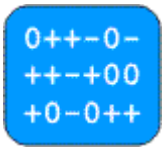

Cytomics, from Prognostic to Predictive Medicine

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(predprg1.htm in: Cytomics, ed: JP Robinson, Cytometry CD Vol.7, Purdue University, West Lafayette, 2003 (ISBN 0-9717498-8-4)

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1. Background: The future development of diseases is addressed in many instances as **prognosis**. Prognosis reflects the **average statistical experience** with disease development in large patient groups under therapy. Prognostic indicators are often used for **patient stratification** in therapy optimizing trials in an effort to treat as many patients as possible with the most efficient therapy.

- A frequently encountered problem concerns larger or smaller **subgroups** of patients who will **not** benefit from standard therapy and potentially suffer from therapeutic side effects and adverse drug reactions (ADRs).

- It would be a significant help for the clinician if a-priori **non responder** patients could be identified **pretherapeutically** (L1-L6). This would allow individualized therapy modifications as well as the use of alternative or preventive therapies.

- One may think that the description of more and more **independent prognostic factors** may automatically lead to prediction. This is not necessarily the case since prognosis addresses patient groups and not individual patients. Smoking as an example is a good prognostic indicator for later lung cancer but no good predictor since not all smokers will develop lung cancer and lung cancer is also observed in non smokers for other reasons.

2. Goal: With this in mind it seems important to specifically orient multiparameter data analysis in cytometry, chip or bead arrays, clinical chemistry and clinical parameters towards **individualized predictions** with **> 95%** or **> 99%** accuracy.

Individualized predictions in multiparameter data analysis can be addressed by **data sieving** as a fast operating algorithmic method which requires no mathematical assumptions on the value distributions of analysed parameters and no substitution of missing data values or removal of patients with incomplete data sets. The resulting discriminatory data patterns characterize the **molecular cell phenotypes** in disease as they result from **genotype and exposure**. The data patterns are of interest for **bottom-up** hypothesis development and molecular **reverse engineering** of complex intracellular processes.

3. Results: Individualized risk assessment or prediction of therapeutic success by data sieving analysis was amongst other possible in: acute myeloid leukemia (AML), diffuse large B-cell lymphoma (DLBCL), colorectal cancer, intensive care medicine, cardiac surgery and systemic lupus erythematosus (SLE) (further examples).

- The comparison of **predictive** and **prognostic** data patterns seems of particular importance because it

may explain the inhomogeneous therapeutic response in prognostically well characterized patient groups.

- Predictive and prognostic data patterns show only a **limited** coincidence of selected parameters in AML (pred, prog) and DLBCL (pred, prog).

4. Conclusion: The multiparameter cytometric or other molecular information which is typically collected in the clinical environment has the potential for an accurate pretherapeutic **identification** of risk patients (individualized pretherapeutic risk assessment) as evidenced by an increasing number of examples from **everyday medical practice**.

- Besides obvious advantages for the individual patient, the differences in predictive and prognostic data patterns allow significant **new insights** into the **heterogeneity** and **variability** of disease processes.

- Considering the development of new drugs, the availability of **disease specific** predictive and prognostic data patterns provides substantially increased possibilities for the identification of suitable candidate target genes in pharmaceutical developments.

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Internet: https://www.classimed.de
Last Update: Jan 02,2012
First Display: Apr 03,2003
