FAST*facts*

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NON-MEDICAL SWITCHING

While 21st Century medications represent some remarkable breakthroughs, they often come with high costs. As a result, many agencies are exploring ways to minimize drug costs, sometimes without considering the long-term consequences.

Trying to balance the needs of patients against financial constraints isn't easy. But solutions must be informed and protect patients' best interests.

Q: What Is Non-Medical Switching?

Non-medical switching occurs when stable patients are forced to switch from their current medication for reasons unrelated to their health. Decisions often are driven by policymakers and meant to reduce costs.

Substituting a costly medication with a less expensive therapy might sound like a good idea, and switches to a generic, chemically identical treatment may not impact patient health.

Non-medical switching poses concerns, however, for patients who have stabilized their condition with the use of sophisticated medicines such as biologics. These medicines are produced using living systems or tissue. Cost-driven policies may compel patients to switch to a biosimilar, a lower-cost drug with similar but non-identical properties. Without proper precautions, as well as physician and patient involvement, such a switch can disrupt a patient's ability to manage his or her disease.

Patients with chronic diseases often find themselves the targets of non-medical switching policies. This makes sense, as treatment for chronic disease accounts for the vast majority of health care costs.[1] However, patients with chronic diseases are arguably those most dependent upon medications for day-to-day functioning and most affected by disruptions in treatment.

Medical Switching VS Non-Medical Switching

Physician and patient decide to try a different medicine to optimize patient health.

An outside party, such as a government or health care system, compels a patient to change medicines to reduce drug costs.

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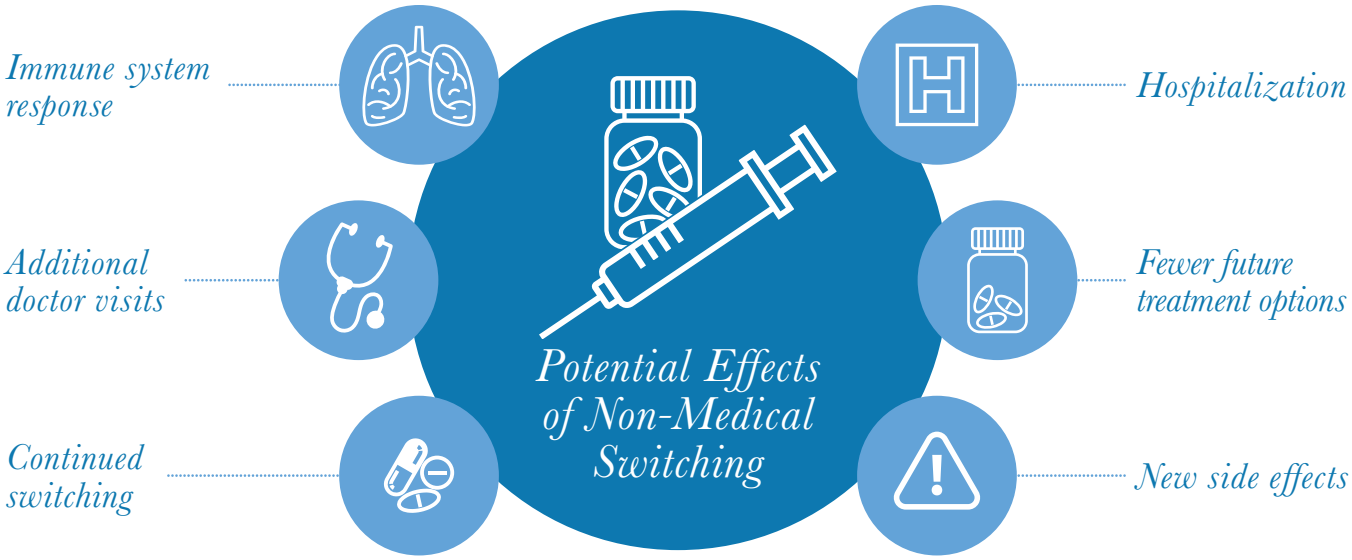

Q: How Does Non-Medical Switching Affect Patients?

The full impact of non-medical switching on patients is still unclear. In some instances, non-medical switching does not present a problem; in others, it may cause side effects, potentially leading to additional doctor visits or even hospitalization. Each patient, medication, and disease is unique, which is why doctors—not policymakers—should determine which drugs their patients receive.

In addition to immediate health risks, non-medical switching can limit future treatment options. In the case of biologics and biosimilars, a switch might adversely stimulate a patient's immune system and neutralize the medication. This could narrow a patient's treatment options since he or she may no longer respond to either the biosimilar or the original biologic.[2]

Aside from the medical risks, non-medical switching can waste valuable time. Patients and physicians put significant effort into tailoring treatments to each individual. Non-medical switching may force patients to repeat the trial-and-error process of adjusting dosage, which could also require additional lab tests and doctor visits. Furthermore, a recent study showed patients who underwent a cost-motivated treatment change were more likely to experience another switch after the first, potentially costing even more.[3]

The act of switching biological medications, regardless of the reason, can cause unforeseen results. Therefore, changing treatment based solely on cost is not a choice to be made—or imposed—lightly.

Q: Does Non-Medical Switching Lower Health Care Costs?

Not necessarily. In fact, some research suggests that switching could actually increase overall costs.

For example, a U.S. study[4] showed that rheumatoid arthritis patients who switched to a more expensive drug showed only a $238 increase in yearly expenses. However, switches to a less expensive drug—which could be characterized as non-medical or cost-motivated—resulted in additional yearly medical payments as high as $14,127.[5]

The same study suggested that keeping a rheumatoid arthritis patient stable on his or her medication could offer cost advantages. Patients who remained on their course of treatment for more than 270 days, or about nine months, had an average annual increase in health care costs of only $200. Patients who spent less time on their medication, however, saw higher yearly cost increases.

Table 1. The Value of a Stable Medication Regimen

Days on the Same Treatment	Yearly Increase in Medical Costs
270+ Days (9 months)	*$201*
181-270 Days (6-9 months)	*$4,205*
91-180 Days (3-6 months)	*$9,390*
90 or fewer Days (≤ 3 months)	*$7,629*

Available research does not stipulate the source of cost increases, which could be the result of additional physician visits and lab tests to adjust medication dosage or perhaps to address reemerging symptoms or side effects.

Q: What Does Clinical Research Tell Us About Non-Medical Switching?

Current research on non-medical switching is inconclusive. For more complete data, each switch must be studied in detail to explore its clinical effectiveness and side effects.

That said, a recent government-sponsored study of non-medical switching in Norway produced preliminary data. In the NOR-SWITCH trial[6], 481 patients participated in a randomized, double-blind study across six inflammatory diseases. Researchers tracked how patients responded to being switched from an original infliximab biologic, Remicade®, to the biosimilar infliximab Remsima®. Patients were followed for a total of 18 months, during which all participants switched medicines at least once. The results of NOR-SWITCH were generally positive, with less than a 5% difference in outcomes between the two medications.

Still, the study was narrow in scope, assessing the effects of one specific switch on patients with specific inflammatory diseases. While encouraging, the results do not clinically justify other non-medical switches or predict how they may affect patients with other diseases. **Each disease and its corresponding treatment is different, and more research is needed to explore the costs and effects of each potential switch.**

Q: How Should Policymakers Handle Non-Medical Switching?

Very carefully, and while keeping the patient in mind. Non-medical switching doesn't just affect budgets, it affects people's health.

Policies governing switching should reflect accurate data and analysis. They should also demonstrate an understanding of long-term effects.

In addition, switching policies should be clear about the role of physicians and patients. For example, the attending physician should be consulted prior to any switch. Doctors—not accountants or policymakers—are best suited to caring for the needs and interests of their patients.

Likewise, switches should require informed consent from the patient. All patients, particularly those who struggled to find a medication that works, deserve to understand the timing, nature, and rationale for a treatment change. Patients must be informed, willing participants in such changes.

Policies on Non-Medical Switching Should:

- ✓ *Reflect relevant, current data*
- ✓ *Demonstrate an understanding of long-term consequences*
- ✓ *Require patients' informed consent*
- ✓ *Preserve physicians' role in health care decision-making*

CONCLUSIONS

Health agencies, understandably, are seeking more cost-effective solutions to providing care. Yet sound financial decisions require sound data, and current data on non-medical switching are minimal. Thus, policymakers should proceed with caution, letting data drive policy and keeping patient health front and center.

To protect patients' health and safety—and to maintain physicians' ability to guide patient care—decisions about non-medical switching should always include physician input and require patient consent. Only then can policies appropriately balance the need for cost savings with the health of patients.

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