Development and implementation of a Pharmacovigilance Daily Monitoring Tool at Standerton TB Specialised Hospital

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Abstract

Prior to the development and implementation of a Pharmacovigilance Daily Monitoring Tool at the Standerton TB Specialised Hospital in the Mpumalanga Province, the hospital did not record any adverse drug reactions (ADRs) and had patients defaulting on their tuberculosis (TB) medication. Subsequent to the implementation of the tool, in collaboration with all healthcare professionals, ADRs are identified and managed, with an increase in the number of patients who completed their TB treatment. Lessons learnt through this intervention can be useful for other healthcare facilities in the country.

Faith Dhladhla is the responsible pharmacist at Standerton TB Specialised Hospital. This paper is based on the Best Poster presented at the SAAHIP Conference 2020.

Faith Dhladhla

Introduction

Multi-drug-resistant tuberculosis (MDR TB) treatment has changed over the years and new drugs have been introduced, some of which are not yet registered by the South African Health Products Regulatory Authority (SAHPRA). Many drugs are brought to the market without a fully characterised side-effect profile and it is important to address this gap through post-marketing surveillance.[1] Adverse drug reactions (ADRs) have been identified as one of the most important barriers to adherence to treatment, as patients are more likely to discontinue treatment when they experience ADRs, resulting in potential benefit of the treatment being lost.[2] Monitoring of ADRs is therefore important to ensure patient safety and adherence to treatment, allowing ADRs to be identified and managed.[2]

Background

Standerton TB Specialised Hospital is situated in the Gert Sibande District in Mpumalanga and provides TB services to the whole district. In 2017, the responsible pharmacist at the hospital raised a concern about the number of patients who were defaulting on their treatment. Informal discussions with patients pointed to challenges with ADRs, especially when patients were newly initiated on treatment. The challenge was that there was no formal process in place at the facility for monitoring ADRs. Patients were subsequently defaulting on their treatment. Realising the crucial importance of pharmacovigilance, the need to develop a monitoring tool which could be used by healthcare professionals (HCPs) on a daily basis to collect information on side effects experienced by patients was identified. Such a tool would assist the facility by identifying and quantifying ADRs. The ultimate aim was to provide better care to patients, by ensuring improved adherence to treatment. Another observation was that most HCPs did not fully understand the importance of pharmacovigilance, and perceived the reporting of ADRs as the pharmacist's responsibility. The need for training of HCPs on the importance of pharmacovigilance was thus also identified.

Methods

The responsible pharmacist worked with other HCPs at the hospital to develop a Pharmacovigilance Daily Monitoring Tool, comprising of a list of common side effects, as a first step to collect information on ADRs experienced by patients on TB and HIV treatment. This information would be used to complete the National ADR form, with additional patient information, required by the form, obtained from patient files. An initial step in the implementation of the Pharmacovigilance Daily Monitoring Tool was an in-service training programme for all HCPs at the hospital (including nurses, doctors, audiologists, social workers and dieticians). The training was conducted by pharmacists and focussed on the importance of reporting side effects of medicines and how to use the tool for that purpose.

A copy of the daily monitoring tool was placed in each patient's file and used by HCPs when the patient's progress was reviewed. Nurses used the tool twice a day for inpatients and once a month for outpatients, when they visited the hospital for review. Patients experiencing any ADRs would be referred to the treating doctor. When issuing medication, pharmacists would collect any ADRs reported on the tool by nurses from patients' files and ensure that the treating doctor has intervened to manage any ADR experienced by the patient. Follow-up was done for each patient until the ADRs were resolved. Monthly pharmacovigilance meetings, including all HCPs, were conducted to discuss ADRs reported using the tool and to verify that they were associated with the medicines taken. Pharmacists would then report

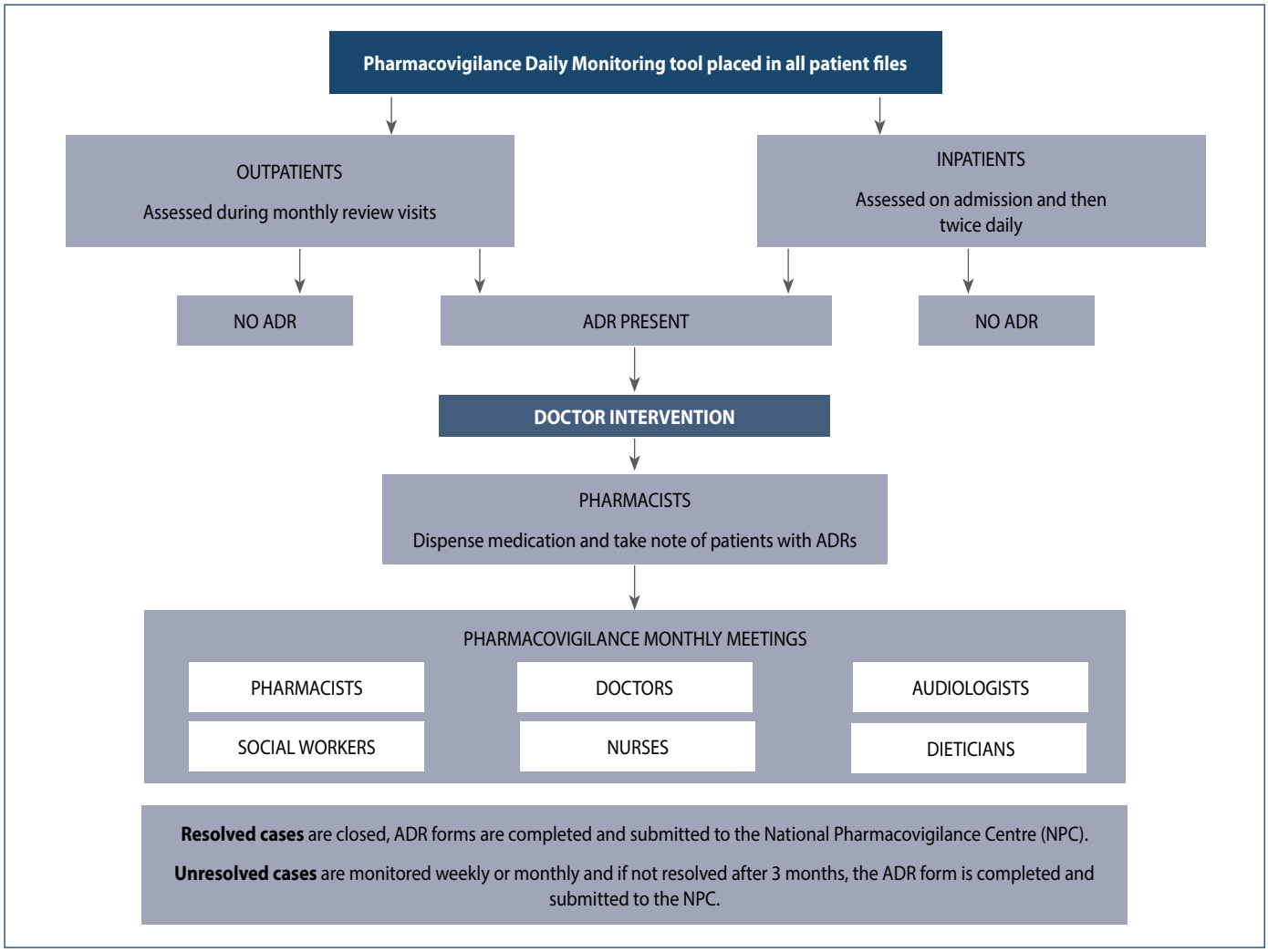

Figure 1: Implementation and use of the Pharmacovigilance Daily Monitoring Tool at Standerton TB Hospital

ADRs that were resolved, as well as those that were not resolved after a 3-month monitoring period to the National Pharmacovigilance Centre (NPC). For all ADRs that were not resolved, the facility continued with patient follow-up and care. Figure 1 shows the process followed in the use of the Pharmacovigilance Daily Monitoring Tool at the hospital.

Results

Before the implementation of the Pharmacovigilance Daily Monitoring Tool, no ADRs were reported to the NPC by Standerton TB Hospital. After the intervention, more than 517 ADRs were reported to the NPC in 2018.[3] All patients with ADRs were followed-up on until the ADR resolved. In 96% of cases reported, the ADRs resolved after treatment. The increase in ADR reporting was recognised by the NPC and featured in the National Pharmacovigilance Bulletin of July 2019.[3]

Figure 2 shows the data on ADRs reported to the NPC for the period 1 October 2018 to 4 October 2019.[4] A total of 605 reports were received from Mpumalanga Province, which accounted for 21% of reports received nationally.[4] Most of these reports (75%; *n* = 454) were from the Gert Sibande District, and Standerton TB Hospital in particular (*n* = 236) (Figure 3).[4] Overall, 77% of 250 patients at Standerton TB Hospital whose ADRs were monitored in 2018, completed their treatment.

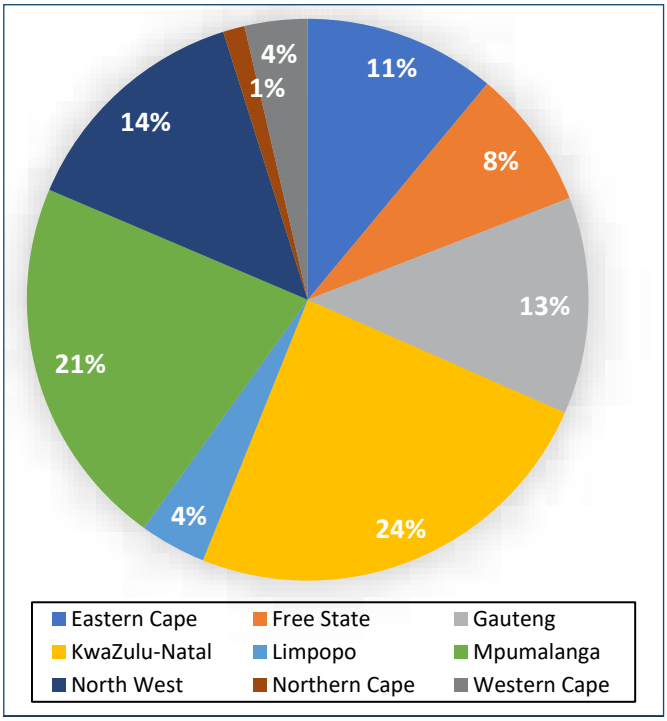

Figure 2: Distribution of ADR reports per province: 1 October 2018 to 4 October 2019[4]

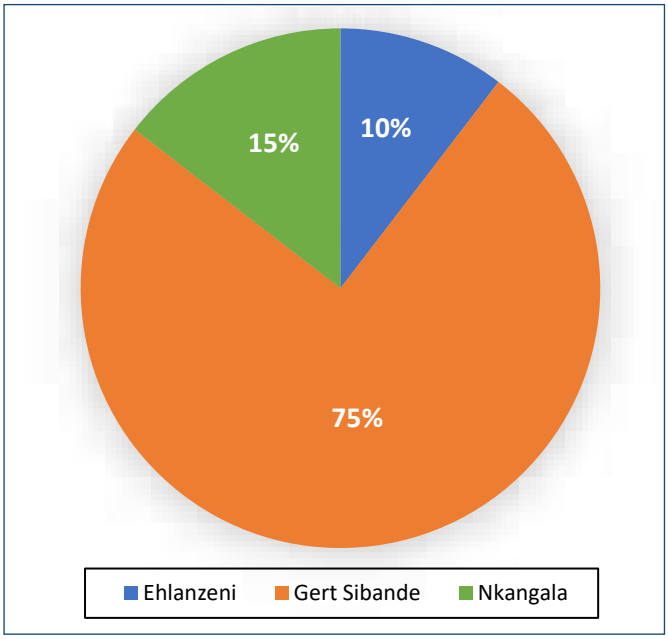

Figure 3: Distribution of ADR reports per district in Mpumalanga (n = 605)[4]

Common side effects reported were nausea, vomiting, hearing loss, pain and tingling sensation in the feet, and joint stiffness.

Lessons learnt

The implementation of the Pharmacovigilance Daily Monitoring Tool highlighted that daily tasks of the pharmacist, such as checking expiry dates of medicines, dispensing of medication and emphasising adherence to treatment, are important but not sufficient. Monitoring and reporting of ADRs is of utmost importance in maximising patients' safety and adherence to treatment. The implementation process also showed that it is not easy to implement new initiatives, and that persistence, teamwork and change management are needed for the outcome to be achieved. All HCPs at the facility had to play their part to ensure that the intervention was successful. Although HCPs were reluctant to change their practice at first, with continuous in-service training and discussions, and when an improvement in the quarterly treatment success rate for the hospital was observed, attitudes changed. Evidently patients were receiving better quality care compared to previously. Furthermore, recognition from the NPC encouraged HCPs to continue with this effort.

Conclusions

The results show that the Pharmacovigilance Daily Monitoring Tool has improved pharmacovigilance at the facility, which was previously non-existent. The initiative resulted in increased awareness amongst HCPs at Standerton TB Specialised Hospital regarding the monitoring of side effects and the tool facilitated the identification and management of ADRs for the benefit of the patient. Valuable lessons learnt through the development and implementation of this tool can be used by other healthcare facilities in South Africa to advance pharmacovigilance and improve patient care.

Acknowledgements

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