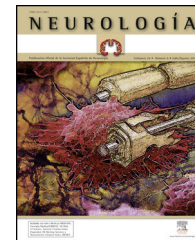




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## LETTERS TO THE EDITOR

### Failure mode and effect analysis applied to the procedure for intrathecal chemotherapy<sup>☆,☆☆</sup>

### Análisis de modos de fallo y sus efectos aplicado al procedimiento de quimioterapia intratecal

Dear Editor:

The purpose of this letter is to present failure mode and effects analysis (FMEA), a tool with clinical safety applications that may be useful for minimising risks associated with healthcare procedures. We also describe our experience with applying FMEA to intrathecal chemotherapy at Hospital Universitario Donostia.

Intrathecal chemotherapy is an invasive procedure associated with numerous adverse events, many of which may be caused by human error.

At Hospital Universitario Donostia, intrathecal chemotherapy has traditionally been prescribed and ordered by haematology or oncology departments, whereas the neurology department is responsible for administering the treatment. Since there have been several severe incidents related to intrathecal chemotherapy, we recently decided to find a way to minimise the risks associated with this procedure.

FMEA was performed according to the following steps:

1. Select a high-risk process. The chosen process was intrathecal chemotherapy.
2. Assemble a team. We gathered a multidisciplinary work team, including doctors and nurses familiar with intrathecal chemotherapy from the haematology, oncology, pharmacy, neurology, and quality control departments.

3. Describe the process. We designed a diagram describing the different steps in the process and how they are interrelated (Fig. 1).
4. Analyse risk. Team members brainstormed to list different possible ways in which each sub-process might fail. Next, cause, effect, and detection method for each failure mode were identified and rated for frequency, severity, and detectability on scales of 1 to 10. Finally, total risk for each failure mode was calculated by multiplying the values of these 3 factors (frequency, severity, and detectability) to give the risk priority number (RPN). As an example, Table 1 shows the model sheet used to collect risk analysis data for the sub-process of administering the drug.
5. Propose improvements and monitor implementation of the redesigned process. A total of 10 improvement actions were defined, with priority given to failure modes with higher RPNs. We also decided which team members would be responsible for implementing each new process (Table 1).

Twenty-eight months after implementing improvements, 141 intrathecal chemotherapy procedures have been performed in a total of 38 patients and no incidents have been detected.

FMEA is a tool enabling systematic and prospective identification and prevention of the risks associated with a process. This technique has been widely used not only in healthcare but also in the aerospace and automotive industries.<sup>1</sup>

In addition to identifying and preventing failures that already occur or may potentially occur, it enables sharing experiences with different units participating in the same process. It is also recommended by several national and international health organisations.<sup>2,3</sup>

However, some of the main limitations of FMEA are the absence of studies verifying its validity or utility, its reliance on team members' previous experiences, the mathematically flawed way in which RPN is calculated, and the fact that costs and healthcare available resources are not taken into consideration.<sup>4</sup>

In conclusion, FMEA is a useful tool since it provides an organised and systematic method which can help resolve failure modes that involve several professionals taking part in a single process.

In addition to intrathecal chemotherapy, neurology departments currently perform many other invasive procedures whose safety could be increased by using this

<sup>☆</sup> Please cite this article as: de la Riva P, Martínez Zabaleta MT, Arruti González M, Urtasun Ocariz MA. Análisis de modos de fallo y sus efectos aplicado al procedimiento de quimioterapia intratecal. *Neurología*. 2015;30:62–64.

<sup>☆☆</sup> This study was presented orally, under the same title, at the 64th Annual Meeting of the Spanish Society of Neurology.

**Table 1** Risk analysis table for the administration sub-process in intrathecal chemotherapy.

Failure mode	Effect	Cause	Detection method	Severity	Frequency	Detectability	Initial RPN	Recommended actions	Responsible department
Delay in drug administration	Lack of effectiveness	No care pathway	Nurse/patient	1	8	1	8	Establishing a care pathway	Neurology
Wrong medication	Toxicity	No care pathway	Nurse/doctor	10	1	8	80	Establishing a care pathway	Neurology
	Toxicity	Administration route not verified	Nurse/doctor	10	2	8	160	Use of minibags	Pharmacy
	Toxicity	Similar drug package	Nurse	10	5	6	300	Container specific to intrathecal drugs labelled 'for intrathecal use only'	Pharmacy
Drug not indicated	Toxicity/lack of effectiveness	Lack of communication/workload problem	Nurse/doctor	10	2	7	140	Electronic prescription	Quality control
Inappropriate technique	Puncture-related complications	Not verifying patient's state (laboratory analyses, anticoagulants)	Nurse/doctor	8	2	10	160	Implementing checklist prior to administration	Neurology, nursing staff
		Doctor's lack of experience	Nurse/doctor	8	2	10	160	Establishing a care pathway	Neurology
Patient identification	Toxicity/reduced effectiveness	Not verifying patient data	Nurse/doctor/patient	10	1	10	100	Implementing checklist prior to administration	
Not checking patient's lab analyses	Complications	Puncture contraindicated because of analysis results or anticoagulant treatment	Nurse/doctor	8	2	10	160	Implementing checklist prior to administration	Neurology, nursing staff

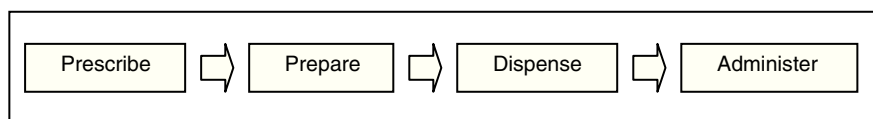


Figure 1 Diagram of intrathecal chemotherapy process.

technique. Examples include immunoglobulin administration, plasmapheresis sessions, and intravenous administration of antibiotics or immunosuppressants.

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(P. de la Riva).

## Adult diagnosis of temporo-occipital leptomenigeal angiomatosis<sup>☆</sup>

### Angiomatosis leptomenígea temporo-occipital de diagnóstico en edad adulta

Dear Editor:

Sturge-Weber syndrome (SWS) or encephalotrigeminal angiomatosis is a sporadically presenting neuroectodermatosis characterised by a facial port-wine stain in the trigeminal distribution, ipsilateral leptomenigeal angioma, and ipsilateral choroidal angioma. Studies have described clinical variants with different combinations within this triad. SWS is primarily diagnosed in children, but it has also been diagnosed in adults in exceptional cases. We present a case of isolated leptomenigeal angiomatosis and symptom onset in an adult patient.

A 44-year-old woman with no relevant medical history came to the emergency department due to sudden-onset right hemicranial headache that was intense, oppressive, and responding poorly to analgesics. Twenty-four hours later, symptoms also included disorientation, psychomotor agitation, and visual hallucinations. Physical examination revealed a herpes labialis sore on her upper lip. Laboratory analyses revealed leukocytosis with left shift and

elevated C-reactive protein (CRP). Cranial axial computed tomography with and without contrast (Fig. 1) showed a right parietal-occipital gyriform hyperdensity and focal meningeal enhancement that was initially reported as being compatible with chronic meningitis. Lumbar puncture yielded acellular CSF with elevated protein levels, so the emergency department started provisional treatment with IV vancomycin, ceftriaxone, and acyclovir for possible meningoencephalitis. The patient was admitted to the neurology department and remained afebrile with an intense headache accompanied by nausea, vomiting, and fluctuating episodes of visual and auditory hallucinations. Neurological examination detected homonymous hemianopsia. Brain MRI scans performed with and without gadolinium contrast (Fig. 2) showed leptomenigeal angiomatosis in the right hemisphere (parietal-occipital-temporal area). Basal amplitude on the electroencephalogram was attenuated in the right temporal-occipital area. There were no data indicating infection (results from 2 blood and CSF cultures and CRP tests were all negative); since a second lumbar puncture yielded acellular CSF with elevated opening pressure and protein levels, antibiotics were discontinued. A consultation with the ophthalmology department ruled out ocular vascular malformation. The patient was diagnosed with SWS without facial angioma and exhibiting temporal-occipital partial seizures and possible venous thrombosis/stasis at the angiomatous lesion. She was treated with acetazolamide (for intracranial hypertension), levetiracetam, and acetylsalicylic acid. Both the headache and the confusional episodes/hallucinations resolved; the latter were thought to be caused by seizure or vascular migraine-like phenomena. The patient subsequently attended follow-up visits as a neurology outpatient. After an additional lumbar puncture yielded acellular CSF with normal opening pressure and protein levels, the dose of acetazolamide was gradually reduced

<sup>☆</sup> Please cite this article as: Gómez-Moreno M, Murrieta-Urruticoechea C, Martínez-Acebes E, Gordo-Mañas R. Angiomatosis leptomenígea temporo-occipital de diagnóstico en edad adulta. *Neurología.* 2015;30:64–66.