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Quantification in Imaging Applications

An engineers view to aspects of a problem in medicine

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August, 2010

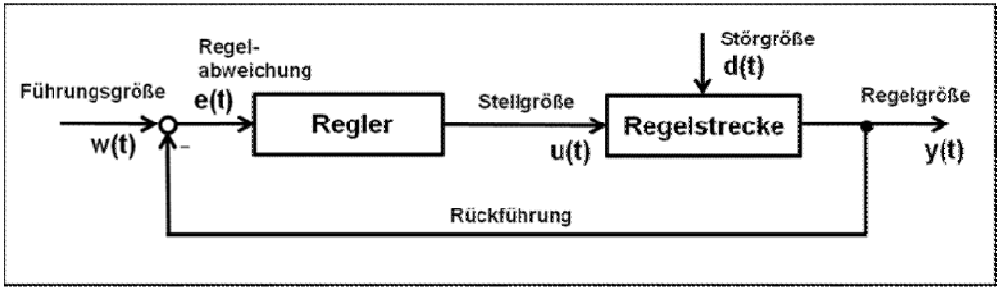
Is our problem really a quantification problem ?

In a first approximation **YES**, because we want to know, if an area is identified as a lesion, the exact size in 1, 2 or 3 dimensions. We call this then segment, plane or volume (voxel) or in a more sophisticated way e.g. RECIST.
And our final judgment shall end up after several (at least two) investigations from one patient in a statement like: the lesion shrinks, remains as it is or growths. This is what imaging is made for; in principle and very simplified.
But with a little bit more detailed view we have to recognize that we do something different in reality and this may lead us to the real difficulties.
What we do during a image examination is to define the border between the lesion area an the non-lesion area or more general (and with respect that we look on a discrete 2D-image on a screen) the border between pixels belonging to a certain structure or not. If we finalized this the quantification is easy. It is trivial math to multiply a number of pixels by the magnification measure and find the longest segment. Therefore the answer is **NO**.

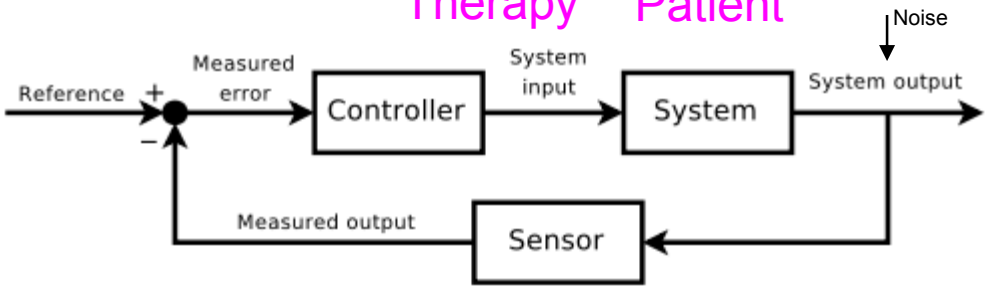
The problem is a classification or allocation issue.

Therefore let us open a solution space for the more detailed consideration!

Patient Treatment – A Control Loop



Therapy Patient



CT-Imaging

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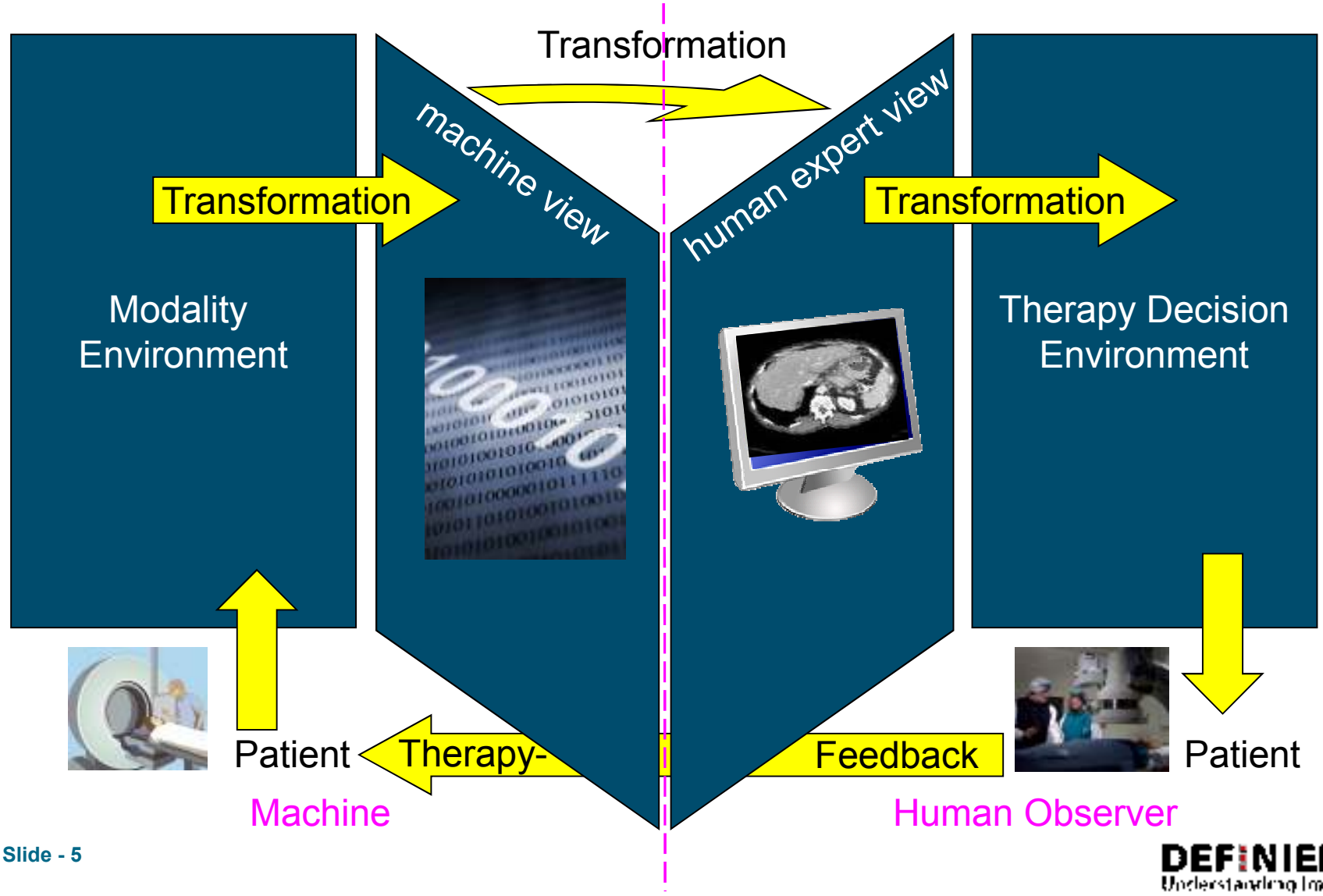
Two sides of a medal – The Solution Space



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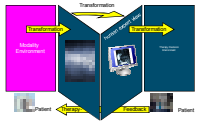
The Modality Environment



Value/Characteristics	Influence to deviations	Remarks/Mitigation
biological variability	important	Mitigation by improvement of diagnostic know-how
sampling method	-	In the meantime more or less standardized (Multislice-Spiral-CT)
beam form (collimation,)	Modality manufacturer know-how	Most of the modality Characteristics are not known regarding their measure deviations → calibration by accepted models for: comparability, independence, reproducibility
energy (dose)		
detector array characteristics: number of rows, dimensions, type, sensitivity, pitch		
breath artifacts		

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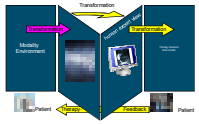
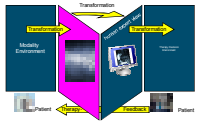
Transformation x-ray attenuation to Houndsfield Units



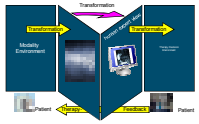
Value/Characteristics	Influence to deviations	Remarks/Mitigation
Convolution kernel	important	Currently there are recommendations available, which are not standardized
Digitalization failures (Use of rounding rules)	not investigated so far in all detail	n.A.
Hounsfield unit setting	important	Depends on the manufacturers algorithms

The machine view



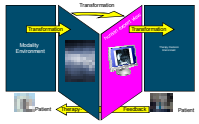
Value/Characteristics	Influence to deviations	Remarks/Mitigation
Memorization format	loss of information, image adulteration	Use of lossless formats
DICOM use (Version, degree of freedom and undetermined entities)	lack of interpretation	Use of well determined data entities only for approved procedures

Transformation machine view to human expert view



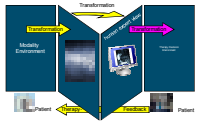
Value/Characteristics	Influence to deviations	Remarks/Mitigation
digitalization failures	Not avoidable	As far as possible standardized procedures necessary
monitor resolution vs. magnification vs. supported grayscale (or false color representation)	Often determining whether a structure is visible or not	Use of approved monitors is mandatory, but look at the real live!
monitor frequency	Not investigated	Closeouts per definition
screen configuration method	Not investigated	Closeouts per definition

The human expert view



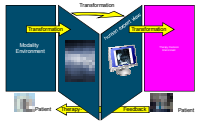
Value/Characteristics	Influence to deviations	Remarks/Mitigation
Intra-reader variability	several sources, already investigated: high, up to 25%	It is the current status of our Ground Truth!
Inter-reader variability	several sources, already investigated: high, up to 30% and more (depending on the author)	
observation illumination	perception	determined conditions/ protocols
anatomical/ radiological know-how	perception	CT-training
visual acuity	perception	continuous control
observation protocol	perception	standardized protocols

Transformation Human Expert View to Therapy Decision Environment



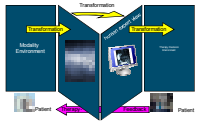
Value/Characteristics	Influence to deviations	Remarks/Mitigation
availability of data	important	standardized diagnostic approaches (in many fields already installed)
medical know-how	important	specialized training
General patient condition	important	Realized by physicians training and experience

The Therapy Decission Environment



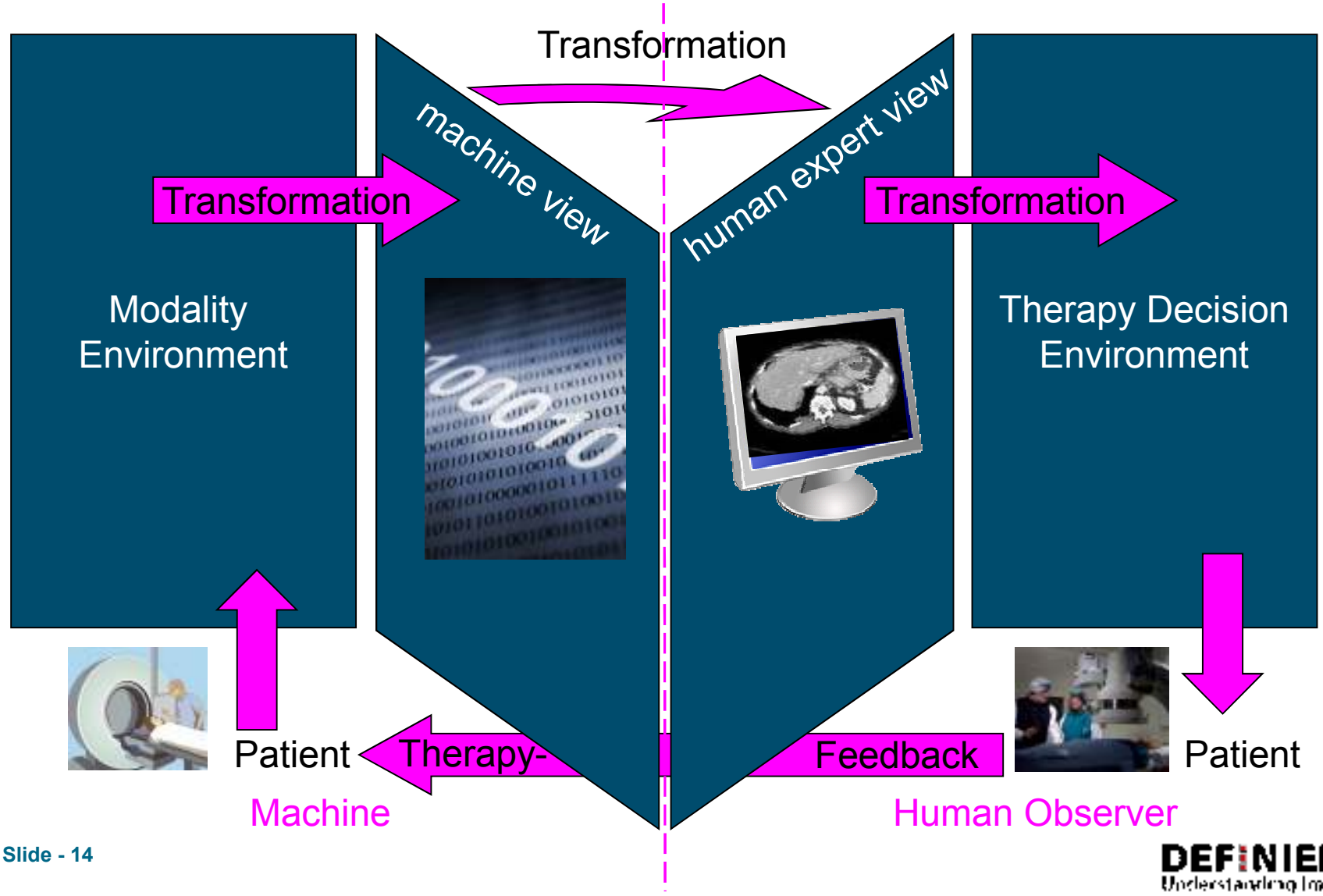
The pure MEDICAL DOMAIN
Not meaningful to be discussed by an engineer.

Feedback issues



Value/Characteristics	Influence to deviations	Remarks/Mitigation
patients conditions for the re-Diagnosis	[biological variability]	Possibly identical to the earlier investigations
use of equipment	variance of results	Use of the same standardized protocol

The Solution Space – The loop is colsed



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The Control Loop and Regulations

Accepted by the Regulatory Authorities:

- **CT and other modalities as Medical Devices Class II**
- **Clinical experience of trained physicians (Ground truth, even if very low regarding it's statistical power)**
- **IT-Support for image examination on a manual basis (restriction to some special fields with huge data basis, special observation conditions and monitors)**
- **PACS-Systems for all IT-Handling without automated detection ability**

As we all know, we are currently in the process of rework of these paradigms. To make this easier the following statements/proposals:

Facts in our Solution Space

We know from the examination of the loop especially:

- **Huge biological variance in all (image) data acquisitions**
- **Low public know-how about internal deviations of modalities**
- **The problem is not measurement it is classification**
- **The most deviation connected transformations are between the two hemispheres machine vs. human observer**
- **The current available Ground Truth is not very powerful (beside some special fields)**

Models (Phantoms) one way out

- Models (Phantoms) are in principle available made from hardware or digital, they are free of variability and easy to use.

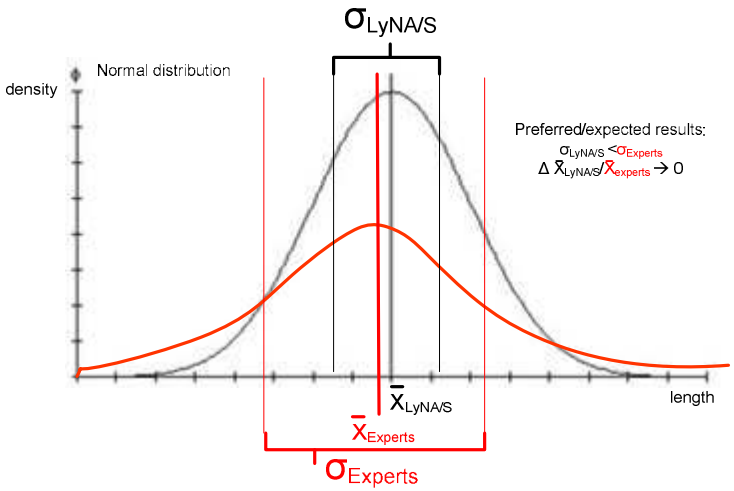
We need:

- Hardware models to calibrate the output of modalities to reach: comparability, independence, reproducibility
- Software models in addition to optimize Ground Truth

This reduces the (failure) influence of the modalities and sharpens the reference for regulatory issues.

Based on this Ground Truth vs. Machine (or machine aided) Truth might be compared as in other industries already usual.

Statistics within the improved loop



With the proposals above it is possible to show standard distributions as shown in this figure (just one example).

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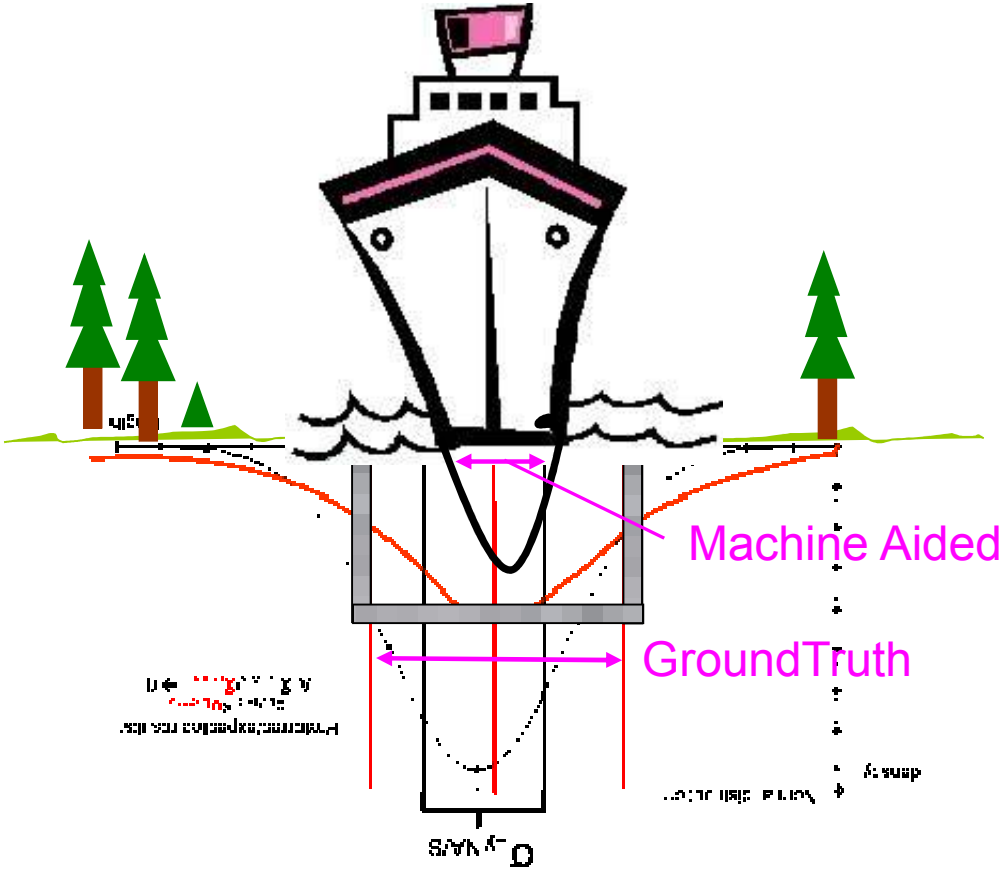
The same again in real live



This should fit our patient‘s needs better and should convince the regulatories.

Thanks for your attention!

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