The BWAT Pictorial Guide and the 60-second Diabetic Foot Screen:

A Commentary on Developing and **Validating Clinical Materials**



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his issue of Wound Care Canada contains articles on two wound assessment tools: the Bates-lensen wound assessment tool (BWAT, see page 33) and the Inlow 60-second Diabetic Foot Screen (see page 40). I have developed this commentary to discuss (a) the development of a pictorial guide that is intended to help clinicians use the former and (b) a form that is intended to facilitate the use of a screening tool. We can learn much about assessment tool development and validation by examining these two tools.

Why Are Assessment Tools Developed?

Assessment tools are developed for three reasons: discrimination, prediction and/or evaluation.1 These terms are defined in Table 1.

Why do we care about the reason(s) for assessment tool development? Because the reasons determine the type of validation that is required to prove that the tool can do what it is intended to do.

Reasons for the development of assessment tools1

Discrimination-to distinguish between individuals or groups on the basis of an underlying dimension or characteristic (e.g., quality of life)

Prediction-to assess the likelihood or risk of future development of an outcome of interest (e.g., ulcer, amputation)

Evaluation—to measure the amount of change that occurs over time (e.g., wound healing over time)

The Reasons Behind the BWAT and the Inlow Tool

I would argue that the BWAT was developed for the purpose of discrimination—to provide a way to describe wound appearance. Some people use the BWAT to track wound healing, which suggests an evaluative purpose. To my knowledge, however, no studies have proven that the BWAT can detect change. If that is true, the BWAT should not be used as an evaluative tool until it has been validated as such. Why not? If you are treating a person and using the BWAT to document wound change, what can you conclude if you do not notice change? One might be tempted to say that the wound has not changed. However, it may be that change has occurred, but has not been detected by the BWAT. If you know that a tool can detect change and you find that your patient's values are not changing, you can conclude with some certainty that your treatment approach is not working. To summarize, an assessment tool should not be developed for one purpose and used for another.

The Inlow 60-second Foot Screen was developed as a screening test for persons with diabetes, with the goal of preventing complications, ulcers and amputations. This suggests that it is a risk assessment or predictive tool that can be used to guide prevention and treatment strategies. It is recommended that the screen be completed on admission and repeated as indicated by risk. This suggests that items can be expected to change over time, and that implies that the tool might be evaluative. The fact that data are collected to classify patients into categories suggests a discriminative purpose.

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For further details on the development of the Inlow 60-second Foot Screen, see the original Inlow article in Wound Care Canada²

Validation of the BWAT and the Inlow Tool

It is not enough that a tool is developed using a careful process. After development, it is necessary to validate the tool or demonstrate its psychometric or clinimetric properties (validity, reliability and/or responsiveness).³ General and specific types of validation and their definitions are outlined in Table 2.

One difficulty in establishing validity using an established criterion measure is choosing an appropriate gold standard.

When predicting risk, it is necessary to validate a tool by determining its predictive validity in relation to a future event (e.g., the development of an ulcer, amputation). This can be described in terms of sensitivity, specificity, positive and negative predictive values, likelihood ratios and/or receiver operating curves.

With this in mind, what are the appropriate types of validation for the BWAT and the Inlow tool in relation to the reasons for their development? Table 3 shows validation that should be conducted according to the reasons for development.

Next, what validation has been done? As described in Harris et al.'s article in this issue, the BWAT is a modified version of the pressure sore status tool (PSST). It has been amended for computer use, and an algorithm has been developed to guide treatment planning. The properties of the PSST that were assessed prior to

TABLE :

Types of validation

Validity, in general, determines if a tool is measuring what it is intended to measure.

Face validity is when a measure only appears to measure what it is intended to measure. It is the simplest form of validation and is not discussed a great deal.

Content validity is when a measurement reflects the specific and whole area of content.

Concurrent validity illustrates the relationship between results obtained using a tool of interest and those obtained using another established measure or gold standard when both are measured at the same time.

Predictive validity illustrates the relationship between results obtained using a tool of interest and those obtained using another trusted measure or gold standard that is obtained in the future (e.g., an outcome or an event).

Reliability describes, in general, the ability to obtain the same score when a measure is obtained repeatedly under the same conditions.

Intrarater reliability (test-retest) describes the same rater's ability to obtain similar results on repeated testing when no change in the patient's condition has occurred.

Interrater reliability describes the ability of two or more raters to obtain similar ratings when measuring the same thing under the same conditions.

Responsiveness describes the ability to detect a real change due to the treatment effect using a measurement tool.

TABLE 3

Types of validation that should be conducted according to the reasons for development

Validation properties	BWAT		Inlow		
	Discrimination	Evaluation	Discrimination	Prediction	Evaluation
Face validity	Yes	Yes	Yes	Yes	Yes
Content validity	Yes	Yes	Yes	Yes	Yes
Concurrent validity	Ideally	-	Ideally	-	-
Predictive validity	-	-	-	Yes	-
Intrarater reliability	Yes	Yes	Yes	Yes	Yes
Interrater reliability	Yes	Yes	Yes	Yes	Yes
Responsiveness	-	Yes	-	-	Yes

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modification are discussed in a chapter on wound assessment in the fourth edition of *Chronic Wound Care: A Clinical Source Book for Healthcare Professionals.*⁴ When a tool is modified, however, it cannot be assumed that the validation of an earlier version is applicable to the modified version. Therefore, further validation must be done to prove that the modified version functions as intended.

Connecting the Dots

In this issue, Harris et al. report on the development of what they refer to as a "validated pictorial guide" for the BWAT. The guide has been designed to help wound-care practitioners perform a systematic and comprehensive wound assessment using the BWAT. This pictorial guide is not a new wound-assessment tool; rather, it complements the current written descriptions of characteristics that need to be identified when evaluating wounds using the BWAT. This pictorial guide provides a good enabler for improving responses to and documentation of the BWAT. As a training enabler, the face validity of the photographs has been tested. This does not mean that the BWAT itself has been validated for discrimination or evaluation (i.e., for measuring healing).

Orsted reports on the development of a bedside form for documenting the Inlow 60-second Diabetic Foot Screen and a method for scoring and categorizing risk. The form is a much-needed enabler for ensuring complete documentation and ascertaining risk. The predictive validity of this screening tool as a risk scale has not yet been shown in a research study. However, with the use of this tool and as clinicians become more aware of the risk of foot ulcers, it is likely that prevention strategies will be implemented and foot ulcer

development reduced. From a clinical perspective that is a good thing, but from the perspective of showing the predictive validity, it is possible that the statistical documentation could be poor. It will require additional testing to determine if the tool's risk categories are associated with ulcer development and amputation.

Summary

The BWAT pictorial guide is an appealing enabler containing photos that are validated to the extent of having face validity. Presumably, clinicians who can identify the response categories accurately will be able to provide more accurate BWAT scores.

The Inlow 60-second Diabetic Foot Screen bedside tool is a valuable new addition to enable consistent assessment and documentation of feet and foot ulcer risk.

Key Points in Understanding Tools

- Know what type of validation to expect for any tool based on the reason(s) for its development (discrimination, prediction and/or evaluation).
- The more purposes a tool has, the more types of validation it requires.
- Appropriate validation, for a particular purpose for development, is required to help understand the results of assessment.
- Tools should be used only for the particular purpose for which they have been validated.
- The words *validated tool* are often used without truly understanding their meaning. A tool must be validated for a particular use. Some tools are validated for one purpose and not another. Be sure you know what you mean!
- Finally, I suggest that we start speaking more specifically about the extent and type of validation in relation to tool usage.

References

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