

Handling a Sudden Tenfold Increase in ICSRs – Lessons Learned During the SARS-Cov-2 Pandemic

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The unprecedented vaccination efforts related to COVID-19 have strained pharmacovigilance systems and resources of stakeholders globally. Anticipating a large increase in reporting of Individual Case Safety Reports (ICSRs), improved tools and procedures simplifying reporting, case processing, and analysis were implemented. Resources for hiring additional temporary staff was made available.

The Norwegian Medicines Agency (NOMA) experienced a tenfold increase in ICSRs from healthcare professionals and consumers during COVID-19 vaccination. Case processing, signal detection and signal management procedures were stretched thin. Still, several international signals were detected and managed early. Despite additional resources supplied, a backlog in handling of non-serious reports accumulated while serious reporting was unaffected. Communication to the public was radically increased.

By implementing various measures NOMA managed to prioritise processing of the ICSRs that added most value to detecting signals of possible new safety issues.

References/Further sources of information

Norwegian Medicines Agency. Reported suspected adverse reactions of covid-19 vaccines. Available at <https://legemiddelverket.no/godkjenning/koronavaksiner/meldte-mistenkte-bivirkninger-av-koronavaksiner>