Editor's Page

How Much Validation Do We Need?

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Significant progress has been made in assessing the risk of developing heart failure (HF) as well as downstream mortality once HF has occurred. Additionally, there are now multiple disease-specific and generic instruments that can be used to evaluate health related quality-of-life (HRQoL) and we know how changes in the scores correlate with changes in a given patient's overall clinical status. However, operationalizing use of both risk calculators and HRQoL instruments in clinical practice appears to be more difficult than anticipated and as a consequence, widespread adoption has not occurred. There are likely many reasons for this including those based on misconceptions about how the tools impact clinical work flow and uncertainty about how the results can or should influence clinical decision-making. This state of affairs exists despite the publication of consensus documents that advocate their use[1,2] and strong support for incorporating them into shared decision-making processes.

There is another consideration that may be overlooked: validation. In this issue of the Journal, we are publishing two papers and two accompanying editorials assessing the application of risk scores in populations not originally included in the development of predictive models (OPTIMIZE-HF and the Seattle Heart Failure Model). Why all this attention? During the editorial review process, it became clear to us that there was a fundamental question underlying the manuscripts that would not be easy to answer: to what degree should we validate predictive models (and by extension HRQoL instruments) in patient cohorts not previously evaluated? If validation is needed, then how far should we take this mandate before applying published tools across different regions, ethnic/racial groups and health systems? It is generally established that when HRQoL tools are translated into different languages, a formal process of validation is required. It also makes perfect sense that when incorporating non-physiological variables that reflect social determinants of health into predictive models, validation is needed since these factors may vary based on the socioeconomic and ethnic milieu extant in different populations. But should we now expect and indeed call for a veritable onslaught of these studies, across multiple different populations and geographies?

It is in this context that I asked two highly regarded investigators in the field (Drs. Douglas Lee and Tom Marwick) to address the validation issue. Both have approached the problem in different but very informative, thought-provoking editorials that help to provide a much needed framework. Their contributions make for informative summer reading but more importantly demonstrate once again that the HF discipline consistently forces us to think and challenge assumptions about data. With regard to the issue of predictive instruments and assessment in diverse populations, I think it is now fair to say that if an "instrument" or "model" is to be used in a population substantially different than the one from which it was derived, local investigators or clinicians may want to conduct some type of validation study prior to implementation, though not necessarily for publication. Stated otherwise, to best take advantage of the predictive models, Drs. Lee and Marwick are telling us to "stay calm and validate on", a suggestion that we need to strongly consider.

References

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