

Assessing the Quality of Biologic Switch Decisions in Psoriatic Arthritis: Results from a modified-Delphi Consensus

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Introduction

Background

Psoriatic arthritis (PsA) is a chronic inflammatory disease commonly managed by rheumatologists. Pharmacological treatment of PsA varies in real-world clinical practice despite the ongoing efforts to guide treatment strategies, especially concerning biologic therapies initiation and switch. Treatment options have expanded in PsA and biologic therapies switch is increasingly more frequent. However, there are no agreed definitions about the quality of biologics' switch in PsA and about which outcome measure should be used for this quality assessment.

Objectives

To develop a measurement tool to evaluate the quality of biologic therapies switch in PsA patients (Figure 1)

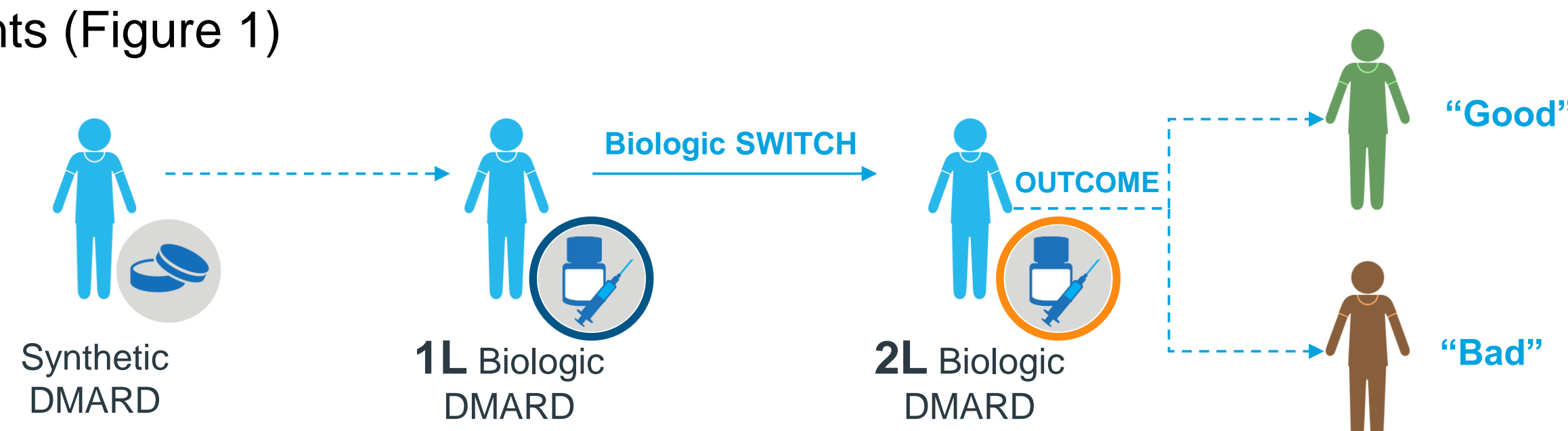


Figure 1: Objectives representation

Methods

Team

A Task Force and an Expert Panel were specifically created for the purpose of this study. The Task Force comprised six members from different backgrounds, including health economics and medical affairs and was chaired by a rheumatologist, while the Expert Panel comprised seven experienced rheumatologists, all but one practicing in Portugal

A modified-Delphi consensus method in a four-step procedure was applied:

- Literature search and experts' opinion collection about quality indicators for disease course management;
- Delphi design to address the development of the switch measurement tool;
- Three Delphi questionnaire rounds to start voting on measurement tool components;
- Consensus Meeting to discuss Delphi rounds results and reach a final decision regarding measurement tool components.

During steps 1 and 2 team members interacted regularly and in different formats (questionnaires, interviews, meetings) to ensure the switch measurement tool comprised all relevant components and to promote an efficient design of the modified-Delphi process. Delphi rounds took place between Dec 2017 and Feb 2018. Consensus Meeting was held in 13 April 2018 and promoted decision making mainly via structured discussion, with democratic voting whenever necessary (Figure 2).

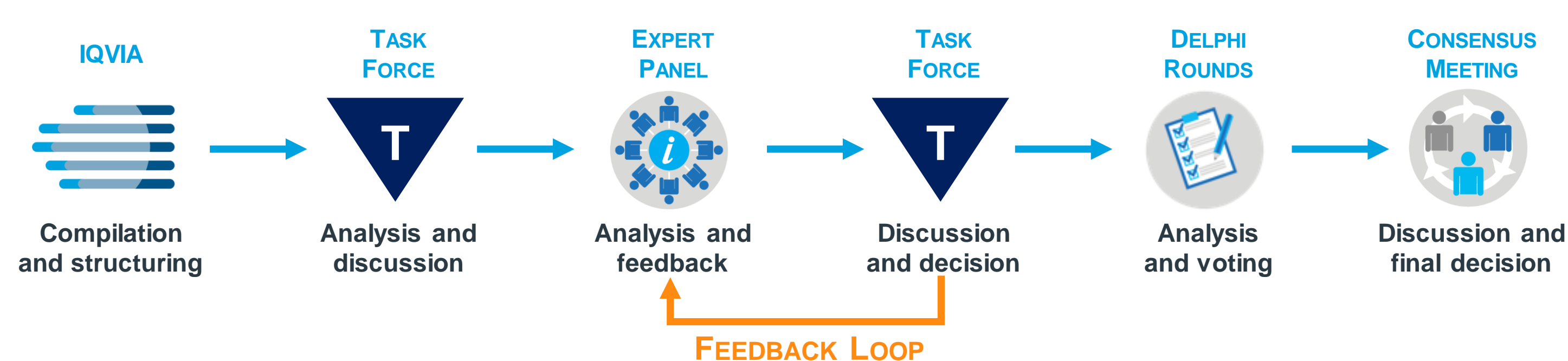


Figure 2: Team workflow and feedback loop representation

Results

The literature search and experts' opinion resulted in the identification of 45 domains for disease management, which were distributed according to three perspectives: physician (n=19), patient (n=20) and society (n=6). During the Delphi process, experts agreed that **biologics switch should be classified into three quality levels: "Good", based on treat-to-target thresholds; "Moderate", based on baseline improvement thresholds; and the remaining as "Insufficient".** Through the Delphi questionnaires experts pre-selected 11 domains to be included in the measurement tool (physician=5, patient=4, society=2).

At the Consensus Meeting experts agreed the tool should be practical to implement in the daily clinical practice. As such, some domains were clustered (e.g. Disease Activity) and then a total of 6 domains were included in the measurement tool (physician=4, patient=2, society=0). "Skin and Nail manifestations" assessment inclusion was agreed to be optional. Domain, instrument and threshold definitions were developed for **both peripheral** (Table 1) **and axial disease** (Table 2).

Table 1: Domains, instruments and threshold definitions for Psoriatic Arthritis Peripheral Joint Disease switch measurement tool

Domains	Instrument	"Good" threshold	"Moderate" threshold
1: Disease Activity	DAPSA ^a	≤ 4	50% reduction
2: Dactylitis	Number of fingers	≤ 1 finger	Clinical improvement (Yes/No scale)
3: Enthesis	SPARCC ^b	≤ 1 entheses	50% reduction
4: Physical Function	HAQ-DI ^c	≤ 0.5	0.33 reduction
5: Quality of Life	EQ-5D ^d	(To be confirmed) ^f	(Minimal important difference) ^f
6: Skin and Nail Manifestations	Physician VAS ^e	≤ 1	50% reduction

a: Disease Activity in Psoriatic Arthritis is a composite instrument that covers 5 domains of the initial pool; b: Spondyloarthritis Research Consortium of Canada index; c: Health Assessment Questionnaire Disability Index; d: EuroQol five-dimensional questionnaire; e: Visual analogue scale performed by physicians based on the GRAPPA 0-5 scale; f: Task Force and Experts will discuss these thresholds further following literature search.

Table 2: Domains, instruments and threshold definitions for Psoriatic Arthritis Axial Disease switch measurement tool

Domains	Instrument	"Good" threshold	"Moderate" threshold
1: Disease Activity	ASDAS ^a	< 1.3	1.1 reduction
2: Dactylitis	Number of fingers	≤ 1 finger	Clinical improvement (Yes/No scale)
3: Enthesis	MASES ^b	≤ 1 finger	50% reduction
4: Physical Function	BASFI ^c	≤ 2 points	> 2 points / 2 points reduction
5: Quality of Life	EQ-5D ^d	(To be confirmed) ^f	(Minimal important difference) ^f
6: Skin and Nail Manifestations	Physician VAS ^e	≤ 1	50% reduction

a: Ankylosing Spondylitis Disease Activity Score – measures of Axial Spondyloarthritis disease activity; b: Maastricht Ankylosing Spondylitis Enthesis Score; c: Bath Ankylosing Spondylitis Functional Index – measures disease activity and function of axial spondyloarthritis; d: EuroQol five-dimensional questionnaire; e: Visual analogue scale performed by physicians based on the GRAPPA 0-5 scale; f: Task Force and Experts will discuss these thresholds further following literature search.

A **"Good" switch** was defined as comprising a majority of domains with "Good" outcome, including Disease Activity, and up to 1 or 2 domains with "Moderate" outcome, out of 5 or 6 evaluated domains respectively (Figure 3).

A **"Moderate" switch** outcome was defined as comprising a majority of domains with "Good" or "Moderate" outcomes, including Disease Activity, and up to 1 or 2 domains with "Insufficient" outcome, out of 5 or 6 evaluated domains respectively.

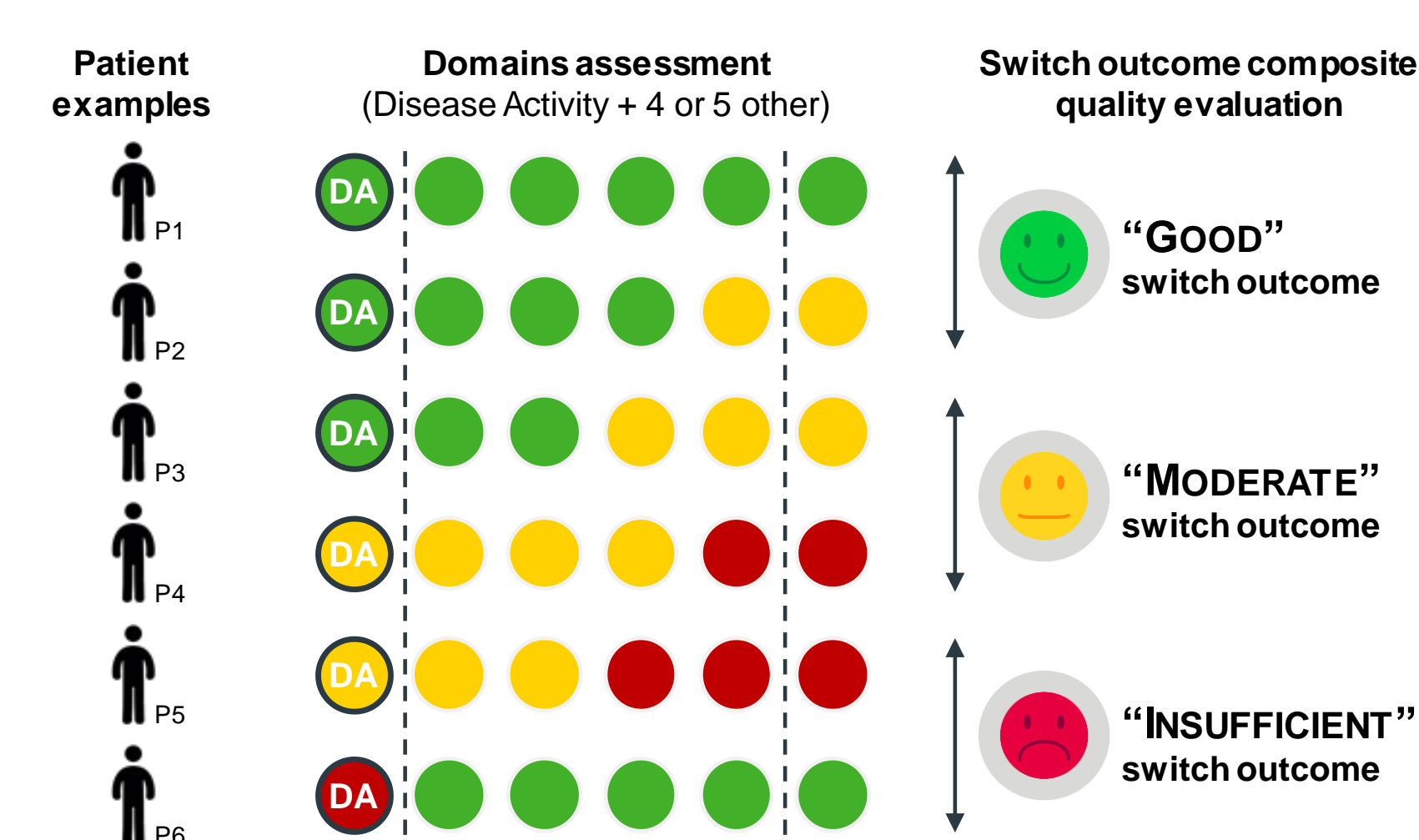


Figure 3: Definition of "Good", "Moderate" and "Insufficient" switch outcomes

Conclusions

The proposed measurement tool is a first attempt to address the quality of treatment decisions regarding biologics switch in PsA in clinical practice. In the future, this tool needs to be validated and then may be used to evaluate the quality of switching strategies. Its implementation is expected to support rheumatologists in making better and more informed therapeutic decisions.

Next Steps

At the Consensus Meeting, the team discussed several relevant next steps to this study, namely: (1) Define Quality of Life thresholds for EQ-5D instrument; (2) Clarify that biologic therapy persistence is a sine qua non condition to implement the switch quality measurement tool; (3) Validate tool by comparing tool's classification of real clinical cases against clinical judgement (i.e. gold standard); (4) Prospectively study tool's sensitivity to changes in real patients clinical outcomes and revise thresholds accordingly; (5) Analyze tool's correlation with "Productivity and Activity Impairment" domain and consider including this in the tool.

Disclosure of Interest

This work was developed under the project "Switch to Quality: Psoriatic Arthritis biologic switch consensus" that was sponsored by Novartis and executed with the collaboration of IQVIA.

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