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**Systematic review of diagnosis of infection in diabetic foot ulceration**

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**Aim:** To undertake a systematic review of the diagnostic performance of clinical examination, sample acquisition and sample analysis in infected diabetic foot ulcers (DFUs).

**Methods:** Nineteen electronic databases plus other sources were searched up to November 2002. To be included, studies had to fulfil the following criteria: (1) compare method of clinical assessment, sample collection or sample analysis with a reference standard; (2) recruit people with DFUs; (3) present 2x2 diagnostic data. Studies were critically appraised using a 12-item checklist.

**Results:** Three eligible studies were identified, one each on clinical examination, sample collection and sample analysis. For all three, study groups were heterogeneous with respect to wound type and a small proportion of participants had DFUs. No studies identified an optimum reference standard. Other methodological problems included non-blind interpretation of tests and the time lag between index and reference tests. Individual signs or symptoms of infection did not prove to be useful tests when assessed against punch biopsy as the reference standard. The wound swab did not perform well when assessed against tissue biopsy. Semi-quantitative analysis of wound swab was found to be a potentially useful alternative to quantitative analysis. Given the heterogeneity of the population and the methodological issues with each of the studies, these findings should be interpreted cautiously.

**Conclusion:** The available evidence is too weak to draw reliable implications for practice, and did not add anything useful to existing clinical guideline recommendations. Further studies of the diagnostic performance of clinical assessments and microbiological sampling are required.