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## Effect of counselling mothers on their children's exposure to environmental tobacco smoke: randomised controlled trial

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### Abstract

**Objective** To test the efficacy of behavioural counselling for smoking mothers in reducing young children's exposure to environmental tobacco smoke.

**Design** Randomised double blind controlled trial.

**Setting** Low income homes in San Diego county, California.

**Participants** 108 ethnically diverse mothers who exposed their children (aged < 4 years) to tobacco smoke in the home.

**Intervention** Mothers were given seven counselling sessions over three months.

**Main outcome measures** Children's reported exposure to environmental tobacco smoke from mothers in the home and from all sources; children's cotinine concentrations in urine.

**Results** Mothers' reports of children's exposure to their smoke in the home declined in the counselled group from 27.30 cigarettes/week at baseline, to 4.47 at three months, to 3.66 at 12 months and in the controls from 24.56, to 12.08, to 8.38. The differences between the groups by time were significant ( $P = 0.002$ ). Reported exposure to smoke from all sources showed similar declines, with significant differences between groups by time ( $P = 0.008$ ). At 12

months, the reported exposure in the counselled group was 41.2% that of controls for mothers' smoke (95% confidence interval 34.2% to 48.3%) and was 45.7% (38.4% to 53.0%) that of controls for all sources of smoke. Children's mean urine cotinine concentrations decreased slightly in the counselled group from 10.93 ng/ml at baseline to 10.47 ng/ml at 12 months but increased in the controls from 9.43 ng/ml to 17.47 ng/ml (differences between groups by time  $P = 0.008$ ). At 12 months the cotinine concentration in the counselled group was 55.6% (48.2% to 63.0%) that of controls.

**Conclusions** Counselling was effective in reducing children's exposure to environmental tobacco smoke. Similar counselling in medical and social services might protect millions of children from environmental tobacco smoke in their homes.

### Introduction

The World Health Organization has estimated that the health of almost half of the world's children is threatened by exposure to environmental tobacco smoke.<sup>1</sup> In the United States the prevalence of US children living in homes with a smoker has been estimated to be 43%, with state specific estimates of exposure in

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the home ranging from 12% to 34%<sup>2</sup>; nationally, about 15 million US children and adolescents are exposed.<sup>3</sup> Similarly, about 43% of Australian children,<sup>4</sup> 33% of Canadian children,<sup>5</sup> and 41% of British children are exposed to environmental tobacco smoke.<sup>6</sup> Exposure increases children's risk of respiratory tract infections, otitis media, asthma, and the sudden infant death syndrome.<sup>7-9</sup> The costs to children's medical care from exposure were \$703m-\$897m (£439m-£561m) in the United States, \$239.5m (£150m) in Canada, and \$267m (£167m) in Great Britain (in 1997 prices).<sup>10</sup>

Two trials reported significant decreases in children's exposure to environmental tobacco smoke after counselling of parents. Greenberg et al decreased children's reported exposure, but infants' urine cotinine concentrations increased.<sup>11</sup> Hovell and colleagues found similar reductions in reported exposure, which were sustained over two years, but did not measure cotinine concentrations.<sup>12-15</sup> We extended our earlier research by measurement of cotinine concentrations and by testing counselling (in person and by telephone) with high risk, ethnically diverse, and low income families recruited from the US supplemental nutrition programme for women, infants, and children. We hypothesised that counselling would decrease children's exposure, decrease mothers' smoking, and increase rates of stopping smoking.

## Participants and methods

### Protocol

#### *Inclusion criteria*

We included English and Spanish speaking mothers who smoked at least two cigarettes a day and exposed their child (aged <4 years) to the smoke from at least one cigarette a day. We excluded women who were currently breast feeding, to avoid confounded cotinine analyses,<sup>14-15</sup> and women who did not have a telephone, to ensure exposure to the intervention.

#### *Recruitment*

Nine months' screening at sites of the supplemental nutrition programme for women, infants, and children identified 1147 possibly eligible families. Of these, we contacted 832: 162 (19.5%) qualified and were offered financial incentives (\$60-\$90) to participate. We enrolled the first 108 women who signed informed consent forms, an adequate sample size based on previous research.<sup>12</sup> After we had taken baseline measures, we randomly assigned the families to counselling or control conditions.

#### *Counselled group*

Counselled mothers were told that quitting smoking was not required. They were given seven individualised counselling sessions (three in person and four by telephone) during three months. Counselling was based on shaping procedures.<sup>16</sup> The mean duration of sessions ranged from 12.6 to 28.0 minutes. Graduate students with 20 hours of training and weekly supervision by case review provided the counselling.

At the first session, mothers set long term goals for reducing children's exposure to environmental tobacco smoke and signed contracts. Counsellors explained the shaping process (in which complex

smoking practices were gradually altered to reduce exposure to the child) and assisted mothers in writing fortnightly objectives that resembled medical prescriptions. Between sessions, mothers recorded their smoking and their child's exposure on pictorial charts. Mothers were provided with "No smoking" signs and stickers to serve as cues for reducing their child's exposure. In subsequent sessions, counsellors reviewed progress and negotiated possible solutions to barriers to reducing children's exposure. New objectives and strategies were set. Contingencies included praise from counsellors and low cost "self rewards." In the last session mothers were helped to write final goals and objectives for maintaining low exposure or for further decreasing exposure. Details about the counselling programme are published elsewhere.<sup>17</sup>

#### *Control group*

Mothers received the usual nutritional counselling of the supplemental nutrition programme and brief advice to quit smoking and not expose their children to environmental tobacco smoke.

### Measures of exposure to environmental tobacco smoke

#### *Mothers' reports*

Interviews were conducted at baseline, at three months (after counselling), and at six and 12 months. The baseline interview was conducted in person in the mothers' homes, and follow up interviews were by telephone. The mean length of interviews was 57.2 (SD 15.8) minutes. Content included information on mothers' demographics and tobacco use and their child's exposure to environmental tobacco smoke.

Mothers reported their smoking and their child's exposure on typical work days and non-work days during the past seven days. They reported children's exposure to smoke from others living in and visiting the home, and from all smokers outside of the home. We measured exposure as the number of cigarettes smoked while the child was in the same room and calculated children's weekly exposure to mothers' cigarettes in the home and to all cigarettes. Acceptable test-retest reliability and validity in relation to cotinine and nicotine assays are reported elsewhere.<sup>18-19</sup>

#### *Children's urine cotinine concentrations*

Urine samples (collected at baseline and three and 12 months) were analysed for cotinine (a metabolite of nicotine and recommended biomarker)<sup>20</sup> at the Centers for Disease Control and Prevention by means of isotope dilution liquid chromatography and tandem mass spectrometry with a limit of detection of <50 parts per trillion. We obtained samples from children who were not toilet trained by placing two sterile 15 cm cotton rolls in diapers and removing these when they were wet. The cotton rolls were packed into a sterile 20 ml syringe (without needle), and the urine was expressed into a 5 ml vial. Previous research showed that cotton rolls do not alter the cotinine concentration.<sup>21</sup> Samples from toilet trained children were collected with a standard urine collection cup. Samples were frozen at -29°C and packed in dry ice for shipping. The laboratory was blind to subjects' identity and group assignment.

### Mothers' saliva cotinine concentrations

Mothers' saliva was obtained at each interview with Episcree collection devices (Epitope, Beaverton, OR) and stored frozen at  $-29^{\circ}\text{C}$  until laboratory analysis by enzyme linked immunoassay (STC, Bethlehem, PA). The laboratory was blind to subjects' identity and group assignment. Mothers who reported stopping smoking were tested and cessation confirmed by cotinine concentrations  $< 30$  ng/ml.

### Nicotine monitors

We conducted nicotine monitoring to provide objective validation of mothers' reported levels of smoking and to enhance reporting accuracy.<sup>22</sup> Inactive monitors were placed in three rooms per household where children's greatest exposure to environmental tobacco smoke was reported. These were used to sensitise the mothers to possible confirmation of their reports of exposure. One week before the three month interview, we placed an active monitor in the room of greatest exposure for a randomly selected half of the families. The monitor was a 37 mm diameter cassette containing a Teflon coated glass fibre filter (Emfab TX 40h120WW, Pallflex, Putnam, CT) saturated with 4% sodium bisulphate and 5% ethanol and dried. Gas chromatography was used to assess nicotine levels.<sup>23 24</sup> Assays confirmed the validity of mothers' reports.<sup>19</sup>

### Assignment and masking

Random numbers were used to stratify assignment by three ethnic groups. After the baseline measures, assistants opened an envelope to reveal assignments. Measurement assistants were blind to group assignment. Control families were unaware of counselling procedures, and investigators were blind to results until all data were collected.

### Statistical analyses

Analyses were based on intention to treat. We adjusted dependent variables by logarithmic or square root transformation to reduce skewness and present geometric and untransformed means. Differential rate of change in reported exposure and cotinine estimates of exposure relied on analyses of repeated measures over time. Estimated power to detect differential change between groups exceeded 0.80 for all dependent variables. We analysed the effects of counselling using the generalised estimating equations approach, with linear components of time as "within subjects" factors and the interaction as a "between subjects" factor (SAS version 6.12).<sup>25</sup> Modelling procedures based on generalised estimating equations are superior to models based on analysis of variance in that they do not require repeated measures to be equally spaced from one another and they retain cases with missing data at one or more times. We first calculated differential change from baseline to end of follow up and then repeated this for baseline to three months (counselling effect) and from three months to end of follow up (maintenance effect).

## Results

### Participant flow and follow up

Figure 1 shows the number of mothers enrolled through completion of measures. Forty nine (92%) of

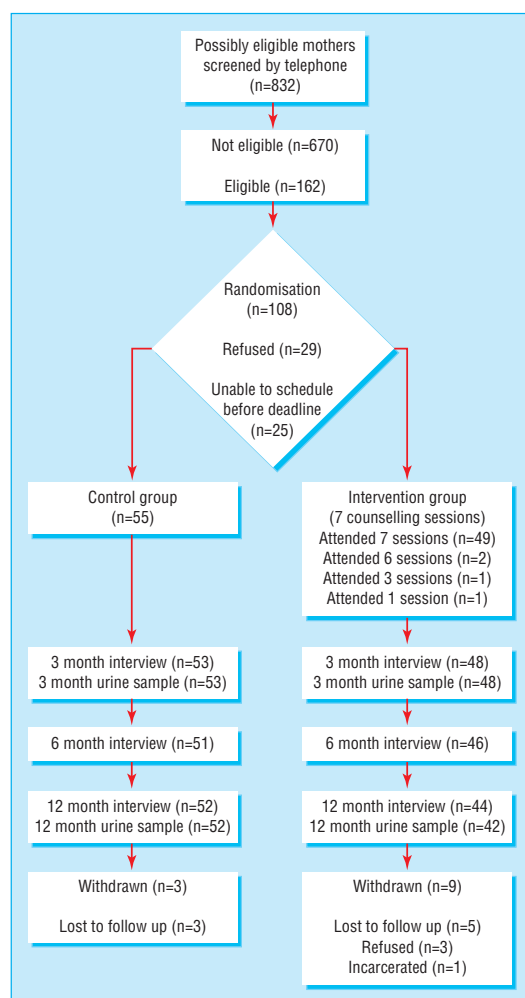


Fig 1 Flow of participants through trial

the mothers assigned to the counselling group completed all seven counselling sessions.

### Participants

Table 1 shows the demographic characteristics of the mothers and children. Families were white, black, or Hispanic and had low income with limited education.

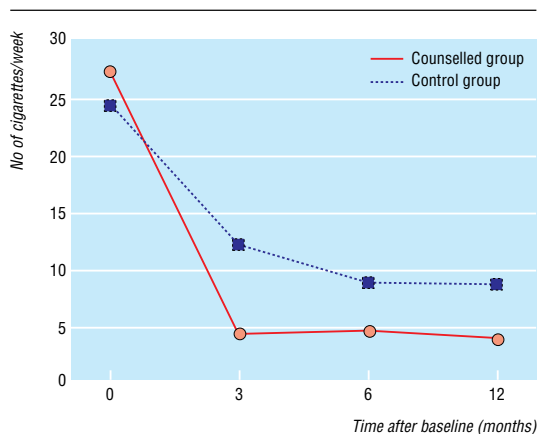
### Sampling and success of random assignment

The two groups were well matched in their demographic and dependent variables, suggesting successful random assignment.

### Analyses

#### Reported exposure

Figure 2 shows that in both groups the children's reported exposure to their mothers' tobacco smoke in the home declined steeply from baseline to three months (end of counselling) and then only slightly during follow up. Our analyses of repeated measures showed significant differences between groups by time ( $P = 0.002$ ), indicating that exposure declined more for the counselled group than for the control group. Analyses of changes from baseline to three months also showed significant differences between groups by time ( $P = 0.011$ ). From three months to 12 months, the difference between the two groups remained signifi-



**Fig 2** Children's reported exposure to mothers' cigarettes in the home (No of cigarettes per week) in families with a young child (<4 years old) and a mother who smoked who received either three months of counselling or standard advice to reduce smoking in the presence of the child. Values are geometric means

cant ( $P=0.017$ ), but neither showed any significant change over time, suggesting that the counselling effect was maintained but that no later improvement occurred. Student's *t* tests showed a significant cross sectional difference between the groups at three months only ( $t(99) = -2.74$  (95% confidence interval  $-1.503$  to  $-0.240$ );  $P=0.007$ ). Thus, the effects of counselling were obtained by three months and sustained through follow up. Table 2 shows the geometric means for children's exposure to environmental tobacco smoke at baseline, three months, and 12 months.

Children's reported total exposure to environmental tobacco smoke followed a similar pattern (table 2), with the counselled group showing a significantly

greater decline ( $P<0.008$ ). Both groups showed significant declines from baseline to three months ( $P<0.001$ ). From three months to 12 months, the difference between the two groups remained significant ( $P=0.043$ ), but neither showed any significant change in exposure over time. Student's *t* tests showed significant differences between the two groups at three months ( $t(94) = -2.30$  ( $-1.244$  to  $-0.092$ );  $P=0.024$ ) and 12 months ( $t(91) = -2.10$  ( $-1.430$  to  $-0.039$ );  $P=0.039$ ), suggesting that counselling had an effect and that this was maintained.

*Children's urine cotinine concentration*

Figure 3 shows that children's cotinine concentrations increased from baseline to three months in both groups but that the concentration then declined slightly in the counselled group whereas it continued to increase in the control group. Our analyses of repeated measures showed significant differences between groups by time ( $P=0.008$ ). Student's *t* tests showed significant differences between the two groups only at 12 months ( $t(90) = -2.05$  ( $-0.948$  to  $-0.015$ );  $P=0.043$ ). These results suggested a prevention effect that lasted through follow up.

*Mothers' saliva cotinine concentration*

From baseline to three months, the mothers' cotinine concentrations increased significantly in both groups—from 75.8 ng/ml to 91.2 ng/ml for counselled women and from 76.9 ng/ml to 89.7 ng/ml for controls ( $P<0.001$ ). During follow up, counselled mothers' cotinine concentrations decreased to 80.6 ng/ml at 12 months, while those of the controls increased to 112.9 ng/ml. This difference between groups by time neared significance ( $P=0.06$ ), suggesting a possible decrease in the relative level of smoking for counselled mothers compared with controls. There were no significant differences in the numbers of mothers who stopped smoking (six in the counselling group and four in the control group).

**Table 1** Baseline characteristics of families with a young child (<4 years old) and a mother who smoked who received either three months of counselling or standard advice to reduce smoking in the presence of the child. Values are numbers (percentages) unless stated otherwise

Variable	Counselled families (n=53)	Control families (n=55)
Ethnic group:		
Black	11 (21)	12 (22)
Hispanic	14 (26)	16 (29)
White	25 (47)	26 (47)
Other	3 (6)	1 (2)
Children's sex (girls)	31 (58)	26 (47)
Single parent families	23 (43)	27 (49)
Employed mothers	8 (15)	5 (9)
Mothers' education:		
Less than high school or GED*	22 (42)	20 (36)
High school or GED*	14 (26)	13 (24)
Trade school	4 (8)	4 (7)
Some college	12 (23)	16 (29)
College graduate	1 (2)	2 (4)
Mean (SD) age:		
Mothers' (years)	28.5 (6.6)	29.0 (6.9)
Children's (months)	14.1 (7.0)	14.3 (6.9)
Mean (SD) No of times mothers had stopped smoking for 24 hours	11.6 (25.0)	19.4 (48.0)
Mothers' mean No of cigarettes smoked/day	12.6†	12.2†

\*GED=Generalised equivalency degree.  
 †Means are squared estimates of means adjusted by square root transformation and so do not include standard deviations. These estimates provide an indication of the levels in clinically meaningful units.

**Discussion**

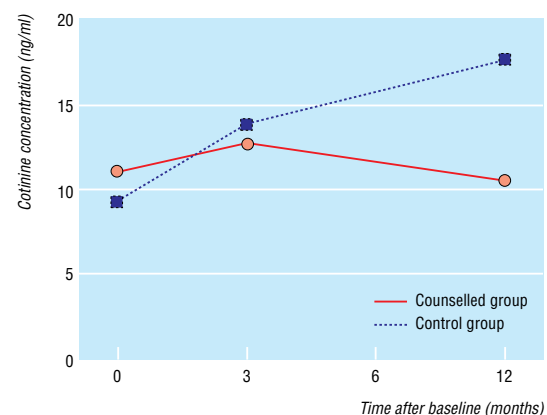
This is the first study to show therapeutic benefits of counselling mothers on their children's exposure to environmental tobacco smoke based on cotinine concentrations. In the counselled group the children's cotinine concentrations decreased slightly (4%) by 12 months, whereas those in the control group increased substantially (85%), suggesting that counselling prevented an increase in exposure to environmental tobacco smoke. Reported exposure to environmental tobacco smoke decreased more after counselling and was sustained for nine months, suggesting maintenance of effects consistent with our previous findings.<sup>13</sup>

Our present results extend earlier work by showing the efficacy of counselling delivered in part by telephone to women receiving services from the supplemental nutrition programme for women, infants, and children. The successful decrease (or prevention of increase) in children's exposure to environmental tobacco smoke in this low income, racially and ethnically diverse, high risk population suggests that counselling is generalisable, as does the similarity of our results to those from earlier studies.<sup>11-13</sup> Such counselling in medical and social services might

**Table 2** Measures of children's exposure to environmental tobacco smoke in families with a young child (<4 years old) and a mother who smoked who received either three months of counselling or standard advice to reduce smoking in the presence of the child. Values are geometric means (interquartile ranges) unless stated otherwise

Variable	Time		
	Baseline	3 months (after counselling)	12 months
<b>Reported exposure to environmental tobacco smoke (No of cigarettes/week)</b>			
Exposure from mothers in home:			
Counselled families	27.30 (32.91)	4.47 (26.11)	3.66 (28.08)
Control families	24.56 (31.03)	12.08 (33.09)	8.38 (45.99)
Relative value for counselled group v controls (% (95% CI))*		32.8 (26.3 to 39.3)	41.2 (34.2 to 48.3)
Total environmental exposure:			
Counselled families	51.30 (73.43)	12.99 (42.94)	8.60 (44.15)
Control families	50.68 (63.68)	26.28 (59.79)	19.23 (66.91)
Relative value for counselled group v controls (% (95% CI))*		50.0 (42.8 to 57.2)	45.7 (38.4 to 53.0)
<b>Urine cotinine concentration (ng/ml)</b>			
Counselled families	10.93 (17.29)	12.65 (12.12)	10.47 (24.28)
Control families	9.43 (13.28)	13.88 (18.00)	17.47 (21.61)
Relative value for counselled group v controls (% (95% CI))*		84.2 (79.0 to 89.4)	55.6 (48.2 to 63.0)

\*Means were adjusted for baseline levels to calculate relative values.



**Fig 3** Children's urine cotinine concentrations (ng/ml) in families with a young child (<4 years old) and a mother who smoked who received either three months of counselling or standard advice to reduce smoking in the presence of the child. Values are geometric means

protect millions of children from exposure to environmental tobacco smoke.

Smoking decreased slightly among counselled mothers but increased by half among controls. Counselling may have prevented an increase in mothers' smoking over time, although it did not result in more mothers quitting. Increased smoking among the controls probably contributed to their children's increased cotinine concentrations.

Parental reports of reducing their children's exposure could reflect the parents smoking in a different room but still close enough for the child to inhale smoke. Similarly, as children begin walking, they may be exposed to nicotine from dust on carpets and furniture. This would not be easily monitored or reported by parents and might account for the control mothers reporting decreased exposure to environmental tobacco smoke whereas their children had increased cotinine concentrations. Additional research is needed to determine the source of increasing cotinine concentrations in control children.

### Conclusions

Both mothers' reports and cotinine analyses confirmed the benefits of counselling on children's exposure to

environmental tobacco smoke. The most conservative interpretation of the results suggests that counselling prevented an increase in exposure to environmental tobacco smoke. Future studies should be directed to interventions that combine formal counselling for quitting smoking with counselling for reducing children's exposure to environmental tobacco smoke. Future studies should also extend follow up to assess how long the effects of counselling are maintained and the developmental trends in exposure to environmental tobacco smoke. These results set the stage for research to determine the effects of reducing exposure to environmental tobacco smoke on morbidity and mortality.

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### What is already known on this topic

The World Health Organization has estimated that the health of almost half of the world's children is threatened by exposure to environmental tobacco smoke

Two trials reported significant decreases in children's exposure to environmental tobacco smoke after counselling of mothers, but neither provided an objective outcome measure of efficacy

### What this study adds

A randomised trial of counselling to reduce children's exposure to environmental tobacco smoke used measures of cotinine concentrations in addition to mothers' reports

Counselled mothers reported significantly greater decreases in exposure to environmental tobacco smoke compared with controls, and children's urine cotinine concentrations decreased slightly for counselled families while increasing substantially for controls

The findings confirm the efficacy of counselling to reduce children's exposure to environmental tobacco smoke

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Contributors: MFH, as principal investigator, had primary responsibility for the study design, administration, quality assurance, planning of statistical analyses, and writing of the manuscript. JMZ, as project coordinator, was responsible for overseeing data collection, intervention delivery, and data preparation and also conducted statistical analyses and contributed to writing the manuscript. GEM collaborated on design of measures, statistical analyses, and editing the manuscript. CRH conducted statistical analyses and assisted with study design and editing the manuscript. JTB conducted urine cotinine analyses and assisted with interpretation of results and editing the manuscript. JP assisted with the study design and editing the manuscript. MFH and JMZ are the guarantors of the paper.

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## My Cuban experience

After passing the first part of the MRCP examination, I thought that I would treat myself to an exotic holiday. One of my friends, who is now a consultant psychiatrist, thought that Cuba would be a good place to go. Cuba is a great place to live provided that you have money and that you are not Cuban. For tourists there was always fresh meat and vegetables available. There was no food rationing and we did not have to wait in queues for things like bread. Petrol was expensive and rationed, but we were allowed an unlimited petrol allowance as we had dollars.

Towards the end of our holiday we found ourselves in the capital, Havana. The problem now was trying to get back to our initial resort so that we could catch our flight back home. We weren't really keen on buses or trains as they took so long and so we decided to catch a taxi. Finally one driver agreed to take us. To manage the round trip he had to borrow a friend's petrol ration. As it turned out his English was rather good and so we began chatting. It soon came round to him asking what we did for a living. We both proudly told him that we were doctors in Britain. Without batting an eyelid he pulled out a chest radiograph from behind his seat and asked us to look at it.

"This shows a right pleural effusion with a chest drain," I said. "Correct," he replied.

"I know," I said. "We told you before we are both doctors." "Yes," he casually replied, "so am I."

We were most surprised to find out that he wasn't really a taxi driver but a cardiothoracic surgeon and that he was testing our skills. As surgery did not pay well he drove taxis to earn extra cash. We made sure we gave him a nice tip for his trouble when he finally dropped us off.

What have I learnt from this experience? Firstly, never assume anything by a person's profession, and, secondly, do not choose cardiothoracic surgery as a career in Cuba.

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We welcome articles of up to 600 words on topics such as *A memorable patient, A paper that changed my practice, My most unfortunate mistake*, or any other piece conveying instruction, pathos, or humour. If possible the article should be supplied on a disk. Permission is needed from the patient or a relative if an identifiable patient is referred to. We also welcome contributions for "Endpieces," consisting of quotations of up to 80 words (but most are considerably shorter) from any source, ancient or modern, which have appealed to the reader.