Identifying optimal care for hepatitis C and overcoming barriers to scale-up: MSF pilot programme

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Introduction

Direct-acting antivirals (DAA) have revolutionized access to hepatitis C treatment, however experience with DAAs in resource-constrained countries is limited, and a significant proportion of patients lack access to treatment. MSF developed a pilot hepatitis C programme in Phnom Penh, Cambodia, involving a simplified care model suited to resource-limited settings.

Methods

We used a step-wedge design. For the first 6 months this involved a full care model based on European Association for Study of the Liver guidelines. We prospectively collected data on patient characteristics, laboratory tests, side effects, and outcomes (cured/failure, lost to follow-up, death), and used this to develop simplified care models. The simplified model involved task-shifting activities from doctors to nurses/pharmacists, decreasing laboratory testing, and removing less clinically meaningful consultations. We switched to rapid diagnostic tests and point-of-care viral load monitoring, removed genotype tests, reduced some endoscopies and ultrasounds, removed liver enzyme follow-up tests, and reduced the total number of visits from 16 to 8, along with pre-initiation visits from 8 to 2.

Ethics

This study was approved by the Cambodia National Ethics Committee for Health Research and Comite de Protection des Personnes, Saint-Germain-en-Laye, France.

Results

Between Oct 2016 and Mar 2017, 910 patients were treated under the full model. Between Mar 2017 and Jun 2017, 906 patients were treated under different stages of the simplified model. Ledipasvir/sofosbuvir and daclatasvir/sofosbuvir were provided based on genotype(GT) under the full model and daclatasvir/sofosbuvir were provided without GT under the simplified model, with 45% GT6, 45% GT1, and 10% GT2 among the study population. The baseline characteristics of patients in the two models were comparable; mean age 57 years (SD 9.6) in both models, 58% versus 55% female patients in the full and simplified models (p=0.1), and a slightly higher proportion of patients with advanced fibrosis in the simplified model (86% vs 90%). Sustained virological response in intention-to-treat analysis was 95.7% (95%CI 94.2-96.9), and 95.0% (95%CI 93.4-96.3) in full and simplified models respectively; difference in response aOR 0.7 (95%CI 0.4-1.2). Adverse events were rare in both models (full model=8, simplified model=5, aOR 1.6, 95%CI 0.5-4.9). Treatment capacity increased threefold, with comparable human resources.

Conclusion

We demonstrated a simplified model of care was feasible for hepatitis treatment, while the outcomes remained comparable. Key challenges during simplification included identifying how to provide same-day diagnosis; what constituted minimal laboratory testing and patient counselling sessions; and what constituted essential referral services. We plan to scale up to 10000 patients, establish a rural model of care, and further integrate this model with national Ministry of Health services.

Conflicts of interest

None declared.