

Clinical Epidemiology

You are a public health researcher tasked with developing a new prognostic model to predict 10-year cardiovascular disease (CVD) risk in a low-resource country in West Asia. Currently, clinicians in your setting use a CVD risk prediction model that was developed in a high-income Western population. You have collected data on 5,000 patients from your local population, including their clinical features (age, blood pressure, cholesterol, smoking status, diabetes) and outcomes over 10 years. A colleague suggests that once you develop the model using your local data, it can be immediately implemented in clinical practice across the country without further testing, as local data is the most relevant. However, you recall the methodological standards and framework proposed by the PROGnosis REsearch Strategy (PROGRESS) partnership for prognosis research.

Question 1) According to the PROGRESS framework, what are the essential phases required for the proper development and implementation of a prognostic model? (Maximum choice 6)

(محدودیت انتخاب: 6 گزینه - انتخاب گزینه غلط، نمره منفی دارد)

گزینه	گزینه صحیح	گزینه نادرست	خطای فاحش	وضعیت نمره
Develop the prognostic model using the local dataset.	*			مثبت
Implement the model immediately in clinical practice after development because local data is the most relevant.		*		منفی
Externally validate the model in a different setting or population.	*			مثبت
Assume that if the model works well in the development dataset, it will work equally well in all other settings.		*		منفی
Assess the impact of using the model on clinical practice and patient outcomes.	*			مثبت
Use the development phase and skip validation because external validation is too time-consuming.				اثری ندارد
Validate the model in a population with different characteristics (e.g., different country, different healthcare setting).	*			مثبت
Publish the model and let other researchers validate it later; implementation can proceed immediately.				اثری ندارد
Test the model's performance in at least one external dataset before recommending its use in clinical practice.	*			مثبت
Assess whether using the model improves clinical decision-making and patient outcomes, not just whether it predicts accurately.	*			مثبت

Question 2) A hospital administrator argues that external validation is unnecessary because the model was developed using local data from your own country. What should you explain to the administrator about the importance of external validation? (Maximum choice 5)

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گزینه	گزینه صحیح	گزینه نادرست	خطای فاحش	وضعیت نمره
External validation is optional and recommended for models developed in high-income countries.	*			منفی
External validation should ideally be performed in a different setting to test the model's generalizability.	*			مثبت
A model that performs well in the development dataset may perform poorly when applied to a different population.	*			مثبت
The study of four cardiovascular risk prediction models in Malaysia found that one of the models performed poorly, emphasizing the need for external validation.	*			مثبت
If a model performs poorly in external validation, it should still be used because it was developed using rigorous methods.	*			منفی
External validation helps identify whether the model's predictions are accurate across same patient populations or healthcare settings.	*			منفی
External validation is needed if the model was developed using data from a single hospital.				اثری ندارد
If the model was developed using a large and diverse dataset, external validation is not necessary.			*	خطای فاحش
The text emphasizes that methodological standards in prognosis research have lagged behind RCTs, and PROGRESS provides guidance to address this.	*			مثبت
External validation should be performed in a setting that is as similar as possible to the setting where the model will be used.	*			مثبت

Question 3) Your team has completed the development phase of the prognostic model. Now, you are planning the next steps. Based on the text, what are the key considerations and potential consequences of failing to properly validate the model? (Maximum choice 5)

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وضعیت نمره	خطای فاحش	گزینه نادرست	گزینه صحیح	گزینه
مثبت			*	Implementing the model without external validation could lead to inaccurate risk predictions for patients in your setting.
منفی		*		Inaccurate risk predictions usually could not result in inappropriate treatment decisions (e.g., under-treating high-risk patients or over-treating low-risk patients).
مثبت			*	If the model performs poorly in your setting, it could lead to inefficient use of healthcare resources.
منفی		*		The PROGRESS framework emphasizes that external validation is a "nice-to-have" but not essential.
اثری ندارد				The Malaysia study showed that commonly used cardiovascular risk prediction models can perform well in different settings, so validation is necessary but not critical
مثبت			*	It is very common for only the development step to be carried out, and this is a limitation in prognosis research.
اثری ندارد				Even if the model performs poorly in external validation, it can still be used if clinicians are aware of its limitations.
منفی		*		External validation could be conducted after the model is widely adopted in clinical practice.
مثبت			*	If the model is not validated, patients could experience harm from incorrect risk stratification.
مثبت			*	The impact of using the model on clinical practice should be assessed after validation to ensure it improves patient care.

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