



Standardized MedDRA® Queries

MedDRA Users Group Meeting
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Pharmaceutical Manufacturers Associations (IFPMA)



SMQs: Formerly known as...

- Standardized Search Queries (SSQs) – CIOMS
- MedDRA Analytical Groupings (MAGs) – MSSO



SMQ Definition

- SMQs are groupings of terms from one or more MedDRA System Organ Classes (SOCs) that relate to a defined medical condition or area of interest. They are intended to aid in case identification.
 - The included terms may relate to signs, symptoms, diagnoses, syndromes, physical findings, laboratory and other physiologic test data, etc., related to the medical condition or area of interest.
 - Lowest Level Terms (LLTs) that are not subordinate to an included Preferred Term (PT) are excluded.



SMQ Development and Maintenance

- Development by CIOMS Working Group (includes MSSO participation)
 - Methodology paper under development
 - “Field testing”
- Ownership of SMQs by IFPMA (owners of MedDRA)
- Maintenance and distribution by MSSO
- File format developed (to be “tested” by user community)
- Version of SMQs – strategies under development

SMQs under development...

- Anaphylactic reaction*
- Acute renal failure*
- Rhabdomyolysis/ myopathy*
- Cardiac failure
- Torsades/QT prolongation*
- Haematopoietic cytopenias
- Haemorrhage
- Stevens Johnson syndrome
- Suicide/depression
- Haemolytic anaemia
- Hepatotoxicity
- Interstitial lung disease
- Vasculitis
- Neuroleptic malignant syndrome
- Pancreatitis
- Lack of effect
- Angioedema

[*Targeted for version 6.1
release of MedDRA]



SMQ Acute Renal Failure

Definition: Acute renal failure is a syndrome characterized by a relatively rapid decline in renal function that leads to the accumulation of water, crystalloid solutes, and nitrogenous metabolites in the body. Clinically significant acute renal failure is usually associated with a daily increase in serum creatinine and urea nitrogen levels (azotemia) greater than 0.5 and 10 mg per deciliter, respectively. Oliguria, a rate of urine flow less than 400 ml per day, may be observed, but in some cases the urine output exceeds this limit (nonoliguric acute renal failure). Complete cessation of urine flow, anuria is relatively uncommon. Primary renal lesions in the majority of drug-induced acute renal failure are intrarenal, at the level of the vasculature or tubule.

Source: 1. Merck Manual 17th edition 2. Cecil Textbook of Medicine 19th Edition



Acute Renal Failure Narrow Terms

Acute pre-renal failure	Peritoneal dialysis
Anuria	Progressive renal failure
Azotemia	Renal failure acute
Dependance on renal dialysis	Renal failure acute on chronic
Dialysis NOS	Renal failure aggravated
Edema due to renal disease	Renal failure neonatal
Hemodialysis	Renal failure NOS
Hepatorenal failure	Renal impairment NOS
Neonatal anuria	Renal impiarment neonatal
Nephritis interstitial	Renal transplant
Nephritis NOS	Renal tubular disorder NOS
Nephropathy toxic	Renal tubular necrosis
Oliguria	Tubulointerstitial nephritis



Acute Renal Failure

Broad Terms

Albuminuria
Blood creatinine abnormal
Blood creatinine increased
Blood urea abnormal
Blood urea increased
Blood urea nitrogen/creatinine ration increased
Creatinine renal clearance decreased
Proteinuria
Renal clearance NOS decreased
Renal function tests NOS abnormal



Discussion points...

- Utility of SMQs to the user community?
- Regulator use of SMQs?
- User participation in development/maintenance of SMQs?
- Fate of Special Search Categories (SSCs)?