Project T2T Portugal 2014-2016:
T2T Monitor

Revised version Date: 02 Fev 2015

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Overview

Over the past two decades, great developments have been achieved in the treatment of rheumatoid arthritis (RA) in parallel with other rheumatic diseases (RD). These are supported by new medications but especially by innovative strategies characterised by the "Treat-to-Target" (T2T) concept. "However, (…) many of these changes have not been brought into effect in most countries in Europe and other parts of the world" (Smolen, Aletaha, Bijlsma *et al.*, 2010:631).

1. State of Art

In RA, joint damage and physical disability are the major adverse outcomes associated with reduction in quality of life and premature mortality. Disease activity—as reflected by swollen and tender joint counts, levels of acute phase reactants (CRP or ESR) or by composite indices of disease activity—is a good predictor of damage and physical disability (*idem*). Disease remission represents the best possible opportunity to halt joint damage, prevent disability and protect quality of life, thus representing the ideal target of therapy, as substantiated by several articles (Grigor *et al.,* 2004; Fransen *et al.,* 2005; Goekoop-Ruiterman *et al.*, 2005; Sokka *et al.*, 2006; Verstappen *et al.*, 2007; Goekoop-Ruiterman *et al.*, 2007; Vermeer *et al.*, 2011; Pope *et al.,* 2013). Moreover, with modern medication, remission has become a frequently achievable goal (Emery & Salmon, 1995; Smolen & Aletaha, 2006). Sustained remission reduces healthcare service utilization costs, as recently demonstrated by Barnabe, Thanh, Ohinmaa *et al.* (2013) in a study involving a cohort of 1086 RA patients using anti-TNFα therapy. Benefits from brief periods of remission and low disease activity were also observed.

The European League Against Rheumatism (EULAR) recommendations for the management of RA (Smolen, Landewé, Breedveld *et al.*, 2010; EULAR, 2013) clearly states that the treatment with disease-modifying anti-rheumatic drugs (DMARDs) should be initiated as soon as a diagnosis of RA is made, with the aim of reaching a target of remission or low disease activity in every patient. By different words, a "(…) tight control using composite measures of disease activity and appropriate switching of drug treatment are highly efficacious approaches" (Smolen, Landewé, Breedveld *et al.,* 2010:964).

In many areas of medicine, treatment targets have been clearly defined to improve outcomes, leading to a reduction in the risk of irreversible organ damage. For instance, in the care of patients with diabetes these aspects have been adopted widely in practice: the therapy is adapted to achieve pre-defined blood glucose and HbA1c levels. Patients know these values and are aware of the treatment targets (Smolen Aletaha, Bijlsma *et al.*, 2010).

1.1. The Treat-to-Target initiative

Incorporating this concept, the T2T is an international initiative based on recommendations that define treatment targets in RA and encourage the adoption of strategies to achieve them as early and consistently as possible.

In a more complete description, the T2T principles, which precede the 10 recommendations, are (Smolen, Aletaha, Bijlsma *et al.*, 2010):

a) The treatment of rheumatoid arthritis must be based on a shared decision between patient and rheumatologist.
b) The primary goal of treating the patient with rheumatoid arthritis is to maximize long-term, health-related quality of life through control of symptoms, prevention of structural damage, normalization of function and social participation.
c) Abrogation of inflammation is the most important way to achieve these goals.
d) Treatment to target by measuring disease activity and adjusting therapy accordingly optimizes outcomes in rheumatoid arthritis.

The currently consensual target is remission, as this offers the best probability of long-term quality of life and preservation of function.

The definition of remission has evolved since the earliest concepts devised by the ACR in 1981 (Pinals, Masi, Larsen *et al.*, 1981) towards more restrictive constructs designed to guarantee the absence of relevant inflammatory process. In 2011 an EULAR and ACR committee in collaboration with the Outcome Measures in Rheumatology Initiative (OMERACT) developed two new definitions of remission. The first definition is Boolean-based and states that (Felson, Smolen, Wells, *et al.,* 2011):

> At any time point, patient must satisfy all of the following:
>
> - Tender joint count ≤1
> - Swollen joint count ≤1
> - C-reactive protein ≤1 mg/dl
> - Patient global assessment ≤1 (on a 0–10 scale)

The second definition is based on a composite index of RA activity, the Simplified Disease Activity Index (SDAI), which must be <3.3 at any time. The SDAI score is defined as the simple sum of the tender joint count (using 28 joints), swollen joint count (using 28 joints), patient global assessment (0–10 scale), physician global assessment (0–10 scale), and C-reactive protein level

(mg/dl) (Felson, Smolen, Wells, *et al.,* 2011).

These definitions are of utmost importance not only for clinical trials but also for clinical practice.

1.2. Implementation of T2T

The impact of this T2T initiative upon patient outcomes at a population level will, obviously, depend on how disseminated and implemented it is in clinical practice.

Rheumatologists appear to be well informed and accept the importance of these recent insights on treating RA (Schoels *et al.,* 2010). However, two recent surveys (Schoels *et al.,* 2010; Haraoui *et al.*, 2011) concluded that "additional efforts may be needed to encourage application of the recommendations among certain clinicians who are resistant to changing their practice" (Haraoui *et al.*, 2011:1). These aspects have never been formally studied in Portugal and there have been no structured initiatives to promote and monitor the application of T2T in clinical practice.

The success of T2T in our country and its positive impact upon patient's health will depend on a few essential conditions, which need to be assessed and promoted:

a) the establishment and acceptance of remission or low disease activity (LDA) as guiding targets;

b) informed and committed physicians and nurses, determined to measure outcomes on a regular basis and to achieve the target rapidly and consistently;

c) informed patients about the relevance of the target and how they can contribute to achieve it;

d) professional settings that facilitate the above.

In fact, the full success of these strategies requires the involvement of patients and relatives, who, therefore, also need to be informed and motivated (Schildmann *et al.*, 2008). A version of the T2T recommendation designed for patients have been created (Wit *et al.,* 2011) but still needs to be disseminated, implemented and assessed. Nurses may play a central role in engaging patients and families in this strategy, namely trough Patient Education Programmes (Hill**,** Bird & Johnson, 2001; van Eijk-Hustings, 2011).

Finally, implementation can be facilitated or made difficult by the logistical systems in place in terms of joint counts, secretarial and information technologies (IT) support for registries and regular follow-up. "The Portuguese National Register of Rheumatic Diseases" (Reuma.pt – www.reuma.pt) which promotes the regular registry of disease activity core parameters, can be a

pivotal instrument in the promotion of the T2T strategy in Portugal. However, it is not used as regularly and thoroughly as it might ideally be. Physicians have voiced several reasons for this, including lack of clinical time and the suboptimal adaptation of the website to clinical practice. Nurses might be very helpful but the web system does not predict their involvement, despite the recognition of their role in caring for these patients in other countries (Ndosi *et al,* 2011a, 2010b, 2013; Primdahl *et al.*, 2013; van Eijk-Hustings *et al.*, 2013; Koksvik *et al.,* 2013).

Concluding, we strongly believe that the implementation of current recommendations for the treatment of RA, with emphasis on T2T strategies, would represent a major step towards the goal of providing patients with the best possible treatment at the lowest possible cost. Studies are needed at a national level to establish the current standards of clinical practice understand the hurdles to the implementation of modern treatment strategies and design and test strategies to resolve them.

2. Objectives:

This project aims to:

2.1. Increase the level of adherence to treatment recommendations for RA in Portuguese Rheumatology Departments;

2.2. Identify the factors that affect the implementation of the 'T2T' strategy in our country;

2.3. Promote the regular use, in Portuguese Rheumatology departments, of the metrology instruments essential to the application of the T2T strategy and the registry on the Reuma.pt database of a core data set for RA;

2.4. Increase the awareness of the T2T strategy among Portuguese Rheumatologists, Nurses and RA Patients;

2.5. To incorporate RA patients' perspectives and willingness to adhere to T2T strategy;

2.6. To incorporate these findings into newer strategies for promotion of T2T.

3. Work Plans

3.1. Increase the level of adherence to current treatment recommendations for RA in Portuguese Rheumatology Departments by taking in consideration the perspectives of Rheumatologists

3.2. Identify the factors that affect the implementation of the 'T2T' strategy in our country

3.2.1. To promote discussions with all Portuguese rheumatologists trough web and/or at the Portuguese National Congress

3.2.2. To promote cconsensus about strategies to overtake obstacles, and produce recommendations for action

3.3. To Promote the regular use, in Portuguese rheumatology departments, of the metrology instruments essential to the application of the T2T strategy and the registry on the Reuma.pt database of a core data set for RA

    3.3.1. To seek adherence and commitment to the recommendations above by as many Rheumatology Departments as possible

    3.3.2. Identifying technical obstacles to data registration (questionnaires, work on site) and raising potential solutions (training and involvement of nurses, changes of IT system, …)

    3.3.3. Identifying psychological hurdles (reluctance, resistance, suspicion,…) and initiatives to help resolve them (educational sessions, focused discussions groups, team work sessions,…)

    3.3.4. To meet with informatics and patient statistics departments from each hospital to find opportunities for cooperation and development

    3.3.5. To assist department directors in their negotiations with hospital administrations/managers, regarding issues pertinent to the objectives of this project.

3.4. Increase the awareness of the T2T strategy among Portuguese Rheumatologists, Nurses and RA Patients;

    3.4.1. To assist in the promotion of national meetings on current treatment strategies and national state of the art

    3.4.2. To produce a newsletter on relevant recent publications and ongoing results of this project

    3.4.3. To produce a leaflet for patients explaining the core concepts of T2T strategies and how patient can help to achieve them

    3.4.4. To promote the visit to the official T2T website (http://www.t2t-ra.com), namely through a stand on the main rheumatology events in Portugal.

    3.4.5. To organize educational sessions and workshops for nurses on these topics, where necessary and desired. An educational booklet will be considered

3.5. To incorporate the health professionals' and RA patients' perspectives into strategies to enhance adherence to T2T strategy;

    3.5.1. To promote discussion and awareness among Portuguese nurses working at rheumatology departments trough web and/or at the Portuguese National meetings

    3.5.2. To promote discussion and awareness among Portuguese rheumatology RA patients at trough web and/or trough patient associations

    3.5.3. To promote clarification sessions for RA patients in collaboration with RA patient associations;

    3.5.4. To develop a website which congregates information in plain language about T2T and also about self-help strategies, diet and exercise, etc.

    3.5.5. To develop meetings aiming at understanding the potential of RA patients contribution to T2T strategy, based on:

        - *understanding the patients' difficulties and perspectives on active involvement in decision-making;*

        - *understanding the sociodemographic, health and psychological variables that influence patient participation and adherence to T2T strategy;*

- *to promote the potential of patient-centred data sets (eg: RAPID 3, RADAI, RAID,) as guiding instruments for T2T*
- *promoting the capacity of Portuguese RA patients to determine their disease activity and act accordingly on the basis of a decision algorithm*

3.6. To incorporate these findings into newer strategies for promotion of T2T

3.6.1. To produce a detailed annual report regarding the degree of adhesion to the T2T strategy at each centre and at a National level, including proposals for action.

4. Project Management

4.1. ARCo will be responsible for the logistical management of the project.

The project will be conducted between the 1st of February 2015 and the 31st January 2018

5. Budgeting

Research schedule				
Activities/ Time	2015	2016	2017	Total Budget
Project Design - Protocol Signature				20.000,00
Literature Review				4.500,00
HCP Focus Groups by Rheumatology Departments				26.000,00
Awareness Sessions				20.000,00
Educational Materials				10.000,00
Improvements in Reuma.pt Web tool				15.000,00
Data analysis and reports				10.000,00
Communications at the Rheumatology Annual Congress				4.545,00
SPR Overheads				9.955,00
Total Budget / Year €	**20.000,00**	**50.000,00**	**50.000,00**	**120.000,00**

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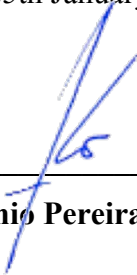
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Coimbra, 25th January 2015.

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