to proceed from the general to the particular must be stated. At this time all these matters are left almost entirely to the fallible cerebral computing circuits of the clinician. All we get is a value related to a 'normal range' which is usually ill defined in relation to our patient at this time. Furthermore, the feedback loop to which I have referred before (Dudley 1974, *British Medical Journal* i, 275–277) which would enable the chemical pathologist to audit his work for relevance both as a predictor or as a helper is completely absent. Specifically, if we determine the serum sodium concentration on a patient of 65, three days after a radical gastrectomy for cancer, we do not get a report which relates to this situation. The pathologist is not auditing his performance in context and in response to the patient's need; therefore neither he nor we are learning. Audit can be more specifically defined here as an analysis of the proper use of information contained in the data produced. In this regard chemical pathology is a grossly, almost criminally, wasteful procedure. What is required here, as in so many fields of clinical medicine, is the definition of a number of categories in which detailed knowledge is necessary, and the deliberate organization of our information system to cater for this. Under such circumstances a meaningful assessment of effectiveness is possible.

As a subsidiary of this problem, it has been my experience (and here again I am inevitably being slightly critical) that the needs of the clinician in regard to visual display are rarely met. An audit of effectiveness of what is done must include a measure (non parametric at this stage) of how data in single or serial form are, or are not, used. Often the tabular way in which data are presented militates against their usefulness. New displays are possible and may have been achieved in more places than I am giving credit to. For example the updated Xerox sheet is in a form which allows one to run the eye up and down or across a column or row of figures. We transcribe in my service manually into this form on our records and in addition signal abnormal values. I would like to feel that this form of prediction could become more common.

Columns and rows of figures do not easily send out a signal of change. We respond better either to graphical presentation or to a derived signal which either exaggerates the change or compares with a normal as previously discussed. If the number of biochemical and hæmatological requests were halved, perhaps we could use the money and manpower to audit what we do more effectively in relation to clinicopathological interaction in the biochemical field.

I do not wish to suggest that an aim of pathologists should be to keep clinicians happy and that a pathological audit might be based on the frequency of irate clinicians looking for a better service. However, we are, I presume, united in our desire to help the patient. To do so we have to agree on what information needs to be passed from one to another (in both directions) and we can audit performance by seeing how often this is achieved, and how the information influences decision making. At St Mary's Hospital, thanks to the enthusiasm of Dr Keith Blenkinsop and Dr Malcolm Carruthers among others, we have gone a long way in morbid anatomy and chemical pathology towards establishing what is needed from the pathologist to facilitate clinical decision making. Continued interest in audit procedures between clinician and pathologist will be one way that we can meet the intellectual challenge thrown up by two things: the undoubted cost containment activities of our political and administrative masters; and the absurd growth in one-way requests for information from clinician to pathologist that is like a cancer in the body of good clinicopathological services.

The whole emphasis of what I have said rests on the audit procedure of outcome, that is, the determination of what information went into decision making about patients and where this was useful. This is in sharp contrast to the process-orientated situation which, as I have already mentioned, is most common in the United States. Process orientation has in my mind three disadvantages: (1) It is on occasion tangential to the objective of helping the patient as distinct from establishing that clinical behaviour is arbitrarily good or bad. (2) It is easily grasped and understood by administrators, particularly those

concerned with economics, and thus may be used as a stick with which to beat the clinician who is endeavouring to do the best for his patient as distinct from making his primary aim the containment of cost. (3) Of most philosophical importance, to me, is the fact that externally agreed norms derived from the analysis of process will inevitably lead to regression towards a mean, and this mean may be below that to which we would all wish to aspire; such would be particularly the case if the norm was used by some official body to determine not only the lower but also the upper limits of resources which were to be made available.

I make these observations for a specific reason. Process orientation is very popular in other parts of the world and has been worked up into an effective weapon. There is a considerable risk that it could be introduced into this country from outside the profession, particularly if we leave a vacuum by failing to launch appropriate audit procedures ourselves. Therefore it is important to us all to be highly and objectively self-analytical, to pursue the most appropriate framework for self-assessment and rapidly to bring in careful audit in relation to outcome which may then lead to more logical application of resources where these are truly needed.

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Treatment of the 'Persistent Offender'

'State of the art' techniques for assessing laboratory proficiency are used by many quality control schemes, including the National Quality Control Scheme (NQCS) operated by the Laboratory Development Advisory Group of the DHSS. Results obtained by the NQCS in clinical chemistry (Whitehead, Browning & Gregory 1973, *Journal of Clinical Pathology* **26**, 435) illustrate that certain laboratories consistently fail to perform satisfactorily by 'state of the art' criteria. Such laboratories have been labelled 'persistent offenders'.

The evidence of most quality control schemes demonstrates that all laboratories produce unacceptable or poor performance on occasions; thus it is essential that the procedures used to identify persistent offenders should have a sound scientific basis and be acceptable to participants.

A system of depicting long-term performance has been devised by the NQCS in clinical chemistry. This system allocates a score for each assay performed in the scheme, determined by the difference of the result from the mean of all results obtained by a specific method. The scores obtained for different assays are averaged to produce a running score termed the 'variance index'. In 1973 when approximately 400 laboratories were participating in the NQCS, limits of variance index were specified which included 90% of all participants; 10% were excluded, 5% as 'good' performers and 5% as 'poor' performers. Fig 1 illustrates the record of a laboratory (Lab. A) with persistently good performance and of a poor laboratory (Lab. B) which has achieved considerable improvement. Since the designation of the limits of the 90 percentile in 1973 they have not been modified. The persistent offender or poor performer could be defined as a laboratory with a variance index consistently in the 5 percentile of poor performers. The number of laboratories that have maintained a variance index consistently in the 5 percentile of poor performers has not been disclosed. However, the existence of evidence such as that illustrated in Fig 1 demands that the problem of treatment of poor performers must be considered.

If treatment of the persistent offender is to be effective then the reasons for poor performance must be known. Only when this information is available will it be possible to provide help and advice to poor laboratories.

Certain provocative measures have been advocated to reduce the number of laboratories that persistently perform badly in quality control schemes. These measures include: (1) Compulsory participation in quality control schemes. (2) Abandonment of anonymity in quality control schemes. (3) Provision of information to Regional Health Authorities regarding poor performance by laboratories in their region. (4) Closure of laboratories or replacement of laboratory directors in the event that performance does not improve.

These measures have been adopted in principle in certain countries.

There is little doubt that the criteria of assessment must differ between the disciplines in pathology. The function of the clinical chemist's work, with its major commitment to the production of numerical data, often using automated equipment, is quite different from the subjective assessment of a tissue section by the histopathologist. At the same time, there can be no justification for lack of concern when surveys demonstrate wide

[1] Dr Wilding is a member of the DHSS Laboratory Developments Advisory Group in Standardization and Quality Control and also a member of the Scientific and Technical Committee of the Association of Clinical Biochemists; the views given in this paper are those of the author alone, and do not necessarily represent those of either of the above organizations.