



New Evidence from Leprosy Research

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ILEP Technical Forum
24th March 2010



ILEP Technical Commission Plan of Work 2008 - 2011

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1. MONITORING
 - Advise on monitoring of leprosy data
2. IMPLEMENTATION
 - Training
 - Tool kit of quality indicators
 - Improve coverage and quality of POD
 - CBR guidelines
3. RESEARCH & DEVELOPMENT
 - Synthesis of new research findings
 - New methods of early diagnosis
 - Research in nerve damage and reactions
4. STIGMA
 - Research needs and best practice
5. LIAISE WITH ILEP MEMBERS
 - Through emails and ILEP Forum



Synthesis of New Research Findings

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- 2002 ILA Forum – Leprosy Review
- Identify key topics of interest
- Systematic literature search
 - EBM Reviews, Medline, Embase and CB abstracts
 - Papers and data extractions are available from ILEP
- Focus on interventions:
 - systematic reviews (13)
 - controlled trials (21)
 - ongoing trials (10)



Presentations and Discussion

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A. 7 Topics Presented

- prevention, diagnosis, chemotherapy, reactions, prevention of disability, stigma and rehabilitation

B. Discussion

- the evidence and its implications



1. Prevention – Immuno-prophylaxis

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BCG: New evidence

- 3 systematic reviews (1 in tuberculosis and leprosy and 2 on leprosy)
- 1 case control study (in Brazil on effect of age on BCG protection)
- 2 controlled trials (*Mw* in India, and BCG revaccination in Brazil)



Immuno-prophylaxis – systematic reviews

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Barreto 2006

- BCG 14 – 80% effective
- Adverse reactions rare (0.1 – 5 per 1000)
- BCG safe for HIV +ve infants but not if clinical signs of immunodeficiency

Setia 2006

- trials show BCG 26% protective effect
- observations studies show 61% protective effect

Zodpey 2007

- trials show BCG 43% protective effect
- observation studies show 58 – 62% protective effect



Immuno-prophylaxis – new studies

Rodrigues, 2007 (Brazil)

- case control study shows decline protective effect with increasing age (no effect over 40 years)

Sharma, 2005 (India)

- RCT of Mw
- 24,060 house old contacts
- 69% protective effect at 3 years reducing to 39% after 9 years

Cunha, 2008 (Brazil)

- RCT of BCG revaccination of 42,060 children
- No protective effect after 6.7 years

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Immuno-prophylaxis - conclusions

- BCG is a widely used vaccine
- New studies but evidence remains same:
 - BCG is protective against leprosy
 - Leprosy programmes should support continued use of BCG in infants
- Revaccination with BCG has no added value
- Mw can provide reasonable protection in contacts
- Research to study the effect of combined BCG and chemoprophylaxis is recommended

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Prevention – Chemo-prophylaxis

- No new systematic reviews of chemoprophylaxis
- Bakker 2005 (Indonesia)
 - island cluster study
 - blanket versus contact strategy
- Moet, 2008 (Bangladesh)
 - RCT of household contacts
 - single dose of rifampicin
 - 57% protection after 2 years
 - no further protection after 3 – 4 years
 - difential effect in sub-group
 - BCG complements rifampicin chemoprophylaxis

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Chemo- prophylaxis - implications

2011 – 2015 Strategy

- explore use of chemoprophylaxis as a tool to prevent new leprosy cases among household contacts

Research and Development Recommendations

- pilot projects under routine conditions
- assess acceptability, cost-effectiveness feasibility and ethical issues

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Prevention - Discussion

1. Immunoprophylaxis
2. Chemoprophylaxis

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2. Early Diagnosis

Two new systematic reviews identified
Considerable research ongoing – IDEAL consortium

Moet, 2004

- risk factors in contacts

Nicholls, 2006

- interventions to reduce delay in diagnosis

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Risk Factors for Leprosy (Moet)

- Contacts of MB cases – 8 fold risk
- Contacts of PB cases – slight increased risk
- Neighbours and social contacts also have increased risk
- Hereditary factors also play a role
- Age – shows 2 peaks – children and adults
- Men at high risk than women in most studies
- Bacterial load related to risk
- Anti PGL-1 antibodies associated with increased risk
- Lepromin negative associated with increased risk
- BCG associated with decreased risk



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Reducing delay in diagnosis (Nicholls)

- Few publications
- Focus on health education aimed at patients, families, and key groups
- No studies of women
- 4 published studies of community education
- 2 studies of patient counselling
- 1 study of new patients and contacts
- Conclusions – more worked needed.



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Recommendations for further research

- Operational research on management of contacts – identification, counselling, examination and prophylaxis
- Development and assessment of immunological markers for *M leprae* infection and early disease
- Development and evaluation of health education activities including targeted groups



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Early diagnosis - Discussion

- Risk factors
- Reducing delay, promoting early diagnosis
- Ongoing research