ADVERSE DRUG REACTIONS DURING HEPATITIS C TREATMENT WITH DIRECT-ACTING ANTIVIRALS: THE ROLE OF MEDICATION ERRORS, THEIR IMPACT ON TREATMENT DISCONTINUATION AND THEIR PREVENTABILITY. NEW INSIGHTS FROM THE CAMPANIA REGION (ITALY) SPONTANEOUS REPORTING SYSTEM

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Introduction: Medication errors, such as unnecessary treatment discontinuation during treatment with direct-acting antivirals (DAAs), can lead to imbalances in the benefit-to-risk ratio. This risk is especially high when the medication error leads to adverse drug reactions (ADRs). However, to date, evidence on the frequency of this phenomenon is scarce. This study aims to provide better insight into ADRs possibly due to medication errors leading to DAA discontinuation and their preventability.

Material and methods: The Italian Pharmacovigilance Network database was used to extract individual case safety reports (ICSRs) generated from July 2012to March 2017via the Campania Region (Italy) spontaneous reporting system. ICSRs that included ledipasvir/sofosbuvir, ombitasvir/paritaprevir/ritonavir, dasabuvir, daclatasvir, sofosbuvir, simeprevir or elbasvir/grazoprevir as suspected drugs were included in this study. A preventability assessment was then performed utilizing the "P-Method," an algorithm that evaluates known risk factors due to medication errors that can be detected in ICSRs.

Results: Of the 355cases included in this study, 6(1.69%) were classified as preventable and 52(14.6%) were classified as potentially preventable. The most frequently identified critical criteria (risk factor) for preventable or potentially preventable cases were drug-drug interactions and incorrect drug dosing as part of the antiviral treatment scheme. In total, 89of the 355cases (25.1%) discontinued use of the DAAs due to ADRs, of which 20 of the 89cases (22.5%) were due to an unimportant medical event as classified by the European Medicine Agency important medical event list.

Discussion and conclusion: This study found a proportion of preventable/potentially preventable ADRs involving DAA, which could be improved in the Campania Region (Italy). Additionally, the study identified a high proportion of seemingly unnecessary DAA discontinuations among patients who experienced ADRs.