6.1.2.1 Clinical Goals for Measurement of Hemoglobin in Primary Care as Assessed by Paper Vignettes

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ABSTRACT

A random sample of 10% (273) Norwegian general practitioners (GP) received a questionnaire including 11 case stories. For each case the GP was asked to fill in an action value for hemoglobin which should represent the minimal change considered necessary by that general practitioner to take action towards the patient. These minimal changes could then be used for calculation of imprecision goals assuming that there was no change in the bias of the two measurements. The analytical imprecision goals (CV) derived from the different case stories varied between 0% and 7.8% with a mean of 2.8% accepting a false positive rate of 5%. The GPs assessment of a single case story also varied substantially.

INTRODUCTION

Hemoglobin is the analysis most often requested in primary care[1]. The quality of the measurement, however, varies considerably. What then is the goal for hemoglobin measurement in primary care? Studies have been carried out to assess the goals for hemoglobin measurement, based either on intraindividual variation [2] or clinical needs [3, 4, 5]. However, the earlier "clinical studies" have largely concentrated on the hospital setting and on few clinical situations. But since hemoglobin is requested in a variety of clinical situations and the clinical goals will probably depend on these situations. The present study examines how the clinical goals vary with (a) different clinical situations in primary health care and (b) among general practitioners assessing the same clinical situations.

METHODS

A 10% (273) random sample of Norwegian general practitioners received a questionnaire including 11 case stories. It was stated that the main purpose of the study was to survey the clinical assessment of hemoglobin in general practice and that no "correct" answers were available. The clinical situations were chosen in accordance with reasons for encounter and frequent diagnoses in general practice. For each case, the general practitioner was asked to fill in an action value for hemoglobin which should represent the minimal change considered necessary by that general practitioner to take action towards the patient. Possible modes of action could vary from retesting to hospitalization, but the GP was not asked to state his mode of action. Two typical case stories are given below. For a full report of the methods , and a complete set of case stories see [6].

Case 5:
A man of 62 years who two years ago had a hemicolectomy for cancer of the colon. During the last months he has been a bit tired, but then "It has been a rotten summer". Haemoglobin 6 months ago was 132 g/l, and your examination is still quite normal.

State how low the haemoglobin must be (at least) before you take action: .... g/l.

Case 6
A 37 years old man has suffered from duodenal ulcer twice previously. The first time he was sent to a hospital because of bleeding, but was not operated on. Last month his indigestion has recurred, and it has become a great deal worse this last week. Five weeks ago his haemoglobin was 147 g/l.

State how low the haemoglobin must be (at least) before you take action: .... g/l.

Calculations

Assuming that there was no change in the bias of the two measurements, hemoglobin changes were transformed to so-called medically useful coefficients of variation (CV_m),

$$CV_m = \frac{\partial Hb \cdot 100}{\overline{X}} \cdot \frac{1}{Z_p \cdot \sqrt{2}}$$ where ∂Hb is the hemoglobin change indicated by the GPs, $\overline{X}$ is the mean of the previous value given and the value stated, and Z_p is the preselected level of probability (the changes being unidirectional). The analytical coefficient of variation is then calculated as: $CV_a = \sqrt{(CV_m^2 - CV_i^2)}$ where CV_i is the intraindividual variation = 2.7 % [7, 8].

RESULTS AND DISCUSSION

We received answers from 207 (76%) of the general practitioners of whom 31 did not fulfil our inclusion criteria [6].
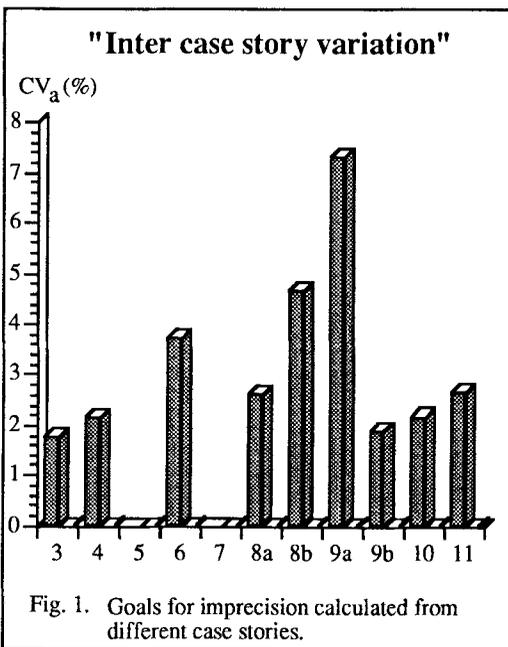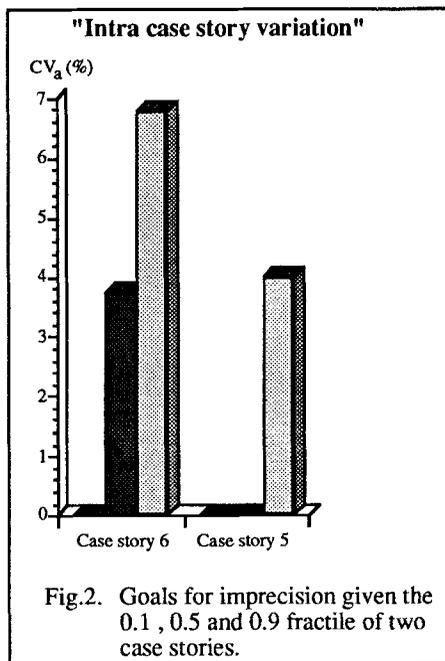

Fig. 1. Goals for imprecision calculated from different case stories.

The analytical goals for the different case stories are calculated from the 0.50 fractile of the results assuming a false positive rate of < 0.05 and an intraindividual coefficient of variation for hemoglobin of 2.7% (figure 1.) The goals vary from below 0 which means that the general practitioners accept a higher rate of false positives than 0.05 (see below) to 7.8 % which is a rather wide limit for the analytical CV.

The imprecision (CV) of haemoglobin measured in general practice varies between 2.2%, and 4.3% [9, 10]. Using 4.3% the GPs will have their clinical demands fulfilled in only two cases. In contrast, four cases require analytical imprecision better than 2.2%.

"Intra case story variation"

CV_a (%)

Case story 6   Case story 5

Fig.2. Goals for imprecision given the 0.1 , 0.5 and 0.9 fractile of two case stories.

The variation among the general practitioners in assessing case stories 5 and 6 is given in fig.2: 10% of the general practitioners feel that they will be able to deal with the patient if their instrument has a CV of about 4-7%. On the other hand, 10% will not be able, with 95% certainty, to detect the requested change in hemoglobin since the requested imprecision is lower than the intraindividual variation.
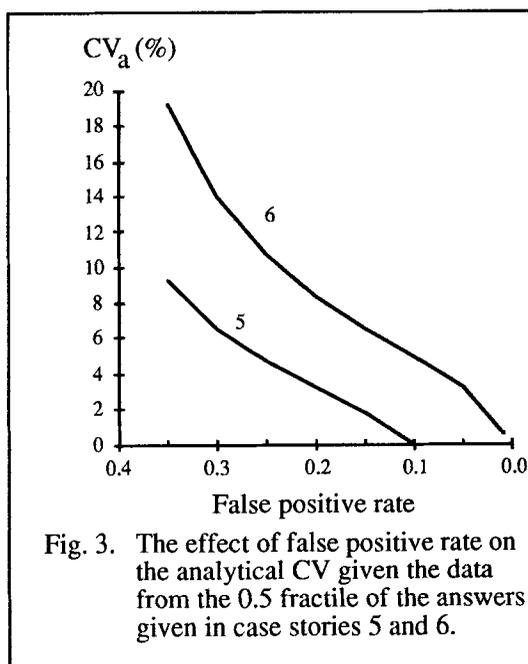
It is also possible to calculate the analytical imprecision goals assuming different false positive rates (fig.3). The smaller the false positive rate accepted, the greater the need for good analytical precision. With an analytical imprecision of e.g. 6%, the requested changes in case story 5 will result in about 30% false positives whereas case story 6 will give about 10% false positives.

A full report of the results are given elsewhere [6]. In addition, our results are also further elaborated with respect to goal-setting for patient monitoring when two analytical methods are used [11] and with respect to the theory of reference changes [12].

Conclusions

The use of paper vignettes to estimate clinical goals for laboratory analyses gives an impression of what analytical quality the clinicians deem necessary in each case. The estimated analytical quality varies depending both on the clinical condition and, within each clinical situation, from physician to physician.

It is therefore impossible with this strategy to end up with one analytical goal for each constituent. Setting analytical goals must take into account the clinical situation in which the results are used in addition to biological variation.

CV_a (%)

False positive rate

Fig. 3. The effect of false positive rate on the analytical CV given the data from the 0.5 fractile of the answers given in case stories 5 and 6.

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