

past occupations, toxic exposures, and places of residence is underway.

Medical Screening of VC Workers

Together with the Occupational Health Studies Group of the University of North Carolina, NIOSH-CDC recently concluded a cross-sectional medical screening examination of 530 workers at a plant in Pennsylvania which contains both a large tyre-building facility as well as one of the oldest PVC polymerization plants in the United States. Included in the study were approximately 130 current PVC polymerization workers and a similar number of control workers from the tyre plant who had never worked in the polymerization facility. The 2 groups were comparable in age, alcoholic intake, and socioeconomic background; the controls were chosen from those areas of the tyre plant where exposure to solvents and dusts was least.

Preliminary review of the results shows no significant differences between the 2 groups for any of the 6 liver function tests performed (SGOT, bilirubin, alkaline phosphatase, LDH, GGTP, and ornithine carbamyl transferase). Additional analyses based on levels of VC exposure, duration and type of job, and other subgroupings are being done; these preliminary results however do not suggest the occurrence of liver function abnormalities on a broad scale secondary to VC exposure. One should of course be cautious about generalizing from the results at a single plant, and it will be important to compare these findings to studies at other PVC plants. It is also important to realize that since liver function tests are relatively insensitive to the early finding of VC-induced hepatic disease (i.e. fibrosis), the results of this type of testing are not a reliable estimate for the prevalence of VC-induced disease. Liver scans were also performed on all workers with more than 10 years duration of work in the PVC polymerization plant, and no cases of HAS were detected. Some increase in frequency of palpable livers on physical examination was found, however, among VC workers. A full report of findings from this comprehensive medical screening study is in preparation and will be available shortly.

Cohort Mortality Study at Four PVC Polymerization Plants

One of the results of this NIOSH-CDC study was the demonstration of an increased SMR for respiratory system cancer among members of the cohort (Waxweiler *et al.* 1976). On preliminary pathologic review, it was also noted that of the 12 lung cancer cases all 8 for which pathologic specimens were available were either large cell undifferentiated or adenocarcinoma of the lung;

Table 3

Lung cancer among workers at PVC polymerization plants in the United States by histologic type and extent of VC exposure

Histologic type	Extent of VC exposure			Total
	None	Less than one year	More than one year	
Epidermoid	1	1	0	2
Small cell undifferentiated	0	3	0	3
Adenocarcinoma	1	1	4	6
Large cell undifferentiated	4	0	6	10
Unclassified	1	0	0	1
	7	5	10	22

if confirmed, this unusual cell type distribution may support the association between VC exposure and occurrence of lung cancer.

There are, however, two additional features which should be considered in evaluating this potential relationship. When all of the workers at these 4 plants are considered, including those who were not part of the defined VC-exposed cohort, a total of 22 cases of lung cancer (out of 48) were available for pathologic review. The increased incidence of large cell undifferentiated and adenocarcinoma of the lung was seen in VC workers with more than 1 year of exposure, while a distribution more closely resembling the expected small cell predominance was seen for VC workers with less than 1 year of exposure. Interestingly, however, cases of lung cancer in non-VC workers at these plants, although small in number, appeared to have a cell type distribution which was also predominantly large cell undifferentiated (Table 3). In addition, unlike the situation for HAS in these plants where all but one of the cases were long-term reactor cleaners and operators, the workers with large cell undifferentiated and adenocarcinoma of the lung were distributed in a number of different job categories. As a result, cases of lung cancer seem not to correlate as tightly with VC exposure as cases of HAS and it is conceivable therefore that some additional chemical exposure at these plants may be working together with VC (or even separately) to produce this effect. Further studies are currently underway in an effort to confirm these preliminary pathologic findings.

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DISCUSSION

Dr Mitchell R Zavan (*Baton Rouge, Louisiana*) asked whether the clinical examiners at Pottstown knew whether or not the person being examined worked in vinyl chloride.

Dr H Falk replied that none of the clinical examiners were aware of the occupational status of the workers at the time of the examination.

Dr R I McCallum (*University of Newcastle upon Tyne*) asked Dr Falk to give in more detail the way in which histological diagnosis was made in the case of lung cancer shown in his slide. Was this done by one individual or by a panel of pathologists? How were the specimens of tissue obtained: by biopsy, surgical resection or at autopsy? It was remarkable that in none of the cases was an oat cell carcinoma diagnosed, as this was the type often considered a characteristic result of exposure to a chemical carcinogen.

Dr H Falk replied that the WHO lung cancer classification scheme of Kreyberg (1967) was used. Four pathologists reviewed the slides and agreed on the interpretation (Dr Louis B Thomas and Dr T Powell, National Institutes of Health; Dr M Kushner, State University of New York; and Dr Laszlo Makk, St Anthony Hospital, Louisville, Kentucky). All available pathological material for each case was reviewed.

The expanded pathological review currently underway would include the selection of multiple control cases of lung cancer from the same hospitals (with similar age and date of diagnosis to the study cases) and a blind review by a panel of pathologists in a more detailed evaluation of available pathology material.

To Dr Falk's knowledge large cell undifferentiated carcinoma of the lung had not been related to exposure to chemical carcinogens, which made the findings in the VC cohort even more intriguing.

Dr A J Fox (*Employment Medical Advisory Service, London*) asked how many factories had been studied individually in the USA. What proportion of these had indicated vinyl-chloride-associated disease?

Dr H Falk replied that cases of hepatic angiosarcoma had been seen at 5 of the 8 PVC polymerization plants opened prior to 1950.

There was some confusion in this area in that a number of the VC worker mortality studies had been overlapping. Three separate studies, for example, the

NIOSH-CDC study, the Tabershaw study, and the Monson-Peters study) had all looked at the Louisville, Kentucky plant where the initial angiosarcoma cases occurred as well as at a varying number of additional plants. Compounding the problem was the fact that the definitions for entrance into the cohorts studied differed from study to study, so that the results even at the same plant were not identical.

Dr J A Bonnell (*Central Electricity Generating Board*) asked whether, since vinyl chloride monomer was a carcinogenic agent, there was any evidence in experimental animals or in human clinical experience that the skeletal or skin changes described might be pre-malignant conditions.

Dr H Falk said that cases of angiosarcoma in the USA did not have a history of acro-osteolysis or skin problems, although they did not have the multiple tests for early changes of acro-osteolysis. It would seem, therefore, that the skin changes were not pre-malignant conditions.

Professor I J Selikoff (*Mount Sinai School of Medicine, City University of New York*) said that a review of known details of identified cases of vinyl-chloride-associated angiosarcoma of the liver by Dr Lloyd (1975) of the National Institute for Occupational Safety and Health had demonstrated that the median duration from onset of exposure was approximately seventeen years. These cases were derived from the rather small number of polymerization workers employed during the establishment and initial growth of the vinyl chloride industry. Attempts were underway to identify and trace the initial groups of workers, employed during the years 1938-55, since analysis of their experience would allow evaluation of the risks which might be suffered by the very much larger group of vinyl chloride workers exposed more recently, in a period during which PVC production was increasing at the rate of approximately 10% per annum.

Limited data bearing on the problem had been obtained. In one polymerization process studied, 257 men had been employed for five years or more in the period between 1946, when the plant opened, and 1964. Each man had been traced to 1 July 1974, with 25 deaths from all causes: 3 of the deaths were due to angiosarcoma of the liver (Nicholson *et al.* 1975), each confirmed on review of autopsy material (Thomas & Popper 1975); in addition there was one death due to ruptured oesophageal varices. Another worker, examined during the clinical survey at this facility (Lilis *et al.* 1975) had had a successful portacaval shunt operation for the same condition. These experiences suggested that vinyl-chloride-associated disease would be an important hazard for vinyl chloride workers in the future, unless control of exposure resulted in at least some reversal of the risk.

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Dr B W Duck
(*Occupational Health
BP Research Centre
Sunbury on Thames*)

Medical Surveillance

Following the announcement of the first cases of workers exposed to Chemical Industry Kingdom set up with a number of including one on his

The first task of which comprised four British companies of vinyl chloride (PVC), was to review toxicological information what action should of exposed employees one aspect of the

At that time, sarcoma of the liver, there was its natural history early diagnosis. malignant forms fibrotic changes, vinyl chloride was suspected, but the chances of liver failure to the development be established respect of the pre-acro-osteolysis conditions, since it was some common

To complicate term carcinogenesis had not only produced also a considerable tumours.

The situation leagues in Government and specialists in advice was received overseas source United States. It that there was early detection serve as a basic programme in possibilities we diagnostic value certain, vinyl asked to volunteer the grounds that disease of the

Dr B W Duck

(Occupational Health Unit,
BP Research Centre,
Sunbury on Thames, TW16 7LN)

Medical Surveillance of Vinyl Chloride Workers

Following the announcement in January 1974 of the first cases of angiosarcoma of liver among workers exposed to vinyl chloride in the USA, the Chemical Industries Association in the United Kingdom set up a Vinyl Chloride Committee, with a number of specialist working groups, including one on health aspects.

The first task confronting this working group, which comprised medical representatives of the four British companies engaged in the production of vinyl chloride (VC) and polyvinyl chloride (PVC), was to review all the relevant medical and toxicological information available and decide what action should be taken to protect the health of exposed employees. This is an interim report on one aspect of the group's work.

At that time, little was known about angiosarcoma of the liver and its treatment. Due to its rarity, there was considerable doubt about both its natural history and appropriate methods of early diagnosis. Reports indicated that non-malignant forms of liver pathology, such as fibrotic changes, might be more prevalent among vinyl chloride workers than had hitherto been suspected, but the significance of such disturbances of liver function and structure in relation to the development of angiosarcoma had yet to be established. Similar considerations arose in respect of the previously recognized condition of acro-osteolysis (AOL) and its various manifestations, since it was speculated that there might be some common underlying vascular pathology.

To complicate the situation still further, long-term carcinogenicity tests on laboratory animals had not only produced many angiosarcomas, but also a considerable number of renal and other tumours.

The situation was discussed with medical colleagues in Government and Trade Union agencies, and specialists in liver disease, and much helpful advice was received from them and from various overseas sources, especially from doctors in the United States. It soon became apparent, however, that there was no established procedure for the early detection of liver angiosarcoma that could serve as a basis for a large-scale screening programme in industry. As practical screening possibilities were very limited and the early diagnostic value of suitable techniques was uncertain, vinyl chloride workers could not be asked to volunteer for medical examination on the grounds that this would detect early malignant disease of the liver; nor could they assume that

such examinations would be beneficial to individuals in terms of preventive medical action. In the latter context, effort had to be concentrated on urgent measures to reduce exposure to vinyl chloride, a task which was being energetically tackled by our technical colleagues.

Nevertheless, there were many arguments in favour of inviting vinyl chloride workers to attend site medical centres to participate in a standard medical examination programme: (1) Opportunity for personal discussion. (2) Establish prevalence of disease. (3) Establish prevalence and significance of liver dysfunction. (4) Correlate positive findings. (5) Identify possibly susceptible individuals. (6) Compare findings in VC workers and controls. (7) Assess feasibility and value of medical surveillance. (8) Establish data base for further studies. For these reasons it was decided to carry out an initial clinical survey on all sites where VC and PVC were produced, based as far as possible on the application of standard procedures to both vinyl chloride workers and controls. A programme of action was discussed and agreed with medical representatives of Government and Trade Union agencies and it was accepted that one of the main objectives was to gather clinical and epidemiological data to provide a reasonable foundation for future decisions concerning regular medical surveillance.

The survey population was divided as follows: Vinyl chloride workers Group 1 - all autoclave floor workers, vinyl chloride monomer (VCM) production workers with five or more years' service; Group 2 - vinyl chloride monomer production workers with less than five years' service, all other VCM/PVC production workers. Controls - workers from same sites with no history of VC exposure.

A standard medical examination procedure was adopted: Initial examination comprising medical history (questionnaire), physical examination, biochemical tests (SGOT, SGPT, GGTP, alkaline phosphatase, bilirubin), platelet count, urinalysis. Follow up of abnormal findings, with repeat biochemical tests and platelet count, and persisting abnormalities referred to consultant for specialist investigation.

The programme was introduced simultaneously on the six production sites and the employees concerned were informed that it was not an individual screening test, but a joint investigation to provide data that would help to establish future medical policy. It was also explained that any individuals with suspicious findings, notably persistently abnormal test results, would be referred for appropriate specialist investigation by arrangement with their family doctors.

Due to a variety of reasons, not least the problem of interpreting the significance of borderline

abnormalities and workload difficulties experienced by both medical advisers on sites and consultants and laboratory staff in National Health Service hospitals, the programme has taken longer than expected and is still incomplete. Hence interim findings only can be presented at this stage and no firm conclusions can be drawn until all the facts have been elicited and the mass of data obtained has been appropriately analysed. So far, 1357 vinyl chloride workers and 429 controls have been examined. The examinations of vinyl chloride workers include 882 from Group 1 (representing an average response rate of 80%) and 475 from Group 2 (in which the proportion volunteering for examination is lower). Initial liver function test abnormalities have been found in 12.5% of the vinyl chloride workers and 16.5% of the controls. Repeat tests on vinyl chloride workers with abnormal findings have revealed persistent abnormalities in about one-third of the individuals concerned (56 men, 4.1% of the original group). No comparable data for the controls can be presented at this stage.

The 56 vinyl chloride workers with persistently abnormal liver function test results have been referred to consultants at local NHS hospitals for further investigation. These investigations have not revealed any cases of angiosarcoma and the consultants concerned have already attributed many of the persistent abnormalities to pathological conditions unrelated to vinyl chloride exposure. At present, the causes of liver dysfunction remain uncertain in about one third of these 56 cases, where precise diagnosis rests largely on the final conclusions reached by expert pathologists who are studying relevant liver biopsy specimens. To put these interim results in perspective, it should be noted that almost all the men in the latter group remain in full employment, although many of them have been transferred to work involving no further exposure to vinyl chloride in case their liver dysfunction renders them unduly susceptible to potentially hepatotoxic agents.

While this survey was in progress, previously established procedures for the detection of AOL and related conditions among vinyl chloride workers remained in force and 2 new cases of AOL have been diagnosed. The survey provided an opportunity to assess the prevalence of Raynaud's phenomenon among controls on three sites and comparisons with findings in vinyl chloride workers suggest that the condition may be equally prevalent in the two groups. However, no standard diagnostic criteria were applied and the prevalence of the condition varied widely between sites. No association has been observed between Raynaud's phenomenon and liver function abnormalities in individuals, which is of

interest in view of the apparent rarity of AOL in the cases of liver angiosarcoma that have been reported in the literature. The routine urinalyses have revealed no relevant abnormalities.

Tentative Conclusions

Abnormal liver function test findings were relatively common in both vinyl chloride workers (12.5%) and controls (16.5%) even though results had to fall well outside (2 or 3 standard deviations) the normal range in order to be classified as abnormal. Repeat testing revealed persistent abnormalities in one third of the vinyl chloride workers in whom the initial findings were abnormal and these 56 men were referred for further investigation. Comparable data for the controls are at present unavailable.

If less stringent criteria of abnormality had been adopted, the number of individuals for retesting would have been considerably greater and the effect this might have had on specialist investigation and disease detection is a matter for conjecture. The definition of abnormality is critical in this context and merits further consideration and study if the correct balance is to be achieved.

In view of the findings to date, it is not surprising that opinions of working group members about the value of periodic liver function tests in vinyl chloride workers are divided. No obvious liver disease due to vinyl chloride exposure has been identified so far, but evidence of non-cirrhotic fibrosis has been found in some cases and until the results of blind interpretation of the liver biopsy specimens become available no firm opinions can be expressed about the presence or absence of any specific pathology related to vinyl chloride in the survey population. The procedure has enabled individuals with persistent liver dysfunction to be detected and removed from exposure to vinyl chloride, and some doctors propose to continue regular liver function tests for this and other reasons, such as the need to assess sequential changes. On other sites, the yield of significant clinical findings has been so low in comparison with all the difficulties encountered that it is considered liver function tests should only be applied on a discretionary basis in future. In this connexion, it is argued that, in order to be effective, the tests used should: (a) yield positive findings at an early stage of disease; (b) produce few false positive and negative results, and (c) ideally, be able to differentiate between pathological conditions due to vinyl chloride and those due to other causes, such as alcohol.

It is also argued that continued application of a battery of tests to vinyl chloride workers is likely to cause considerable alarm and disquiet if the

results serve only to raise fusion. At the present time of structural rather than screening purposes, as is now being focused ultrasonography as a technique for the per-chloride workers.

In conclusion, although incomplete, it has already value for planning intended. From now concentrate effort on studies that are designed specific hypotheses, fact that the stringent now in force are to eliminate, any risks exposure to vinyl chloride.

DISCUSSION

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Dr B W Duck replied abnormal liver function consultants for doctors were kept of the findings the concerned decided whether work was indicated advised accordingly. decide whether to accept only one man had the rest had been transferred no loss of pay.

Dr Robert Murray (a real problem which Employment Protection in Parliament. This preventive reasons, absorption, the right of lay-off. The medical diagnosis or the exposure, the great system to cover the which was not correct. In large organizations the individual, with work not involving this might be difficult.

Dr L Magos (MRC that in Dr Duck between data on

results serve only to raise further doubt and confusion. At the present time, it appears that detection of structural rather than functional changes in the liver is likely to be more rewarding for screening purposes, and for this reason attention is now being focused on evaluation of grey-scale ultrasonography as an acceptable, noninvasive technique for the periodic examination of vinyl chloride workers.

In conclusion, although the survey is incomplete, it has already yielded information of value for planning purposes, as originally intended. From now on, it seems advisable to concentrate effort on smaller and more detailed studies that are designed especially to evaluate specific hypotheses, particularly in view of the fact that the stringent environmental standards now in force are expected to minimize, if not eliminate, any risks to health associated with exposure to vinyl chloride.

DISCUSSION

Dr A John Robertson (*Liverpool*) asked what was done for those whose tests, under the surveillance scheme, were abnormal. A man had been mentioned who was refused life insurance because of abnormal liver function tests. Taking a parallel with lead, a man could be suspended because of a raised blood lead level, and could then be refused industrial compensation because he did not have a scheduled disease, and yet the employer would not pay his wages.

Dr B W Duck replied that men with persistently abnormal liver function test results were referred to consultants for further investigation and their family doctors were kept informed throughout. In the light of the findings the consultants and other doctors concerned decided whether removal from vinyl chloride work was indicated and the men in question were advised accordingly. It was then left to the men to decide whether to accept or reject this advice. To date, only one man had rejected such medical advice and the rest had been transferred to alternative work with no loss of pay.

Dr Robert Murray (*Sudbury*) said that this was a very real problem which it was proposed to deal with in the Employment Protection Bill currently under discussion in Parliament. This would give to a man laid off for preventive reasons, because he showed early signs of absorption, the right to full wages during the period of lay-off. The more sensitive the methods of early diagnosis or the more stringent the standards of exposure, the greater would be the need to have some system to cover the no man's land between absorption which was not compensatable and disease which was. In large organizations it was usually easy to transfer the individual, without loss of money, to alternative work not involving exposure, but in smaller industries this might be difficult or impossible.

Dr L Magos (*MRC Toxicology Unit, Carshalton*) said that in Dr Duck's paper no distinction was made between data on workers from a factory where poly-

vinyl monomer pollution had decreased rapidly over the past few years (as in the plant described by Mr A W Barnes) and data on those employed in a factory where (as in Dr Anne Walker's cases) even in recent years acute narcotic episodes had occurred. This lack of distinction might completely distort Dr Duck's statistical evaluation of clinical data obtained during the survey.

Dr B W Duck replied that Dr Magos' point was well taken. However, as explained in the text, the paper presented interim findings from which no firm conclusions could be drawn. When all the data were complete it was envisaged that the industrial doctors and their consultant colleagues would publish the results obtained from individual factories.

Mr H F Henning

(*Health and Safety Executive,*
403-405 Edgware Road, London NW2 6LN)

Environmental Monitoring

It is a common misconception that environmental monitoring is easy, just a matter of collecting a sample, analysing it and getting a figure. Environmental monitoring is never easy and when an industry is faced with a sudden and substantial tightening of the standard to be applied there are equally suddenly many questions to be asked and answered. In addition, when industry and Government have to write a Code of Practice before the event, and therefore without the benefit of experience or hindsight, there are many more questions. Some of these are discussed in this paper.

Instrumental Techniques

When the threshold limit value (TLV) for vinyl chloride monomer (VCM) was 200 parts/10⁶, that is before 1974, the instrumentation used for monitoring was relatively fairly crude and insensitive. One common instrument had a lower response at about 200 parts/10⁶ so that a nil reading was taken to indicate a concentration below 200 parts/10⁶, a very convenient situation. Even the chemical indicator tubes were not designed to show concentrations below 100 parts/10⁶.

With the introduction in early 1974 of the new standard of 25 parts/10⁶ (time weighted average) and 50 parts/10⁶ (ceiling value) other existing instrumental techniques had to be adopted for use in the VCM atmospheres. Unfortunately some of the equipment which had been designed for laboratory use was not flame proof and so could not be installed directly in factory workplaces. However, many of the difficulties were overcome and all the VCM and PVC manufacturing plants have now installed what we originally called

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continuous monitoring but which is more correctly termed automatic sequential fixed point sampling. This is supplemented where necessary by short-term sampling for investigations or for checks on equipment and by long-term personal sampling to show the work people's actual exposure over long periods, e.g. four or eight hours.

Presentation of Results

The Code of Practice requires the results to be available to the workforce and for summaries to be posted in work rooms. Each fixed point monitoring system takes a sample once per minute and therefore provides nearly 500 readings per shift so that trying to decide beforehand how the results should be summarized and presented was a major problem because there was little previous experience of monitoring, and recording the results of monitoring, on such a scale.

One way of presenting the results would be to take an overall average. This has recently been done and figures provided by the industry show that the average concentration in the UK factories had been reduced in a matter of months from 24 to 6 parts/10⁶. Recent figures from some of the plants even show long-term averages of about 2 parts/10⁶. This suggests enormous progress, as indeed it is, and compares favourably with averages published by other countries. However, an overall average such as this is influenced very considerably by selection of the sampling sites and by the frequency of sampling, two aspects which are completely lost in this method of presentation and of course it offers little of use in the protection of the worker, which is the main objective of monitoring.

Influence of Peaks

An average over any period of time is influenced very considerably by peaks. For example, in a 20 point system sampling every minute a single peak of 600 parts/10⁶ due to a transient leak from nearby plant would add 25 parts/10⁶ to the shift average. In the UK we feel that it is essential to record these peaks, because they indicate escapes of VCM due perhaps to defective plant or perhaps to incorrect work practice, both matters which ought to be remedied. If the monitoring points are selected to provide a balance between operator work stations and areas where leaks may occur then we must expect to obtain some high readings. These occasions will generally be investigated and will therefore play an important role in the long-term reduction of atmospheric concentration of VCM, but in the short term they make the picture look bad, both by their presence as peaks and by their contribution to the overall shift average. There is of course no suggestion

that any operator is necessarily exposed to such peaks or to such a raised average, since many of the peaks may have occurred in specially selected areas where no person works regularly or the operator may have known about the situation and worn a respirator during that period.

Influence of Sampling Frequency

The frequency of sampling can also have an influence on the picture. Let us assume that some of the sampling points have been chosen to pick up leaks from the plant so that, say, 10% of the readings are above the ceiling value of 50 parts/10⁶. In a multi-point monitoring system sampling every minute this means that 48 readings per shift for that system alone will be above the ceiling value. Sampling at the minimum frequency required by the Code of Practice, i.e. once per shift, would give on average one high reading in each work area every tenth shift. Sampling at the minimum frequency required by the US standard, i.e. once per month, would give on average one high reading in each work area every tenth month.

We see therefore that frequent static sampling at carefully chosen points can provide much useful information but it does not necessarily tell us exactly what concentrations the work people are actually exposed to. This can be shown best by personal monitoring which is normally done at less frequent intervals because it is time-consuming for the testing staff and somewhat restrictive for the operator wearing the equipment. Nevertheless this is an extremely useful supplement to the general workroom monitoring.

Other Problems

I have said nothing in this short paper about preservation of records, which provides many problems not previously encountered in industry, nor about atmospheric monitoring in the PVC user industry where general atmospheric concentrations are less than 5 parts/10⁶ and usually less than 2 parts/10⁶, with a few known and controllable problem areas.

In short, we in the UK believe that atmospheric monitoring should be used to provide the maximum amount of information. This means that the monitoring schemes incorporating extensive multi-point systems can provide (a) useful information on deficiencies in plant or in operating procedures, (b) information with which to demonstrate progressive improvements in our aim to reduce exposure to near zero, (c) information on personal operator exposure which can be kept for future reference. Unfortunately in the short term it also provides much ammunition for our critics. This, however, is a small price to pay for the long-term benefits which we know will accrue from our efforts.

Acanthosis Nigricans and Eruptive Xanthomas
R W Emmerson
(Royal Berkshire)

B A H, man aged 55
History: 1972: Faint brown patches in axillae and groin and neck had become dark brown and pigmented, had appeared on face and had recently become more extensive. Xanthomas were controlled by diet. Investigations into the cause were negative apart from a large fatty liver.



Fig 1 Acanthosis