New Studies Shed Light on Statin Side Effect Concerns

Usage surveys have found that the majority of people who have been prescribed statins in the United States discontinue using them within a year. The number one reason stated by patients for stopping statin use is concern with side effects.

This issue can be analyzed by building a Cause Map, a visual method for performing a root cause analysis. The first step in the Cause Mapping process is to define the problem by filling in an Outline with basic background information (who, what, when, where, etc.).

Additionally, the Outline is used to capture how the problem impacts the goals so that the magnitude of the problem is well understood. Once the Outline is complete, the analysis is performed by building a Cause Map by asking "why" questions to find the causes that contribute to an issue.

Like most other medications, statins can have serious side effects. According to the U.S. Food and Drug Administration, the value of statins in preventing heart disease has clearly been established and the benefits outweigh the risks, but one of the reasons that patients are concerned about side effects is that there are very outspoken critics of statins that do not agree with this assessment. For the purpose of this example, we will assume that the FDA is correct that patients would benefit from taking statins if they are prescribed and that it is in fact a problem if patients discontinue using statins when their physicians have recommended them.

1. **Problem**
   - **What**: Patients aren't taking prescribed medications; patients are concerned about side effects with statins
   - **When**: Ongoing
   - **Where**: Worldwide
   - **Impact to the Goals**
     - Patient Safety: Patients aren't taking statins as prescribed
     - Patient Services: Side effect concern wasn't adequately addressed

2. **Analysis**
   - **Patients aren't taking statins as prescribed**
   - **Concerned about side effects**
   - **Believed they experienced side effects**
   - **Statins can cause side effects**
   - **Issue has received significant media coverage**
   - **Statins lower cholesterol levels in blood**
   - **Liver produces the majority of cholesterol in body**
   - **Statins can reduce risk of heart disease**
   - **Statins lower cholesterol levels/heart disease**
   - **High cholesterol levels are associated with heart disease**
   - **Liver produces cholesterol**
   - **HMG-CoA controls cholesterol production**

3. **Solutions**
   - **Slow down the cholesterol production process in liver**
   - **Inhibit an enzyme called HMG-CoA reductase**
   - **Patients aren't taking statins as prescribed**
   - **High cholesterol levels are associated with heart disease**
   - **Liver produces cholesterol (blocked arteries)**
   - **Statins lower cholesterol levels in blood**
   - **Statins can reduce risk of heart disease**

The final step in the Cause Mapping process is to come up with solutions that can be implemented to help reduce the risk of a problem occurring in the future. So how can the risk that patients will discontinue statins be reduced? One possible solution would be to give patients reliable information that shows that statins are relatively safe and are effective at reducing the risk of heart disease. If patients believe that the benefits of statins outweigh the risks, they will be significantly more likely to take them. More information is becoming available as researchers continue to study the benefits of statins and the frequency and severity of side effects.