



Framework of a "special follow-up" for the introduction of a new technology in the Galician Health Service

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The **OBJECTIVE** of this project is to design the "special follow-up" mechanism applied to the specific technique of canaloplasty, which is an alternative for treatment of patients with open angle glaucoma.

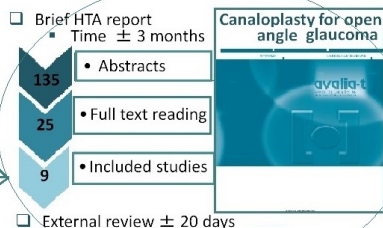


The Methodological Guideline about Post-Introduction Observation of Health Technologies published by avalia-t for the Spanish Ministry of Health in 2009, defines "Special follow-up" as a mechanism that is proposed to generate and collect data systematically on new technologies for which there is insufficient information, enabling rule on safety, efficacy and effectiveness, before being financed by the regional public health system, for general population.

Using canaloplasty as an example, we aim to present the framework and steps regulated by law for incorporating new technologies with uncertainties in the evidence, into The Galician Health Service.

The process starts when a Health Care professional or Service applies for the authorization of a new technology to be incorporated into our regional health care basket. In order to do so, the physicians compile the relevant information regarding the important aspects of the new technology or procedure, including as well the organizational requirements.

This application is sent to the Healthcare Assistance Division who moves the request to the Planning and Insurance Department, who have the responsibility to oversee the regulation and the healthcare basket. In all cases, this unit, introduction into, must request an assessment carried out by the Galician Agency for HTA (avalia-t). This agency carries out a systematic review and delivers conclusions and recommendations for additional data requirements to the Advisory commission who is responsible for the appraisal.



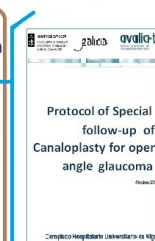
The avalia-t reports to the Advisory Commission who appraises results and recommends a resolution.

The proposal for a non inclusion
Post-introduction observation

The proposal for a inclusion
Post-introduction observation

The proposal is sent for resolution to the highest level of the organization, the head of the Planning and Insurance Department, who confirms the legally binding resolution.

The Healthcare Assistance Division authorizes the center to develop the procedure, but before this, in collaboration with the agency, they work together to reach a consensus regarding the medical protocol with its different variables and assessment of the results of the 'special follow-up', the length of the 'special follow-up' and the period in which patients will be checked. When the period finishes, results are again presented to the medical group and later to the Advisory commission in order to issue final conclusions about the inclusion or not of the technology within the regional healthcare portfolio.



Requirements: authorized centre and signing of commitment letter
Aim: Assess 1st year implementation of canaloplasty
Type of study: Case-register
Patients:

- All patients treated with Canaloplasty
- Patient-informed consent

 Data collection:

- Administrative and socio-demographic variables
- Procedure complications
- Long term effectiveness and adverse event (6 months, 1 year)

 Results: Data analysis

Age	Demographic characteristics				Preoperative			Postoperative (3, 6 and 12 months follow-up)						
	Gender	Side (eye)	Previous surgery		IOP	Visual acuity	Medications (n°)	3 months			6 months			
	Male	Female	Left	Right	Yes	No		IPO	Visual acuity	Medications	Hypheia	Descemet detachment	Hypotony	Bled formation
68	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		20,3 ± 4,7	0,54 ± 0,62	3				
64	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		23,0 ± 10,5	0,44 ± 0,54	4				

CONCLUSION

- ✓ The framework used in Galician Health Service can serve as a reference for other institutions that aim to effectively implement strategies for additional data collection.
- ✓ The collaboration with the clinicians is essential in the design of the protocols and data collection.
- ✓ There exists a need to design tools that facilitate data collection from the centers, and the sending of them to the agency for their analysis. In our experience, these online tools could help make advances in organizational tasks and decision making.
- ✓ It is crucial to be able to count on the best available scientific evidence in order to support decision-making.

