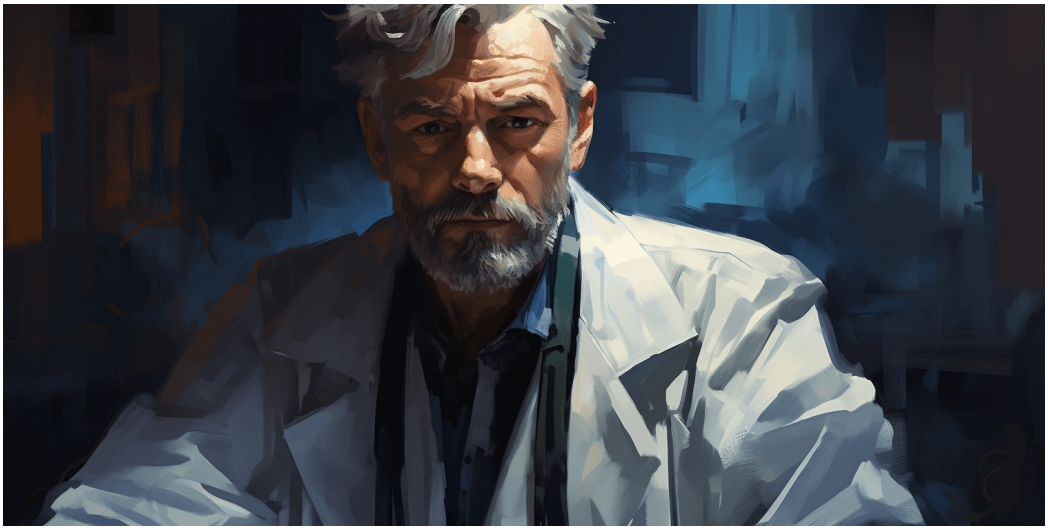

[Commentary] “Form Follows Function (FFF)” – Applying this Rule of Designers and Architects Can Reduce Misinterpretations and Methodical Shortcomings in Healthcare

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Abstract

This commentary explores the application of the “Form Follows Function” (FFF) rule from Ulm’s Academy of Design legacy in healthcare. It addresses misinterpretations and methodical limitations by identifying conflicts in healthcare evaluation. The paper highlights discrepancies between experimental controlled trials and real-world medical practice, emphasizing the need for structured, pragmatic approaches. It emphasizes establishing thresholds for clinical relevance and efficiency to curb overtreatment and advocates aligning measurement strategies with actual functions to enhance healthcare evaluation accuracy.

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effectiveness.

Two historic events in Ulm helped reduce misinterpretations and methodical shortcomings in healthcare: the preservation of Albert Einstein's legacy (born in 1879 in Ulm) and that of the Academy of Design in Ulm (*Hochschule für Gestaltung*, 1953-1968). Albert Einstein left us his Theories of Relativity and lots of helpful advice; for instance, "A problem cannot be solved by the way of thinking that caused the problem." The Academy's legacy entails tenets for design and architecture, such as "Form Follows Function" (the FFF rule) and the requirement to develop not only individual but generally valid solutions with social relevance. Applying these Ulm legacies to healthcare services has succeeded in identifying two scientific conflicts to reduce their undesired results. The first conflict concerns the misinterpretation of the results of randomized controlled trials (RCTs). The second conflict describes the methodical shortcomings in evaluating the need for healthcare provision and the efficiency of all provided healthcare services.

The results of RCTs are internationally accepted to justify ethical, epidemiologic, medical, judicial, and political decisions without taking into consideration that the conditions under which an RCT is performed and evaluated differ in 14 formal and functional criteria from the 'natural chaos' prevailing in everyday medical practice. Examples of these differences are the selection of subjects, the required focus on a primary endpoint, the analysis of risk profiles, and the assessment of dropouts. Accordingly, the results of an experimental RCT can verify a proof of principle under ideal study conditions, but not the 'real-world' effectiveness (RWE) of interventions performed under the non-structured conditions prevailing in the provision of everyday healthcare. Evidence of the suitability of measures provided under everyday conditions is required to optimize healthcare provision. The proof lies in the natural chaos of everyday healthcare provision, for example, through a non-experimental but structured pragmatic controlled trial in which all subjects are evaluated according to stratified endpoint-specific risk profiles (Bayes Principle).

The risk of overtreatment cannot be eliminated without proof of the need for a provided healthcare service and its efficiency under everyday conditions. Therefore, the threshold values of the need for a healthcare service and its efficiency need to be verified before implementing a standard of healthcare provision. The threshold of the clinical relevance of the need for a healthcare service provided under everyday conditions should initially be determined by clinical experts. This initial standard can be readjusted by subsequently gathered data about the baseline risk (control event rate) of untreated cohorts and the clinical relevance of the achievable efficiency of the healthcare service provided (absolute risk reduction). The clinical relevance of the efficiency of a healthcare service can be described as the effect of the intervention under everyday conditions, the absolute risk reduction (ARR), in cohorts characterized by endpoint-specific risk profiles. A threshold of the frequency of a minimally achievable ARR should be determined in addition to the clinically relevant thresholds to achieve the greatest possible additional health benefit with the available resources for every patient.

Measurements that do not align with the expected function derived from the measured result carry a high risk of bias and should be avoided. The concept used to calculate the relative risk reduction (RRR) does not offer any additional information beyond what has already been provided by describing the absolute risk reduction (ARR).

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