



## Screening for Gestational Diabetes Mellitus: Is it Effective?

**Anthony Shannon**

Warrane College, The University of New South Wales, Kensington NSW 1465, &  
Raffles College of Design and Commerce, North Sydney NSW 2060, Australia  
E-mails: [tony@warrane.unsw.edu.au](mailto:tony@warrane.unsw.edu.au), [tonySHANNON@raffles.edu.au](mailto:tonySHANNON@raffles.edu.au)

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**Abstract:** *The purpose of the studies reported here was to examine the problem of the effectiveness of screening for gestational diabetes mellitus. It utilises meta-analysis to examine the conclusions of many studies in order to come up with a practical solution to the problem.*

**Keywords:** *Diabetes mellitus, Meta-analysis, Sensitivity, Specificity, Predictability, Prevalence.*

### Introduction

There is a lack of consistent evidence in the literature about the effectiveness of screening processes for diseases in general. One of the issues is the “worried well” who do not return for diagnostic testing when requested after a positive screening test. In the context of screening and diagnostic tests for diabetes mellitus another issue is the reliability of the measurements of the blood glucose levels, including sometimes less than robust hospital conditions [5]. This paper looks at some aspects of the effectiveness of screening for gestational diabetes mellitus (GDM).

By screening we here refer to 1 hour 50 gram and 75 gram glucose challenge tests (GCT); by diagnosis we here refer to 2 hour 75 gram and 3 hour 100 gram oral glucose tolerance tests (OGTT) [11]. Suitable testing requires a consideration of both

- *sensitivity* (the proportion of subjects with the target disorder who have a positive test), and
- *specificity* (the proportion of subjects without the target disorder who have a negative test).

We shall include these in our discussion, but even more fundamentally, controversies surround many aspects of GDM such as the definition, diagnosis, and management of GDM, as well as the effects on the mother and offspring. Meta-analyses of the literature have been carried out but even they do not convey an unequivocal picture of appropriate procedures. This study, which was part of a larger investigation, is an attempt to get an overall perspective of what works in general, based upon studies considered by other authors in previous relevant studies.

Given the above caveats it was felt appropriate and beneficial for discussion to take a broader overview of the results in the research reports cited.

## Meta-analysis

Meta-analysis is a statistical approach to aggregate and analyse summary statistics from a number of studies [4]. It is especially useful where studies disagree with regard to the magnitude or direction of an effect [6]. For instance, we have used the approach to compare glycaemic control with human and porcine insulins by means of data on glycosylated haemoglobin, fasting blood-glucose and mean blood-glucose levels in various reported studies [7] and to relate multiple injections with glycaemic control [9].

L'Abbé et al., [1] discussed the role of meta-analysis in clinical research. They pointed out that:

- meta-analysis is a systematic reviewing strategy for addressing research questions that is especially useful when results from several studies disagree with regard to magnitude or direction of effect;
- sample sizes may be individually too small to detect an effect and label it statistically significant;
- large trials may be too costly and time-consuming to perform;
- in evaluating medical treatment and planning new studies, a better understanding is needed of the findings of previous clinical studies. Investigators rely heavily on literature reviews to define the present state of knowledge. Meta-analysis takes a more structured approach to literature review than does traditional narrative review, and this way may be more helpful in evaluating the accumulation of evidence.

There are three other methods of research synthesis, namely, the traditional narrative reviews, the vote counting methods, and the combined significance test methods. Meta-analysis is distinguished from these in the way it uses statistics, and from primary studies (the original analysis of data) and secondary analysis (reanalysis of another's data) by the fact that meta-analyses do not require access to the raw data, but only to summary statistics. Thus the data points for meta-analyses are summary statistics, and a sample of *studies* in meta-analysis is analogous to a sample of *subjects* in primary analysis.

A meta-analysis is much more structured and replicable than an ordinary narrative literature review. Based on Chalmers and Lau [2] we have developed a ten step procedure for conducting meta-analyses:

- development of a protocol for conducting the meta-analysis;
- identification of sources of information used;
- definition of the criteria for the selection of trials for inclusion;
- reading, classification, coding, scoring, evaluating and choosing of literature;
- adjudication of differences among readers on the qualitative criteria;
- development of questions, procedures, and analyses to pose of trials for inclusion;
- reading of papers and answering of questions on the checklists;
- combination of results and quality assurance of the data;
- analysis, interpretation and reporting of results.

## Results

Meta-analysis was used to compare and, where appropriate, to combine results from more than 200 published studies. These were selected using Medline and periodic anthologies of diabetes literature. An example of combining six such groups of studies, each with more than 200 subjects, is used.

Some of the parameters of this combination are displayed in the first data column of Table 1 where reference is made to the positive predictability of the screening tests and to the prevalence of GDM in the combined samples. For ease of comparison, the specificity has been maintained at 78% and the other parameters allowed to vary.

Table 1. Comparisons of parameters (%) from meta-analyses

|                |    |    |    |
|----------------|----|----|----|
| Sensitivity    | 95 | 64 | 81 |
| Specificity    | 78 | 78 | 78 |
| Predictability | 14 | 15 | 30 |
| Prevalence     | 4  | 4  | 8  |

The relatively low predictability is not unexpected for a disease with relatively low prevalence, yet it questions the advisability of screening based on risk factors [3, 8] since there is evidence that historical and clinical risk factors are relatively insensitive to GDM because of their relatively high prevalence among healthy patients.

If one argues for universal screening, then, with the same data, to achieve a predictability of 15% the sensitivity would drop to 64%. If, as some evidence suggests [12], the prevalence is about 8% in some Australian communities, then one might be able to achieve a predictability of 30% and a sensitivity of 81%.

## Conclusion

Given that nature only gives us a short window of opportunity in which to manage GDM effectively, even a slight degree of under-diagnosis is to be avoided. Our conclusion is to recommend universal testing of all pregnant women with a 75 gram OGTT at the beginning of the third trimester as it is during this period that the adipose and islet cells are formed in the unborn child [10]. Universal screening with a highly sensitive, but lowly predictable, test almost amounts to the same thing in practice.

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**Anthony G. (Tony) Shannon, Prof., Ph.D., Ed.D., D.Sc.**

E-mails: [tony@warrane.unsw.edu.au](mailto:tony@warrane.unsw.edu.au), [tonySHANNON@raffles.edu.au](mailto:tonySHANNON@raffles.edu.au)



Professor A. G. (Tony) Shannon is an Emeritus Professor of the University of Technology, Sydney, where he was Foundation Dean of the University Graduate School and Professor of Applied Mathematics, and where he is currently Chair of the Key University Research Centre for Health Technologies.

He holds the degrees of Ph.D., Ed.D. and D.Sc. He is co-author of numerous books and articles in medicine, mathematics and education. His research interests are in the philosophy of education and epidemiology, particularly through the application of generalized nets and intuitionistic fuzzy logic. He has taught and mentored at all levels from primary school to post-doctoral.

Prof. Shannon is a Fellow of several professional societies and a member of several course advisory committees at private higher education providers. He is on the Board of Trustees of Champion College, a liberal arts degree granting institution in Sydney. In June 1987 he was appointed a Member of the Order of Australia for services to education.

He enjoys reading, walking, theatre, number theory, and thoroughbred racing.