

Survey of the sputum cytology service in England and Wales

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Brompton Hospital, London SW3 6HP; St. Bartholomew's Hospital, London EC1 7BE; Charing Cross Hospital, London W6 8RF; St. Stephen's Hospital, London SW10 9TH and the Medical Research Council Tuberculosis and Chest Diseases Unit, Brompton Hospital, London SW3 6HP

Oswald, N. C., Hinson, K. F. W., Canti, G., Husain, O. A. N., Girling, D. J., Tall, Ruth, Stephens, R. J., and Fox, Wallace. (1975). *Thorax*, 30, 489-496. Survey of the sputum cytology service in England and Wales. Of the 231 laboratories carrying out sputum cytology in England and Wales, information on the staffing, laboratory procedures, workload, records, and results for the year 1971 was obtained from 228 (98.7%) by means of a questionnaire, which was completed in 1973 in 81% of the laboratories and at the end of 1972 in the remainder.

At the time the questionnaire was completed, the number of laboratories per region offering a service ranged from 6 to 25. Most of the processing of specimens was done by technicians and non-medical screeners (technicians without recognized qualifications) and most of the microscopy by pathologists and technicians. Papanicolaou and/or haematoxylin and eosin stains were used in 97% of the laboratories.

During 1971, the number of specimens tested per laboratory ranged from 9 to 6000. A median of 381 specimens and 165 patients were tested per laboratory. Almost all specimens were submitted by hospitals and chest clinics and only 1% by general practitioners. An estimated median of 6.5% of all cytological specimens were sputum, most of the remainder being cervical smears. Laboratories varied greatly in their positive (0%-24%) and doubtful positive (0%-27%) rates.

An estimated 63 000 patients had their sputum tested in 1971, and about 6300 had positive reports, rather less than one-quarter of all patients diagnosed as having lung cancer in England and Wales in 1971. The cost of the service was estimated to be of the order of £375 000 at 1974 prices; that is, £2.50 per specimen or £6.00 per patient tested.

An improved service might best be provided by district general hospital laboratories testing at least 1000 specimens per year so that a high level of accuracy in reporting could be assured. A large proportion of the microscopy might be done by non-medical graduates and technicians under the supervision of pathologists.

The development of sputum cytology as an aid to clinical diagnosis has led to the provision of a service for routine cytological testing in many laboratories, ranging from well established specialist laboratories to others in which specimens are tested only occasionally. The present investigation was undertaken to determine the overall development of sputum cytology in England and Wales, including staffing, laboratory procedures, the

numbers of specimens and patients tested, the reported results, and estimates of the cost.

Although malignant cells in the sputum of patients with lung cancer were first reported more than a century ago (Walshe, 1860), the development of modern sputum cytology derives principally from the staining techniques advocated by Dudgeon and Wrigley (1935) and by Papanicolaou (1942). Sputum cytology is now undertaken in

most large medical centres throughout England and Wales, and studies in many countries have established its clinical value (Farber *et al.*, 1948; Kuesko and Portele, 1949; Koss, Melamed, and Goodner, 1964; Boddington and Spriggs, 1965; Davies, 1966). Where skilled cytologists are available, it may give pathological proof of bronchial carcinoma in 40–50% of all such patients admitted to hospital and in 70–80% of those submitting three satisfactory specimens, with a false positivity rate of less than 1% (Oswald *et al.*, 1971).

PLAN AND CONDUCT OF THE SURVEY

LABORATORIES Lists of all laboratories in England and Wales offering a sputum cytology service in 1971 were obtained from each of the 15 Regional Hospital Boards. The directors of these 231 laboratories were approached by telephone to explain the purpose of the study, and were asked to complete a questionnaire about their own laboratory. All agreed to do so.

THE QUESTIONNAIRE The questionnaire covered the number of pathologists, non-medical graduates, technicians and non-medical screeners (technicians without recognized qualifications) taking part in the preparation and microscopy of specimens, the amount of time they spent, and the details of any training course they may have attended.

On laboratory procedures and records, information included the numbers and sources of sputum specimens received during 1971; the ap-

proximate percentage of all cytological specimens that were sputum; the number of slides normally prepared from each specimen; the method of staining; the category of staff responsible for the preparation and for the microscopy of slides; the average time spent scanning and checking each slide and each specimen; the statistical summaries of results that were made; and the total number of sputum specimens and patients tested during 1971, with the reported findings.

RESULTS

Of the 231 questionnaires sent out, 228 (98.7%) were returned, 81% during the year 1973 and the remainder at the end of 1972.

POPULATION AND STATISTICS OF THE SERVICE IN 1971 The population and statistics of the sputum cytology service in 1971 are shown in Table I. Questionnaires were not returned from three laboratories, and figures for the number of specimens tested were not available from four others. In consequence, the total number of specimens tested for six regions was incomplete. (At the time the survey was done, England and Wales were divided into 15 administrative regions.)

The number of laboratories in each region offering a sputum cytology service ranged from 6 to 25, the number of sputum specimens tested in each laboratory varying from 9 to 6000. Fewer than 200 specimens per 100 000 population were tested in five regions (South Western, East Anglia, Birmingham, Manchester, and Liverpool) and

TABLE I
POPULATION AND STATISTICS OF THE SPUTUM CYTOLOGY SERVICE IN 1971

| Region | Laboratories doing Sputum Cytology | Population (in thousands) | Specimens examined | | |
|-----------------|------------------------------------|---------------------------|---------------------|----------------------|------------------------------|
| | | | Total | Range per Laboratory | Total per 100 000 Population |
| NW Metropolitan | 25 | 4 253 | 18 104 ¹ | 9–2 565 | 425.7 |
| NE Metropolitan | 22 ² | 3 269 | 16 576 | 28–2 354 | 507.1 |
| SE Metropolitan | 16 ² | 3 429 | 11 803 | 83–2 367 | 344.2 |
| SW Metropolitan | 16 | 3 300 | 14 232 | 162–3 604 | 431.3 |
| Wessex | 6 | 2 054 | 5 609 | 80–1 808 | 273.1 |
| South Western | 12 | 3 177 | 5 799 | 16–1 256 | 182.5 |
| East Anglia | 9 | 1 763 | 1 789 ¹ | 39– 511 | 101.5 |
| Oxford | 8 | 2 000 | 7 457 | 62–2 083 | 372.9 |
| Wales | 20 | 2 725 | 10 502 | 64–4 141 | 385.4 |
| Birmingham | 18 | 5 119 | 8 755 ¹ | 73–2 000 | 171.0 |
| Sheffield | 16 | 4 654 | 12 028 | 20–4 000 | 258.4 |
| Leeds | 13 | 3 230 | 10 226 | 88–4 007 | 316.6 |
| Manchester | 21 | 4 574 | 8 829 | 60– 966 | 193.0 |
| Liverpool | 13 ² | 2 220 | 2 299 ¹ | 15–1 044 | 103.6 |
| Newcastle | 16 | 3 047 | 16 587 | 110–6 000 | 544.4 |
| All regions | 231 | 48 814 | 150 595 | 9–6 000 | 307.3 |

¹In one laboratory the number of specimens examined was unknown.

²One laboratory did not return a questionnaire.

more than 400 in four (North West Metropolitan, North East Metropolitan, South West Metropolitan, Newcastle), the mean for all regions being 307.3.

SOURCE OF SPECIMENS Full information on the source of specimens for 1971 (Table II) was available from 200 laboratories, and incomplete information from a further 14. Of the 128 099 specimens received, nearly all came from hospitals or chest clinics, and only 1% from general practitioners and 0.5% from other sources.

TABLE II
SOURCE OF SPECIMENS IN 1971

| Source supplying Specimens | Laboratories ¹ | | Specimens ² | |
|----------------------------|---------------------------|-------|------------------------|-------|
| | No. | % | No. | % |
| Own hospital | 213 | 99.5 | 77 199 | 60.3 |
| Other hospitals | 131 | 61.2 | 35 041 | 27.4 |
| Chest clinics | 132 | 61.7 | 13 998 | 10.9 |
| General practitioners | 112 | 52.3 | 1 231 | 1.0 |
| Other sources | 18 | 8.4 | 630 | 0.5 |
| All laboratories | 214 | 100.0 | 128 099 | 100.0 |

¹Excluding 14 laboratories which gave no indication of the sources of their specimens.

²Excluding 22 545 specimens from 28 laboratories which gave an incomplete breakdown of the sources of their specimens.

LABORATORY STATISTICS Laboratories varied considerably in the way their records were organized and in the proportion of their work which was sputum cytology (Table III). The majority made

a monthly, quarterly or annual statistical summary, but 67 (31% of 217) kept no more than a laboratory daybook. Sputum accounted for a median of only 6.5% of specimens. (In almost all laboratories, cervical cytology constituted by far the greatest proportion of the cytological specimens tested.) The median number of specimens tested per laboratory was 381 and for the 144 laboratories in which a record of the number of patients with sputum specimens tested was kept, the median number of patients was 165, the average number of sputum specimens per patient in these laboratories being 2.42.

In summary, only a small amount of sputum cytology was done in most laboratories and sputum specimens constituted a small proportion of the total cytology specimens tested during the year.

STAFF CARRYING OUT PROCEDURES The grade of staff preparing and examining specimens, and the time spent in estimated full-time equivalents (10 half days per week) is shown in Table IV. Most of the preparing and staining was done by laboratory technicians assisted by non-medical screeners. Pathologists and non-medical graduates took little part at this stage.

The microscopy of slides (scanning and checking) was done predominantly by pathologists and technicians. In 114 (50%) laboratories pathologists scanned slides, and in 47 (21%) they did all the

TABLE III
LABORATORY STATISTICS IN 1971

| Statistic | Laboratories supplying Statistic | | Laboratories | |
|--|----------------------------------|--|---|---|
| | | | No. | % |
| Statistical summary normally kept in laboratory | 217 | Monthly ± others Quarterly ± annual Annual only No records ¹ | 77 5 68 67 | 35 2 31 31 |
| Percentage of cytology specimens examined that were sputum | 223 | — 1% — 5% — 10% — 20% — 50% — 100% Median 6.5% | 19 83 51 30 20 20 | 9 37 23 13 9 9 |
| Number of sputum specimens examined by the laboratory | 224 | < 100 100— 200— 500— 1000— 2000— 3000— 4000— Median 381 | 29 34 70 47 30 9 2 4 | 13 15 31 21 13 4 1 2 |
| Number of patients with sputum specimens examined | 144 | < 50 50— 100— 200— 500— 1000— Median 165 | 23 27 35 41 12 6 | 16 19 24 28 8 4 |

¹Laboratory day books are not considered to constitute a statistical summary.

TABLE IV
GRADES OF STAFF, AND TIME SPENT CARRYING OUT LABORATORY PROCEDURES
(BASED ON 228 LABORATORIES)

| Grade of Staff | Laboratory Procedures | | | | | | | | | |
|----------------------|------------------------|----------|-----------------|---------------------------------|------------------------|------------|----------|----|-----------------|---------------------------------|
| | Preparation | | | | | Microscopy | | | | |
| | Number of Laboratories | | Number of Staff | Estimated Full-time Equivalents | Number of Laboratories | | | | Number of Staff | Estimated Full-time Equivalents |
| | Preparing | Staining | | | Scanning | | Checking | | | |
| Any | | | All | Any | All | | | | | |
| Pathologist | 8 | 5 | 11 | 1 | 114 | 47 | 219 | 78 | 354 | 25 |
| Non-medical graduate | 10 | 11 | 11 | 1 | 15 | 0 | 4 | 0 | 18 | 2 |
| Technician | 222 | 214 | 578 | 32 | 177 | 95 | 76 | 4 | 368 | 37 |
| Non-medical screener | 40 | 37 | 74 | 10 | 19 | 1 | 1 | 0 | 43 | 5 |

scanning. In 177 (78%) laboratories technicians scanned slides, and in 95 (42%) they did all the scanning. In contrast, pathologists checked slides in 219 (96%) and did all the checking in 78 (34%), and technicians checked slides in 76 (33%) and did all the checking in 4 (2%). Non-medical graduates and non-medical screeners made only a small contribution to microscopy.

In summary, slides were prepared predominantly by technicians and non-medical screeners, and were scanned and checked by pathologists and technicians.

TRAINING OF STAFF Information on training was available for 262 of the pathologists doing microscopy; 113 had attended a course which included training in sputum cytology. Courses had also been attended by 211 of 302 technicians, 8 of 15 non-medical graduates, and 16 of 25 screeners. These courses usually included not more than one day on sputum cytology.

LABORATORY PROCEDURES

Number of slides per specimen The number of slides prepared routinely from each specimen is

shown in Table V. In the majority of laboratories (62%) two slides were prepared, but the number ranged from one to six.

Time spent on microscopy The time spent per specimen on microscopy (Table V) varied from 5 minutes or less in 17 (7%) of the laboratories to more than 20 minutes in 46 (20%), the average being 17.6 minutes. The average time spent on each specimen was 17.7 minutes for laboratories processing fewer than 200 specimens, 19.3 for 200-499, 18.1 for 500-999, and 14.8 for 1000 or more specimens respectively. There was thus no obvious correlation between the number of specimens processed in the laboratory and the time spent per specimen on microscopy, except that laboratories processing 1000 or more specimens in the year spent a somewhat shorter time per specimen.

Methods of staining In 221 (97%) of the laboratories, the Papanicolaou and/or haematoxylin and eosin staining methods were used with or without other methods. Of the remaining seven, methylene blue wet preparations were used exclusively in three. In four the question was left unanswered.

TABLE V
NUMBER OF SLIDES PREPARED AND TIME SPENT ON MICROSCOPY

| | Laboratories | |
|--|--------------|--------|
| | No. | % |
| Number of slides prepared routinely from each specimen | 1 | 30 13 |
| | 2 | 142 62 |
| | 3 | 26 11 |
| | 4 | 23 10 |
| | 5 | 6 3 |
| | 6 | 1 <1 |
| Time spent per specimen on microscopy (minutes) | - 5 | 17 7 |
| | - 10 | 64 28 |
| | - 15 | 34 15 |
| | - 20 | 60 26 |
| | > 20 | 46 20 |
| | Not known | 7 3 |
| All laboratories | 228 | 100 |

TABLE VI
SUMMARY OF LABORATORY RESULTS FOR 1971

| Category of Results | From 133 Laboratories examining 100 or more Specimens and providing Results in all 4 Categories | | From 180 Laboratories providing Number of 'Positive' and 'Doubtful Positive' Specimens | | From 122 Laboratories providing Numbers of 'Positive' and 'Doubtful Positive' Reports both for Specimens and for Patients | | | |
|---------------------|---|-------|--|-------|---|-------|----------|-------|
| | Specimens | | Specimens | | Specimens | | Patients | |
| | No. | % | No. | % | No. | % | No. | % |
| Positive | 7 004 | 7.3 | 8 341 | 7.0 | 6 002 | 7.5 | 3 355 | 10.1 |
| Doubtful positive | 3 159 | 3.3 | 3 449 | 2.9 | 2 401 | 3.0 | 1 257 | 3.8 |
| Negative | 74 329 | 77.9 | 107 628 | 90.1 | 71 601 | 89.5 | 28 742 | 86.2 |
| Unsatisfactory | 10 951 | 11.5 | | | | | | |
| Total | 95 443 | 100.0 | 119 418 | 100.0 | 80 004 | 100.0 | 33 354 | 100.0 |

FINDINGS IN LABORATORIES TESTING 100 OR MORE SPECIMENS There were 133 laboratories (Table VI, first column) providing a complete breakdown of results in which at least 100 specimens were tested in 1971. Of the total of 95 443 specimens tested in these laboratories, 7.3% were reported 'positive', 3.3% 'doubtful positive', 77.9% 'negative', and 11.5% 'unsatisfactory'. However, there was a wide scatter in the proportion in each category between individual laboratories (Table VII). Further analysis showed no correlation between the proportion of 'doubtful positive' reports and the category of staff doing the microscopy.

The second column of Table VI lists the findings in all the 180 laboratories reporting 'positives' and 'doubtful positives'. It includes the 133 laboratories already described, together with a further 47 in which no differentiation was made between 'negative' and 'unsatisfactory' specimens.

PATIENTS EXAMINED BY SPUTUM CYTOLOGY

One hundred and twenty-two laboratories gave the numbers of specimens and patients with 'positive' and 'doubtful positive' reports (Table VI, right-hand section). The figures for *specimens* were similar to those from the 180 laboratories (second column). The proportions of *patients* with 'positive' and 'doubtful positive' reports were 10.1% and 3.8% respectively. The 6002 positive specimens came from 3355 patients, so that approximately 1.8 positive specimens were obtained per patient with positive cytology.

DISCUSSION

On the basis of the results for patients tested by sputum cytology in the 122 laboratories, it is possible to obtain two estimates of the total number of patients tested in England and Wales in 1971. First, assuming that the mean number of

TABLE VII
DISTRIBUTION OF FINDINGS IN 133 LABORATORIES EACH EXAMINING AT LEAST 100 SPECIMENS IN 1971

| Percentage of Specimens | Number of Laboratories in which the Percentage of Specimens was: | | | | | |
|-------------------------|--|----------|-------------------|----------|----------------|-----------------------------|
| | Positive and Doubtful Positive | Positive | Doubtful Positive | Negative | Unsatisfactory | Negative and Unsatisfactory |
| 0 | 3 | 3 | 17 | | 20 | |
| 1 | 2 | 4 | 14 | | 6 | |
| 2 | 6 | 11 | 24 | | 4 | |
| 5 | 21 | 42 | 43 | | 28 | |
| 10 | 38 | 47 | 25 | | 15 | |
| 20 | 51 | 25 | 8 | | 30 | |
| 30 | 9 | 1 | 2 | 2 | 19 | |
| 40 | 2 | | | 0 | 9 | |
| 50 | 0 | | | 3 | 1 | 1 |
| 50- | 1 | | | 8 | 0 | 0 |
| 60- | | | | 23 | 0 | 2 |
| 70- | | | | 31 | 1 | 9 |
| 80- | | | | 40 | | 51 |
| 90- | | | | 19 | | 38 |
| 95- | | | | 3 | | 21 |
| 98- | | | | 2 | | 6 |
| 99- | | | | 0 | | 2 |
| 100 | | | | 2 | | 3 |
| Median | 9.8% | 5.6% | 2.7% | 79.9% | 7.2% | 90.2% |

patients tested per laboratory was the same for all the laboratories as for the 122 laboratories in the right-hand section of Table VI, the total number of patients tested in 1971 would be 63 154. Secondly, assuming that the number of sputum specimens per patient was the same for all laboratories as for the 122 laboratories, the total patients tested would be 62 784. It is therefore probable that approximately 63 000 patients were tested by sputum cytology in 1971 in England and Wales. If 10.1% of these were found to have positive cytology (the proportion for the 33 354 patients examined in the 122 selected laboratories), the total patients in 1971 found to have positive cytology would be approximately 6300.

The incidence of lung cancer for England and Wales in 1971 is not known. The incidence from the cancer registers of the 10 regions from which figures were available at the time this report was drafted was 15 685 cases in a population of 28 604 000, giving an estimated incidence of 26 767 cases for the whole country. This is likely to be an underestimate since information in regional cancer registers is obtained predominantly from hospital records and death certificates. The true incidence is probably higher than the mortality rate for 1971 which was 30 754. With an estimated incidence of known cases of approximately 27 000, and assuming that all the positive cytological reports were made on patients with lung cancer diagnosed during 1971, positive cytology was likely to have been reported from rather less than one-quarter of the new cases of lung cancer diagnosed during the year.

The overall positivity rates in the present study showed a wide scatter from laboratory to laboratory. While positivity rates clearly depend on the population served, the patient selection and the care taken in obtaining satisfactory specimens, it is likely that the number of false positives was high in some laboratories and false negatives in others, although the present survey was not designed to provide information on the reliability of reported results.

There was considerable variation in the proportion of specimens reported as 'doubtful positive'. This may have depended to some extent on the way particular findings, such as squamous metaplasia, were reported, or may have been due at times to a reluctance, as a matter of policy, to make a definitive cytological diagnosis. There was no association between the proportion of 'doubtful positive' reports and the category of staff doing the microscopy.

The survey shows considerable variation in the regional distribution of laboratories undertaking sputum cytology, in the number of specimens tested, and in the percentage that were reported as 'positive' in each laboratory. The establishment of facilities for sputum testing in individual hospitals usually depends on the interests of the pathologists concerned, pressure from clinicians or opportunities for extending the scope of existing centres for cervical cytology.

The estimates made in the laboratories themselves and reported in the questionnaires suggested that in 1971 sputum constituted only about 6.5% of all cytological specimens examined in laboratories doing sputum cytology. This figure accords well with the ratio of total sputum specimens for 1971 to total cervical plus sputum specimens. Laboratory directors frequently commented that their cytological service had become swamped by cervical screening, and that they feared that the reliability of sputum cytology may have suffered in consequence.

Although the service is available to any medical practitioner who wishes to make use of it, almost all the specimens tested in 1971 were collected in hospitals or clinics, and only 1% of them were submitted by general practitioners. It is, indeed, preferable that general practitioners should refer patients to specialized centres instead of requesting sputum cytology themselves since for the test to be reliable, specimens must be of good quality and be processed soon after collection (Coleman, 1969). They should preferably be produced under supervision in hospitals or chest clinics, or even in the laboratories themselves.

The processing of specimens is done mainly by laboratory technicians and unqualified laboratory assistants, and the microscopy mainly by pathologists and technicians. Very few non-medical graduates are employed in the service, in spite of their availability and scientific training, largely because at present they lack a satisfactory career structure. There would seem to be no good reason why much more of the sputum cytology, especially screening, should not be done by non-medical graduates.

In general, staff doing microscopy obtained their skill in laboratories in which training facilities were limited. Although just over half (58%) had attended formal courses of instruction, these courses usually included not more than a single day on sputum cytology. At present, to the best of our knowledge, these formal courses are offered by only six laboratories in England and Wales. Whether there should be longer prescribed

courses of formal instruction and/or a minimum in-service training requirement for sputum cytologists is a question which requires consideration. Perhaps the main point at issue is the maintenance of high standards in any laboratory where in-service training is being provided. There might be selected centres for this purpose, where regular case discussions and tutorials would be held.

The cost of the service can be estimated if certain assumptions are made. If the numbers and categories of staff employed in the service were unchanged since the questionnaires were completed (the great majority were completed during the year 1973), and if all staff were receiving the median of their 1974 salary range, then the total estimated salaries at 1974 prices is of the order of £300 000, made up of full-time equivalents for 26 pathologists at £6000 per year, for three non-medical graduates at £1824, for 69 technicians at £1711, and for 15 non-medical screeners at £1417. If all other laboratory costs amount to 25% of the salaries, the total estimated cost for the year would be approximately £375 000. This gives an estimated cost of £2.50 per specimen, or £6.00 per patient tested, if the same numbers of specimens and patients were tested in 1974 as in 1971.

It may be argued that, for sputum cytology, a more efficient and economical service with higher and more uniform standards could be provided by a few specialized laboratories, each examining large numbers of specimens, such as exists for many microbial and serological examinations in the Public Health Laboratory Service. A sputum cytology service centred on a small number of laboratories would present problems. A system of rapid delivery to the laboratories would be necessary, since many pathologists object to the addition of preservatives to the specimens. Alternatively, slides could be prepared in peripheral centres and then sent to a central laboratory to be read, but this would risk impairing quality control. There might also be delays in reporting results. Sputum cytology, like other forms of *diagnostic* cytology, but unlike the *screening* of cervical smears, is performed in close co-operation with clinicians and loses much of its value when it is carried out in isolation, especially when bronchial washes, brush cytology or needle aspirates are also being examined.

The average rate of sputum tests per 100 000 population in this survey was just over 300—a low average, in all probability well below the requirement in a well used service. If an average group

laboratory in a newly formed NHS district general hospital serves a population of 200 000 to 250 000, then a 'district' cytology department could be expected to carry out more than 1000 sputum tests per year. This would imply a cytodiagnostic service with about 20 000 specimens yearly if material from other body sites, including the uterine cervix, were added. This accords well with the estimate made by the Working Party of the British Society for Clinical Cytology that a district general hospital laboratory should be able to handle 20 000 to 30 000 specimens per year, or possibly more if a full screening service for cervical cancer is included (Husain, 1974, personal communication). Such a department would command a substantial staff and should be able to achieve and maintain a high standard. However, this is impractical at present owing to the scarcity of skilled staff and should probably not be adopted as a national policy until an effective training programme for staff is instituted and the maintenance of quality control can be assured and until the clinical value and accuracy of sputum cytology outside specialist centres can be convincingly demonstrated.

We are grateful to the directors and staff of the 228 laboratories (whose regional distribution is given in Table I) for their wholehearted co-operation in the study and for the completeness of the data.

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