



Safety(norms) in guidelines

Handle with care?

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**Longstanding Debates on Standards as
Regulatory Instruments in Healthcare**





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Safety norms (un)popular



Policy assumption: Ensuring minimum quality through safety norms

- (Let actors) formulate clear norms to ensure safe care
- Facilitates steering quality at several levels:
 - inter-professionals
 - directors
 - inspectorate
- Issue: norms insufficiently developed:
 - lacking
 - implicit
 - leeway in application
- Policy vision:
 - Field-actors *and* inspectorate develop safety norms

Empirical turn on safety (norms) in guidelines

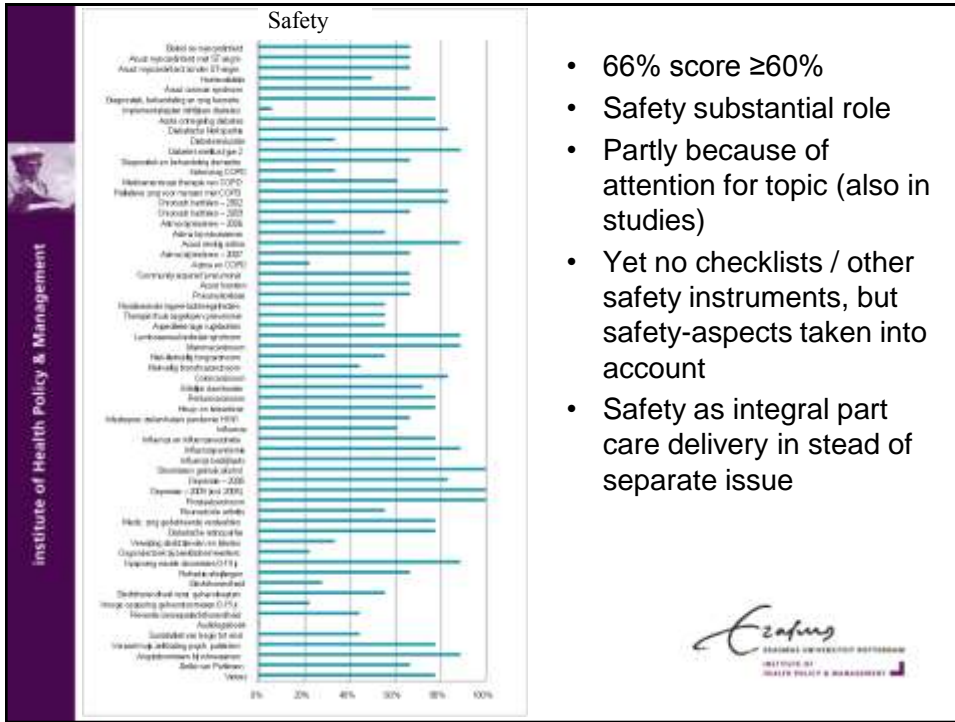
- Can guidelines be used for the **governance of safe care**?
- If so, what is the **role of safety norms** in guidelines?
- Mixed-method study:
 - 62 guidelines (top-25 diagnoses) analyzed for patient safety with adjusted AGREE instrument
 - 18 guidelines for high-risk diagnoses textually analyzed
 - Coronary heart disease, stroke, anti-coagulation, ICU, blood transfusion, etc.
 - Literature study and 20 semi-structured interviews.



Safety in top-25 guidelines

- AGREE question:
 - “11: The health benefits, side effects and risks have been considered in formulating the recommendations”
- Additional items:
 - 11a: There has been an explicit search for safety risks and possible adverse events;
 - 11b: Identified safety risks and adverse events have been taken into account when formulating recommendations





- 66% score $\geq 60\%$
- Safety substantial role
- Partly because of attention for topic (also in studies)
- Yet no checklists / other safety instruments, but safety-aspects taken into account
- Safety as integral part care delivery in stead of separate issue



Safety norms in high-risk guidelines

- Almost all guidelines contain:
 - norms as **aims**
 - highest possible quality under ideal circumstances
 - **considerations**
 - more/less norm-setting based on setting
 - **conditional norms**
 - 'if \rightarrow than'; norm-setting under specified conditions
 - **safety norms**
 - minimum quality under all circumstances
- If and whether a recommendation is an **aim**, a **situated norm**, or a **safety norm** rarely visible in guideline:
 - typically seen as expertise care professionals



Absence safety norms an omission?

- Striking high number seemingly evident safety norms not included:
 - common practice often *not* included as safety norm
 - **excluding** certain norms **condition** for articulating **problematic quality issues**
 - ‘more adequate description’ minimum quality vs truly guiding document



The promises of steering with safety norms


- Opportunities for steering...
 - ... but beware of rapid conclusions about absence norms
- Setting safety norms is a **good solution** for a **particular type of problem**:
 - apply in case of *simple risks*
 - always prevent through rule-application
- A **problematic solution** for **other types of risks**:
 - not suitable as overall infrastructure minimum safety



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Types of risks

		Agreement about normative principles and dominant values	
		+	-
Agreement about the nature of the risk and available knowledge	+	Sepsis bundle	Total mastectomy / Prostate surgery
	-	Multi-morbidity	Obesitas




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Without such differentiation...

		Agreement about normative principles and dominant values	
		+	-
Agreement about the nature of the risk and available knowledge		Simple risks	Complex risks
		Uncertain risks	Ambiguous risks

zero collaboration on other norms vs safety
 complications through comorbidity vs safety
 patient preferences vs safety
 Quality of life vs safety



Back in Politicized Dichotomy



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A situated approach for safety norms in guidelines

- Norm setting where possible but leaving space where needed
 - **Policy / management:** do not **create** implementation problems
 - Steering *only* when safety norm
 - Other modalities for complex, uncertain, ambiguous aspects minimum quality / safety
 - **Guideline developers:** **explicate difference** in recommendations (standard/option)
 - **Professionals:** there **are** simple risks
 - **Researchers:** explain **both** absence and presence safety norms, without assuming they should be there

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Sociological refigurations of patient safety, managers of improvement and 'acting with quality collaboratives in healthcare'
 'Your Evidence-based?': Multiple Meanings About Evidence-Based IM



19

The Sociology of Quality and Safety in Health Care

Studying a Absent and Missing Sociology

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