

REFERENCES

1. BALAKRISHNAN, S. A note on the screening of DDS in urine by spot test. *Lepr. India* **41** (1969) 77–78.
2. BRATTON, A. C. and MARSHALL, E. K. A new coupling component for sulfanilamide determination. *J. Biol. Chem.* **128** (1939) 537–550.
3. ELLARD, G. A. Urine tests to monitor the self-administration of dapsone by leprosy patients. *Am. J. Trop. Med. Hyg.* **23** (1974) 464–470.
4. ELLARD, G. A. Profile of urinary dapsone/creatinine ratios after oral dosage with dapsone. *Lepr. Rev.* **51** (1980) 229–236.
5. ELLARD, G. A. Drug compliance in the treatment of leprosy. *Lepr. Rev.* **52** (1981) 201–213.
6. ELLARD, G. A., GAMMON, P. T. and HARRIS, J. M. The application of urine tests to monitor the regularity of dapsone self-administration. *Lepr. Rev.* **45** (1974) 224–234.
7. ELLARD, G. A., JENNER, P. J. and DOWNS, P. A. An evaluation of the potential use of isoniazid, acetylisoniazid and isonicotinic acid for monitoring the self-administration of drugs. *Br. J. Clin. Pharmacol.* **10** (1980) 369–381.
8. ELLARD, G. A., KIRAN, K. U. and STANLEY, J. N. A. Long-term prothionamide compliance: a study carried out in India using a combined formulation prothionamide, dapsone and isoniazid. *Lepr. Rev.* **59** (1988) 163–175.
9. ELLARD, G. A., PANNIKAR, V. K., JESUDASAN, K. and CHRISTIAN, M. Clofazimine and dapsone compliance in leprosy. *Lepr. Rev.* **59** (1988) 205–213.
10. ELLARD, G. A., PEARSON, M. H. and HAILE, G. S. The self-administration of dapsone by leprosy patients in Ethiopia. *Lepr. Rev.* **52** (1981) 237–243.
11. HUIKESHOVEN, H. Patient compliance with dapsone administration in leprosy. (Editorial) *Int. J. Lepr.* **49** (1981) 225–258.
12. JAMET, P., TRAORE, I., HUSSER, J. A. and JI, B. Short-term trial of clofazimine in previously untreated lepromatous leprosy. *Int. J. Lepr.* **60** (1992) 542–548.
13. JESUDASAN, K., GEORGE, C. J. G., TAYLOR, P. M., KURIAN, P. V. and JOB, C. K. An evaluation of the self-administration of DDS in Gudiyatham Taluk. *Lepr. India* **48** Suppl. (1976) 668–676.
14. JI, B. and GROSSET, J. H. Recent advances in the chemotherapy of leprosy. *Lepr. Rev.* **61** (1990) 313–329.
15. JI, B., PERANI, E. G., PETINON, C. and GROSSET, J. H. Bactericidal activities of single or multiple doses of various combinations of new antileprosy drugs and/or rifampin against *M. leprae* in mice. *Int. J. Lepr.* **60** (1992) 556–561.
16. STANLEY, J. N. A., PEARSON, J. M. and ELLARD, G. A. An investigation of dapsone compliance using an isoniazid-marked formulation. *Lepr. Rev.* **51** (1980) 317–325.
17. STANLEY, J. N. A., PEARSON, J. M. H. and ELLARD, G. A. Ethionamide, prothionamide and thiace-tazone self-administration; studies of patient compliance using isoniazid-marked formulations. *Lepr. Rev.* **57** (1986) 9–18.
18. WHO STUDY GROUP. Chemotherapy of leprosy for control programmes. Geneva: World Health Organization, 1982. Tech. Rep. Ser. 675.

Patient Treatment Compliance in Leprosy; a Reply

TO THE EDITOR:

Dr. Ellard's criticism of our article (*Int. J. Lepr.* **60**, 1992, 587) centers on two main points: namely, measurement and classification of compliance and sample-selection methodology employed in past treatment compliance research in leprosy.

Firstly, it was not our aim to discuss the merits and demerits of various biochemical procedures for measuring dapsone compliance in leprosy. In our view, whatever methods were followed in measuring dapsone intake fell short either in terms of accuracy or ease of application.

However, the crucial question seems to be how one classifies the differing levels of dapsone intake, having measured that intake by whatever means. Unless there is some degree of conformity in labeling the different levels of dapsone intake, the comparison of various different compliance studies in leprosy would be difficult. The Table presented by Ellard in his response to our article uses different terms for the three (in studies A, B, C; in study D, four) different levels of compliance. In Study B he used the variance of the word "Regular" and in Study C and D "Excellent" and

“Poor” are used but the middle category in Study C is “Intermediate” and in Study D, “Fair.” It is these divergences in nomenclature to which we take exception. We still argue that specificity of classification of “spread” of compliance is the ideal to be aimed at beyond the argument of accuracy of measurement of dapsonc intake.

Secondly, Ellard shows that his understanding of the meaning of compliance differs from ours by responding to our criticism of sample selection bias with the statement that “to assess the compliance of patients who either absconded from treatment or collected it very irregularly would not only have been virtually impossible but also irrelevant.” Are we to accept that these patients have nothing whatsoever to do with

compliance research and are irrelevant for leprosy control and eradication? Our argument for the need to employ prospective inception-cohort study design in order to avoid overestimation of compliance in leprosy still stands.

We do not question that the studies conducted by Ellard and his colleagues and many others “helped to demonstrate the reality and ubiquity of irregular drug self-administration.” However, we must repeat the need for methodological rigor in designing compliance studies in order to draw reliable, valid, and informed conclusions.

—Atul Vadhcr, D.Phil.

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