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PREDICTIVE VALUE OF RISK ASSESSMENT INDICES: RISK THAT RISK ASSESSMENT IS MISLEADING

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Background: Classical toxicology provides mathematical models and methods for risk prediction of pure chemicals out of *in vitro* register data and animal study. It is tempting to apply such methods to tattoo ink products.

Aim: To revisit the potential use of toxicological risk assessment models for risk prediction of tattoo inks products relative to key clinical end points in particular the known risk of allergy and the potential risk of cancer. It is an assumption in the ResAp(2008)1 that ban of certain ingredients and limitation of others truly eliminates risks or reduce the incidence of adverse events in the real world scenario making intervention meaningful.

Methods: Register data on toxicity of tattoo ink pigments and ingredients is held against clinical end points using common concepts for estimation of predictive value of laboratory tests, i.e. their applicability, sensitivity and specificity.

Results: *Tattoo and allergy*: Allergy of red tattoos related to azo-chemicals is a significant clinical problem. The allergen is formed as a hapten in the skin and only partly originates from some unknown raw material in the ink with primary aromatic amines (PAAs) being hypothesized to play a role. Prediction of risk of allergy from analysis of specific PAAs in inks and estimation of acceptable threshold concentrations is invalid since an exposure-event relationship cannot be established due to the lack of fundamental knowledge on chemical(s) and causality relative to allergic manifestation in tattooed persons.

Tattoo and cancer: Poly-aromatic hydrocarbons (PAHs) are associated with airway cancer and potentially with CMT-events in human use. PAHs account many chemicals found in the same carbon black. PAHs were present in tattoo inks for a century or more and also present in tars extensively used in dermatological therapy. However, review of the medical literature and long term follow up studies on cutaneous neoplasia related to black tattoos and tars on skin could not verify PAH exposure of skin as carcinogenic in this organ, neither in regional lymph nodes. Sunlight is a powerful skin oncogene. A recent mice study indicated light absorption in black tattoo pigment reduces the risk of skin cancer, hence black tattoos even may prevent skin cancer.

Conclusions: Risk prediction of tattooing from chemical analysis of PAHs and PAAs in tattoo ink products as suggested in the ResAp(2008)1 remains highly controversial, not validated and from present state of knowledge unlikely to be an accurate determinant of tattoo risk in humans.