

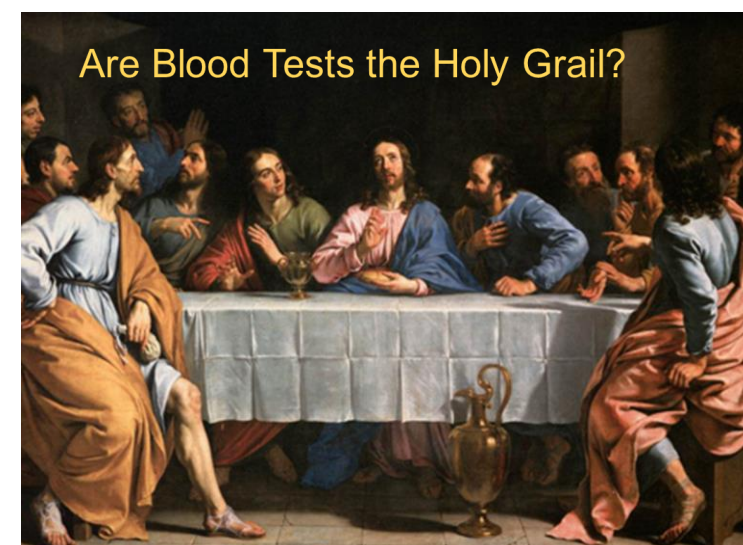


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Evaluating new non-invasive screening tests for colorectal cancer: An in-depth international perspective

Robert S. Bresalier, Graeme P. Young, Carlo Senore





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An efficient strategy for evaluating new non-invasive screening tests for colorectal cancer: The guiding principles

Bresalier* R.S., Senore*, C., Young*, G.P., Allison, J., Benamouzig, R, Benton, S., Bossuyt, P.M., Caro, L., Carvalho, B., Chiu, H.M., Coupe, V.M.H., de Klaver, W., de Klerk, C.M., Dekker, E., Dolwani, S., Fraser, C.G., Grady, W.M., Guittet, L., Gupta, S., Halloran, S.P., Haug, U., Hoff, G., Itzkowitz, S.H., Kortlever, T.L., Koulauzidis, A., Ladabaum, U., Lauby-Secretan, B., Leja, M., Levin, B., Levin, T.R., Macrae, F., Meijer, G.A., Melson, J., O'Morain, C., Parry, S., Rabeneck, L., Ransohoff, D.F., Saenz, R., Saito, H., Sanduleanu, S., Schoen, R.E., Selby, K., Singh, H., Steele, R.J.C., Sung, J.J.Y., Symonds, E., Winawer, S.J. (Members of the WEO CRC Screening New Test Evaluation Expert Working Group)

Gut 2023;72:1904-1918



Topics Addressed in Each of the Principles Established by the Consensus Process

Principle Number	Topic
1	Desired outcomes of CRC screening
2	Screening is a multi-step process
3	A screening test identifies individuals with an increased likelihood of CRC and/or advanced precursor lesions
4	Nature of precursor lesions most important to detect
5	New biomarkers might detect lesions with a different natural history
6	Outcomes to be estimated in a screening population
7	Expectations of a new non-invasive test
8	An adjustable test positivity threshold accommodates different program goals
9	Predicting value by paired comparison to a proven non-invasive test
10	Evaluation proceeds through increasingly complex phases
11	Accuracy required for evaluation in a screening population
12	Analytic specifications, standards, and performance

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Background & Aim

- **Special issue of *Digestive Diseases and Sciences* Commissioned to Expand These and Related Topics**
- **Fully Commissioned**
- **International Author Representation**

- **Do the guiding principles apply: Lessons from the commercial non-invasive tests?**
Josh Melson (USA)
- **Validation of a new test for CRC screening: How we did it**
Beatriz Carvalho and Veerle Coupe (Netherlands)
- **Does colonoscopy as a first (and invasive) screening test still make sense?**
Point/Counterpoint
Yes Douglas Rex (USA)
No Han-Mo Chiu (Taiwan)
- **How good is FIT as a comparator in development of new non-invasive screening tests and what is its role?**
Carlo Senore (Italy)
- **Does an adjustable positivity threshold for FIT and other non-invasive tests make sense?**
Graeme Young (Australia)
- **Modelling and the use of surrogate endpoints: Is this a valid approach?**
Uri Ladabaum (USA)

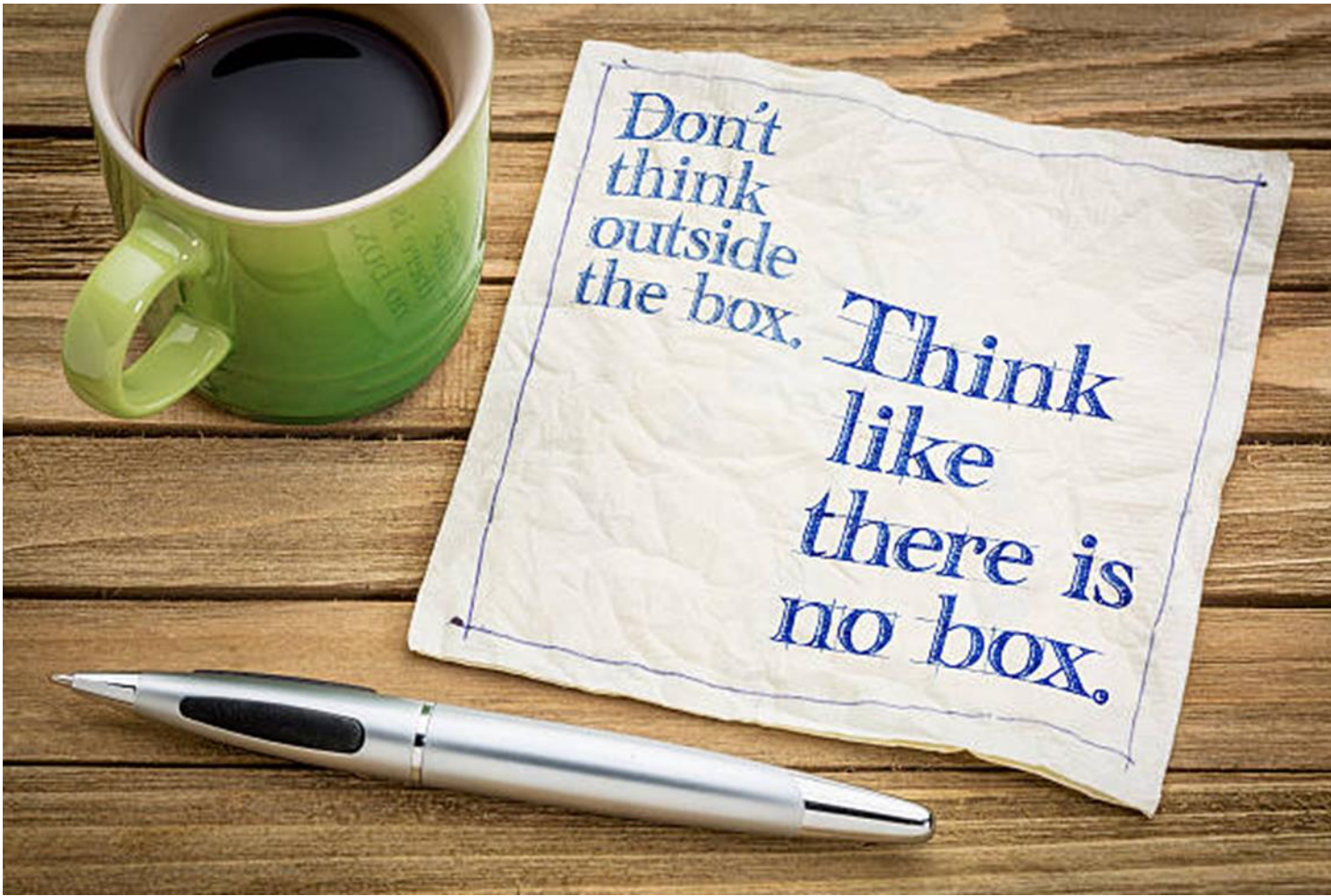


- **Evaluating non-invasive tests for colorectal cancer-sample size and study design**
Patrick Bossuyt (Netherlands)
- **How good is good enough: What should the target be for colon cancer screening?**

US perspective-David Lieberman (USA)
European perspective- Evelien Dekker (Netherlands)
- **Regulatory challenges in bringing new tests to clinical practice**
Gerard Davis (Abbott Labs)
- **When should colon cancer screening begin? The impact of early-onset colorectal cancer and the reality of an unscreened older population (point/counterpoint)**

Screening should begin at age 45 -Iris Lansdorp (Netherlands)
Screening at age 45 is not practical Linda Rabeneck (Canada)
- **Are non-invasive multi-cancer early cancer detection tests the future?**
William Grady (USA)
- **Risk stratification and the role of AI in non-invasive testing for colorectal cancer**
Han-Mo Chiu (Taiwan)





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