Summary

An investigation amongst full-time newborn babies in two nurseries has been carried out in an attempt to discover the usual routes of spread of *Staph. aureus*.

Initially 53 babies were all found to be nasal carriers by the 10th day, and 11 out of 12 of these babies also carried staphylococci in their stools. Examination of bedding suggested that this was not the immediate source of staphylococci, and prevention of possible contamination from the staff by the use of chlorhexidine hand-cream or gowns made little difference.

The use of triple dye to the umbilicus and individual gowns for each baby, both as separate and as combined measures, produced a reduction in the nasal carriage rate on the 12th day of life by about 25–30%.

No evidence was obtained that babies gained staphylococci from their mothers, but there was evidence that staphylococci on the mothers' breasts came from their babies.

We would like to thank Dr. C. F. Harris and Mr. J. Beattie for permission to conduct these trials; we are also much indebted to the Sister in Charge of the Maternity Ward and her staff for their co-operation. Dr. R. E. O. Williams kindly carried out the phage-typing for us.

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MASKING AND GOWNING IN NURSERIES FOR THE NEWBORN INFANT

EFFECT ON STAPHYLOCOCCAL CARRIAGE AND INFECTION

BY

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Reports from various parts of the world testify that staphylococcal infection of the newborn infant is a widespread problem in maternity units, a problem to which, unfortunately, no easy solution is apparent. There is general agreement that in the control of this infection prophylaxis rather than the treatment of established lesions is the prime objective. As a prophylactic measure masks and gowns are worn extensively if somewhat uncritically by attendant personnel. Between one maternity unit and another the practice of masking and gowning can vary considerably, from a strictly regulated conscientiously performed regime to a meaningless ritual or mere gesture.

This paper describes a controlled trial carried out in a maternity unit with the object of determining the effect of masking and gowning on staphylococcal carriage and infection of the newborn infant.

The Experiment

In a 50-bedded maternity unit over a period of three months two nurseries were set aside for a controlled experiment.

At birth babies were allotted at random to one of these two nurseries. In one nursery (the "masked" nursery) a strict masking and gowning regime was in operation, in the other (the "unmasked" nursery) no masks or gowns were worn. The attendant staff was common to both nurseries. In the masked nursery all personnel entering the nursery, whether doctors, nurses, or cleaners, donned a mask and gown. The masks consisted of four layers of gauze with a "cellophane" insert, and extended below the chin. The nursing staff changed their masks at least every hour. The masks were autoclaved in a drum and when required were removed from the drum with sterile forceps. The instructions were that while being worn the mask should not be touched at all by hand. On discarding, the masks were dropped into a lidded receptacle containing antiseptic. Gowns donned before entering the nursery were put on in an ante-room, where they were kept hanging when not in use. In addition to the gown worn on entering the nursery each cot carried a folded gown which was worn when the baby in that cot was being handled. All gowns were changed every 24 hours or when soiled. They were not autoclaved, but one stage of the laundering was to raise the temperature of the washing water to 200° F. (93° C.) for 10 minutes. In the unmasked nursery nurses wore their ordinary uniform, the apron of which was changed daily or when soiled.

For the first two days the babies were taken to their mothers for feeding. In the case of the babies from the masked nursery the mothers were masked and gowned with the baby's "individual" gown. Thereafter the mothers fed their infants in the nurseries, and again in the masked nursery they were appropriately masked and gowned. Mothers were permitted to handle their own babies only. If any baby developed an infection in either nursery he was immediately removed to an isolation nursery. The babies from the masked nursery were bathed in a bathroom kept for them only; those in the unmasked nursery were bathed in another bathroom. There was thus no direct contact between the babies from the two nurseries. Bathing was carried out daily from the fourth day onwards.

So far as possible other factors were kept constant in the two nurseries. The rule that hands should be washed between handling each baby applied in both. Daily cleaning, by wet mopping, was carried out in both. Temperature, floor space per cot, and ventilation were the same.

Between occupants cot clothing was dealt with as follows. The cot mattress was aired unless the baby had suffered from an infection. If so, the mattress was autoclaved. Blankets were washed at 90° F. (32° C.). Other cot clothing, mattress cover, canvas bassinet, sheet, wrap, gown, napkin, and cot cover underwent a stage in laundering in which they were washed at 200° F. (93° C) for 10 minutes.

Understandably the amount of traffic in the masked nursery was somewhat less than in the unmasked nursery, as the masking and gowning regulations in that nursery deterred entry for other than essential purposes. One other relevant factor was that this experiment was carried out at a time when a high infection rate for minor staphylococcal infection prevailed among the babies. This indeed was one of the considerations which prompted it. All infections in babies, no matter how trivial, were recorded, and, if possible, a swab was taken from the lesion. Each baby had an eye swab taken routinely on the fourth day, a nasal swab taken on the eighth day, and an umbilical swab taken at the time of separation of the cord (which on average was the eighth day). Nasal swabs were taken from the staff four times during the period of the experiment.

The total number of babies admitted to the nurseries during the course of the experiment was 82 to the masked nursery and 85 to the unmasked nursery.

The mean duration of stay in the masked nursery was just over 8½ days, the median being 9 days and the range

1 to 16 days. In the unmasked nursery the mean was 9 days, the median 10 days, and the range 2 to 16 days.

In the tables the bracketed increments are twice the standard errors of the percentage shown. Statistical significance is assessed on this basis.

Infection.—The infection rates in the two nurseries are shown in Table I. These are infections assessed clinically. All were minor infections. The infection rates in the two nurseries were practically the same. The sites of infection

TABLE I.—*Infection Rates*

Nursery	Total No. Admitted	Total Infected	Infection Rate
Masked	82	22	27% (±10)
Unmasked	85	27	30% (±10)

are shown in Table II. As between the masked and unmasked nurseries there is no statistical difference in the incidence of infection at the various sites.

TABLE II.—*Sites of Infection*

Nursery	Eye		Skin		Umbilicus	
	No.	%	No.	%	No.	%
Masked (22 infections)..	13	59 (±21)	8	36 (±20)	1	5 (±9)
Unmasked (27 infections)	10	37 (±19)	16	59 (±19)	1	4 (±7)

Carriage.—The carriage rates for coagulase-positive staphylococci for the various sites on the infant and the staff nasal carriage rate are shown in Table III. There was no significant difference in the carriage rates for staphylococci on the eye, nose, or umbilicus in the two nurseries, and the total carriage rates were very similar. The staff nasal carriage rate was of the same order as the carriage rate on the babies.

TABLE III.—*Carriage*

	Nursery	No. Swabs	Staph. Coag. Pos.	Staph. Coag. Neg.	Others	No Growth	Staph. (Coag. Pos.) Carriage
Eye (4th day)	Masked	80	28	56	4	4	35% (±11)
	Unmasked	79	28	51	6	6	35% (±11)
Nose (8th day)	Masked	67	41	37	1	1	61% (±11)
	Unmasked	66	38	28	4	2	58% (±12)
Umbilicus (cord off)	Masked	62	44	18	27	3	71% (±11)
	Unmasked	65	36	16	36	6	55% (±12)
Total	Masked	209	113	111	32	8	54% (± 7)
	Unmasked	210	102	95	46	14	49% (± 7)
Nose ..	Staff	45	22	20	1	4	47% (±15)

Drug-sensitivity Patterns of Coagulase-positive Staphylococci Isolated

Each coagulase-positive staphylococcus isolated was subcultured and tested by the disk technique for sensitivity to six antibiotics and to sulphonamide. It was therefore possible to work out a drug-sensitivity pattern for the coagulase-positive staphylococci from the masked nursery, the unmasked nursery, and the staff.

These patterns, based on the resistance of the organism to the drugs specified, are shown in Table IV. Strains of coagulase-positive *Staphylococcus pyogenes* are classified as resistant to penicillin when their minimum inhibitory concentration exceeded 3 units per ml. and resistant to streptomycin, chloramphenicol, chlortetracycline, oxytetracycline, erythromycin, and sulphonamide when their minimum inhibitory concentration exceeded 1, 10, 2.5, 2.5, 2.5, and 100 μg./ml. respectively. All were found to be sensitive to erythromycin; thus this antibiotic is not included in the table.

TABLE IV.—*Drug Sensitivity Pattern*

Source	No. Staph.	Percentage of Strains Resistant to:					
		Sulph.	Penic.	Strep.	Chloram.	Chlortet.	Oxytet.
Masked ..	137	39± 8	75± 7	47± 9	14± 6	10± 5	18± 7
Staff ..	25	32±19	44±20	12±12	8±11	8±11	8±11
Unmasked	130	43± 9	75± 8	51± 9	8± 5	15± 6	15± 6

It can be seen that there is no significant difference in the drug sensitivity pattern of the staphylococci found in the babies in the masked and in the unmasked nurseries. If the patterns of the staphylococci found in these two groups of babies are compared with those of the staphylococci found on the nursing staff there is, however, a significant difference. This is seen in penicillin and streptomycin resistance. The highest penicillin and streptomycin resistance which the staff staphylococci could by chance have reached (using twice the standard error of the percentage) would have been 64% and 24% respectively. Both of these fall short of the lowest percentage resistance which could have occurred in the organisms from the masked and unmasked nurseries—namely 68% and 67% for penicillin and 38% and 42% for streptomycin.

Nursing Time Expended and Cost

Nursing Time.—The time expended on the various procedures involved in the masking and gowning regime was determined, using a stop-watch. These figures were applied to the whole 50-bedded unit and a schedule of nursing time expended was drawn up (Table V). At any one time the

TABLE V.—*Daily Nursing Time Expended on Masking and Gowning in a 50-Bedded (About 45 Babies) Maternity Unit*

Masking (Mask on and off=30 seconds)	
7 Nursing-staff change masks hourly ..	84 minutes
Processing of about 200 masks daily:	
Washing—20 minutes ..	
Cellophane inserts—50 minutes ..	110 ,,
Autoclaving—40 minutes	
1% loss of efficiency due to mask	101 ,,
	295 ,,
Gowning (Gown on and off=35 seconds)	
Gown changes—8 baby/day	210 minutes
Provision and disposal of 60 gowns per day	35 ,,
	245 ,,
Total nursing time	9 hours a day

average number of nurses looking after the babies was seven. As the average working day of a nurse is eight hours, more than the full daily working time of one nurse would be employed on masking and gowning.

Cost.—An attempt has been made to estimate the cost of masking and gowning in a maternity unit of this size (Table VI). Many factors are difficult to evaluate, and such

TABLE VI.—*Annual Cost*

	£
9 hours' nursing time a day	300
1,200 masks (each mask lasting 2 months)	65
120 gowns (each gown lasting 6 months)	165
Laundering, sterilizing, and repairing masks and gowns..	100
	630

an estimation must be a very rough one. To the total cost, masking would contribute about £280 and gowning about £350.

Discussion

In this experiment we were concerned only with the effect of masking and gowning on the dissemination of staphylococci. The results would not necessarily be applicable to other bacteria or to viruses. From a quantitative point of view, however, there is no doubt that staphylococcal infection is the most important one affecting the newborn infant in maternity units.

The masking and gowning regime employed was as elaborate as is likely to be practicable in most maternity units. It was certainly more thorough than is practised in many. Yet our results show no difference in the rate of staphylococcal infection or in the staphylococcal carriage rate in the masked as compared with the unmasked nursery. At a time when the neonatal staphylococcal infection rate in the unit was high masking and gowning failed to exert any significant effect in reducing it.

Comparison of the drug-sensitivity patterns of the staphylococci found on the babies in the masked and unmasked nurseries and on the nursing staff probably gives a clue to the ineffectiveness of masking. In the unmasked nursery

there was nothing to stop the free dissemination of staphylococci from the nares and mouth of the nursing staff to the babies should such occur naturally; yet the pattern of staphylococci found on the babies differed from that found on the nurses. This suggests that little dissemination from mouth and nose of nurse to baby did in fact take place. The interposition of a mask between nurse and baby in the masked nursery would therefore not be expected to accomplish anything, and it did not. The same nursing staff did, of course, serve both nurseries. Were the predominant spread of infection to be—as we believe—from baby to baby indirectly, our results would be more easily understood.

Nurses in maternity units usually have a high nasal carriage rate for coagulase-positive staphylococci (Barber *et al.*, 1949; Rountree and Thomson, 1952; Edmunds *et al.*, 1955); it has been suggested that they may be an important source of infection of the infant (Allison and Hobbs, 1947). The drug-sensitivity pattern of staphylococci carried by such nurses may differ from or may resemble that found on the infants. Forfar *et al.* (1953) noted a difference in pattern, and suggested that nurses were not an important source of infection. Two years later, in the same maternity unit, staphylococci from nurses and babies showed a similar drug-sensitivity pattern and were predominantly of the same phage types (Forfar *et al.*, 1955). Edmunds *et al.* (1955) noted that the drug-sensitivity pattern from babies born at home was different from that of the domiciliary midwives attending them daily. Hutchison and Bowman (1957) noted that the drug-sensitivity pattern of babies' staphylococci differed from that of nurses and confirmed the difference by phage-typing. Edmunds *et al.* (1955) noted that the staphylococci carried by infants showed little resemblance to those found on their mothers, arguing against transmission from mother to baby. They suggested transmission from baby to mother as a more likely sequence of events. Hutchison and Bowman (1957) made similar observations, noting that when babies were nursed beside their mothers the mothers tended to pick up the staphylococci which the babies were carrying.

The fact that the babies' and nurses' staphylococci can be different suggests that nurses are not a constant or major source of babies' staphylococci, at least so far as transfer from the nose of the nurse is concerned. The fact that babies' and nurses' staphylococci may at times be similar should not be interpreted as evidence of transmission from nurse to infant. It would be surprising if not infrequently or even usually nurse and baby, dwelling in the same environment, did not pick up the same organisms and did not both have a high carriage rate. The frequent occurrence in both of a high carriage rate for the same type of staphylococci is much more likely to be a reflection of a common environment than an indication of direct transfer of organisms. The baby is probably the important source of infection from a quantitative point of view, but the nurse may act as the agent who introduces a particular staphylococcus into a maternity unit (Colbeck, 1949).

Our results can be related to the evidence regarding transmission of staphylococci from the mouth and nose in droplets. Hare and Thomas (1956) suggest that relatively few staphylococci are transferred direct by droplet spray. Duguid (1945) has shown that in normal breathing over a five-minute period no droplets or only a few may be produced. The investigations of Duguid (1946) and of Duguid and Wallace (1948) have shown that the few droplets originate in the nose rather than the mouth and only a small proportion of these will be infected with staphylococci even in a nasal carrier. From such investigations it would seem that breathing during 10 hours would at most infect the air with 100 or so *Staph. aureus* infected particles, about the same number as result from the liberation of dust from a carrier's clothing during 10 minutes' bodily movement or, as shown by Dumbell *et al.* (1948), from one use or flourish of an infected handkerchief. More droplets are released in coughing, loud talking, and sneezing than in breathing. Presumably such activities on the part of those nursing the newborn infants should be discouraged. Even sneezing, however, produces very few staphylococcal-infected droplets (Duguid and Wallace, 1948). The evidence obtained from experiments on *Staph. aureus* air infection in a maternity unit led Wallace and Duguid (1952) to conclude that air infection was not due in any important degree to droplet nuclei derived from nasal and mouth secretions.

In the light of these findings the unimportant role of the mask in controlling staphylococcal infection is not difficult to understand. It is even possible that a mask may have a negative effect; that the irritation of the face which it produces may encourage touching of a potentially contaminated area and contact infection via the hands. It is also possible that movement of the mask may rub off from the face particles contaminated with staphylococci.

The allocation of an individual gown to a baby is a practice which enjoys a considerable vogue as a prophylactic measure on the assumption that it will limit the transmission of infection which might occur with a communal gown. Yet the very act of putting on a gown at a baby's cot is likely to be a contaminating procedure. Dressing and undressing are activities which can result in heavy contamination of the atmosphere with bacteria-carrying particles, much more so than ordinary movement (Duguid and Wallace, 1948). Nasal carriers of *Staph. aureus* release into the air from their clothing on movement many times the number of bacteria which they release on sneezing (Duguid and Wallace, 1948). Once put on, a sterile gown of the usual surgical type only reduces the number of bacteria-carrying particles dislodged from the clothes on movement by half.

Nursing time is a valuable commodity, but it is usually a limited one. According to our calculations the time spent in carrying out a correct masking and gowning regime in the nurseries of a 50-bedded maternity unit is equivalent to more than the full-time service of a nurse. The nursing time spent on masking and gowning must be met at the expense of other calls on nursing time or, alternatively, an extra nurse must be employed. It must be decided whether among competing claims on nursing time masking and gowning are justifiable procedures or whether the additional cost of extra nursing personnel, etc., is the best way of spending limited funds.

It seems likely that in seeking prophylactic measures against staphylococcal infection in maternity units attention can be more profitably directed to the control of air-borne infection resulting from contamination of the atmosphere by dust from personal clothing, bedding, fomites, etc.; to the avoidance of contact with contaminated bedding, clothes, towels, hands, baths, etc. (Wallace and Duguid, 1952; Colbeck, 1956); and to the rendering non-infective of the baby infected with or carrying pathogenic staphylococci rather than to the masking and gowning of attendant personnel.

Summary

A controlled experiment was carried out in a maternity unit to determine the effectiveness of masking and gowning in reducing staphylococcal infection of and carriage on newborn infants. A strict masking and gowning regime was employed in one nursery (the "masked" nursery) but not in another (the "unmasked" nursery).

In both nurseries the same proportion of infants suffered from minor staphylococcal infections. The sites of occurrence of these infections were the eye and skin predominantly and also the umbilicus. Between the two nurseries there was no significant difference as to site of infection.

The carriage rate for staphylococci in the babies in the two nurseries was determined by examining swabs from the eye, nose, and umbilicus. The carriage rate for staphylococci in the attendant nursing personnel was determined by nasal swabbing. There was no significant difference in the carriage rates for babies in the masked and unmasked nurseries or between the babies and the attendant personnel.

There was no significant difference in the drug-sensitivity pattern of staphylococci isolated from babies in the two nurseries but a significant difference in pattern between babies' and nurses' staphylococci.

It is concluded that direct transfer of staphylococci from the nose and mouth of attendant personnel to the baby is not an important means of infection of the latter, and that masking and gowning in maternity nurseries is unlikely therefore to be an effective preventive measure.

An attempt has been made to assess the cost of masking and gowning in nursing time and money.

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FREEZE-DRIED B.C.G. VACCINE

RESULTS OF LABORATORY TESTS AND OF TRIALS AMONG SCHOOLCHILDREN IN MIDDLESEX

A PRELIMINARY REPORT TO THE MEDICAL RESEARCH COUNCIL BY THEIR COMMITTEE ON THE STANDARDIZATION OF FREEZE-DRIED B.C.G. VACCINE *

In 1956 the first results were published of a controlled trial made to assess the efficacy in adolescents of the liquid B.C.G. vaccine prepared by the State Serum Institute, Copenhagen, Denmark (Medical Research Council, 1956). It was shown that the liquid vaccine was able to induce a high degree of tuberculin sensitivity and to confer, for at least two and a half years after administration, substantial protection against tuberculosis. This vaccine, which is extensively used in the United Kingdom in the vaccination of 13-year-old children and of those known to be in contact with tuberculosis, has certain disadvantages. Its keeping qualities are limited, and the State Serum Institute recommends that it should be used within 14 days of issue. This adds to the administrative difficulties of local health authority vaccination schemes and often results in waste of vaccine. A further disadvantage is that the liquid vaccine must be used before the results of laboratory tests for activity and safety can be known.

A freeze-dried B.C.G. vaccine has now been developed in England by Glaxo Laboratories Ltd., and its preparation has been described by Ungar, Farmer, and Muggleton (1956). It activity has been studied in infants by Lorber, Hart, Farmer, and Muggleton (1956), Griffiths and Gaisford (1956), and Lorber, Farmer, and Muggleton (1957). With the use of batches of this freeze-dried vaccine with appropriate viable counts tuberculin sensitivity was induced in a high proportion of infants; indeed, it proved as effective in this respect as the liquid vaccine. The dried and the liquid vaccines were also similar with respect to the production of local vaccination lesions and the incidence of local complications. As a result of these investigations the manufacturer decided to issue for clinical use a dried vaccine which, when reconstituted, had approximately 5 million viable particles per millilitre.

It is well known that the viable count of any B.C.G. vaccine may vary considerably with different batches; before the British dried vaccine could be used extensively it was regarded as essential to determine whether its viable count was as consistent from batch to batch as that of the Danish liquid vaccine. It was also thought desirable to carry out trials in 13-year-old schoolchildren —since the present local health authority vaccination scheme in this country applies to this age group—to compare the British dried vaccine with the Danish liquid vaccine as regards activity both in inducing tuberculin sensitivity and in producing local vaccination lesions. These trials were not designed to assess the value of the dried vaccine in the prevention of tuberculosis; this would have entailed a very prolonged and extensive investigation.

Laboratory Tests

Determination of Number of Viable Particles

The determination of the number of viable bacillary particles (viable count) in samples of both the dried and the liquid vaccine was made by the Medical Research Council's Biological Standards Control Laboratory, using one method throughout. For each batch the average count was obtained from the results of separate tests on six 1-ml. ampoules. The diluent used for reconstituting the dried vaccine and for making serial dilutions of both the dried and the liquid vaccine was Sauton medium to which 1/4,000 w/v Triton (WR. 1339) had been added to minimize aggregation. The initial suspension of the liquid vaccine was made by adding 1 ml. from each ampoule to 9 ml. of diluent and that of the dried vaccine by suspending the contents of one ampoule in 10 ml. of diluent. From these initial suspensions, serial dilutions were made and plated on nutrient medium, using a method similar to that described by Miles and Misra (1938). After investigating the suitability of a number of media it was decided to use oleic-acid-albumin-agar (Fenner, Martin, and Pierce, 1949). This medium was distributed in Petri dishes, which, after seeding, were kept in sealed "polythene" envelopes during the whole period of three to four weeks' incubation at 37° C. Tests were made with a number of batches of vaccine to determine the effect of including

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