

**Paolo Vineis**  
**Imperial College London and Consiglio Superiore di Sanità**

**Critical issues in guideline production and  
implementation in Italy**

**Workshop on Clinical guidelines in Italy and the UK, London  
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## **Context**

**Italy has currently a strictly regionalized health service, after the change in the “titolo quinto” of the Constitution**

**i.e. the NHS has been “devolved” to Regions except for the introduction of “LEA”, “essential (basic) levels of health care” that have to be the same all over the Italian territory**

**The LEA according to laws 502/92 and 229/99 should be based on the principles of :**

**Scientific evidence  
Appopriateness  
Cost-effectiveness**

**These are the premises that support the introduction of clinical guidelines at a national level, in addition to GL that are aimed at improving the quality of clinical practice (the reform law currently under discussion puts much emphasis on quality)**

## **Critical issues**

**GL are produced at different levels and by different actors, with weak coordination – as many as 10 different institutions participate in the “Strategic Committee”, which does not have a budget**

**In 1999 the PNLG (National Program for Guidelines) was launched, with little empowerment and little coordination with existing institutions**

**Main actors are currently ASSR and ISS, but roles are not completely clear and independence from political institutions is not clearly attained**

**In addition there are a few Regional Agencies with variably defined roles**

## **Other problems**

**Fragmentation and variable quality of GL produced**

**No generalized formal system for  
auditing/assessment of implementation**

**Implementation of GL and auditing are not integrated  
into NHS administration**

**However, good local/regional examples**

## **Plan for GL implementation in Piedmont**

- 1. Production of 4 GL on common cancers by a working group using procedures similar to SIGN**
- 2. Dissemination through meetings and focus groups**
- 3. Enquiry on local GL knowledge and implementation**
- 4. Survey – based on clinical records - of clinical practice modifications after 2 and 4 years**

	Respondents/ Total	%	Knowledge LG / Tot respondents	%
All Depts.	105/143	73.4	95/105	90.5
Surgery	21/32	65.6	19/21	90.5
Oncology	18/21	85.7	18/18	100
Gynecology	23/31	74.2	21/23	91.3
Radiology	20/31	64.5	15/20	75.0
Pathology services	23/28	82.1	22/23	95.6

	Total	Surgery	Gynecology	Pathology	Radiology	Oncology
Preoperative Staging	2 (7%)	2 (29%)	0	0	0	0
Therapeutic plans	3 (10%)	0	0	0	0	3 (43%)
Follow-up procedures	8 (27%)	4 (57%)	1 (25%)	0	0	3 (43%)
Use of cancer markers	3 (10%)	0	0	2 (20%)	0	1 (14%)
Referral practices	4 (14%)	0	0	4 (40%)	0	0
Other	6 (21%)	1 (14%)	1 (25%)	3 (20%)	1 (100%)	0
Total	29	7	4	10	1	7

	Sample of clinical records: breast cancer			p value	Adjusted OR and 95% CI
	All	2002	2004		
% malignant lesions with preoperative cytological or histological diagnosis	626/ 1008 (62.10 %)	297/ 513 (57.89 %)	329/495 (66.46%)	0.01	0.64 (0.49- 0.85)
% conservative surgery in pT1	484/ 540 (89.62 %)	231/ 268 (86.19 %)	253/272 (93.01%)	0.01	0.41 (0.22- 0.75)
% conservative surgery with unaffected margins (>1mm)	660/ 755 (87.41 %)	312/ 368 (84.78 %)	348/387 (89.92)	0.03	0.65 (0.41- 1.01)

## **Comments**

**Reasonable response rate in the enquiry**

**GL were broadly known in the Region**

**GL slightly modified the clinical practice after 2 years,  
based on the enquiry**

**Indicators of quality of care for breast cancer changed  
positively and significantly after 2 years (\*Adjusted by age,  
education, volume of activity, clinical stage)  
(effect of GL?)**

**At a local level one of the strongest predictors of  
compliance with GL was the volume of clinical activity**