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TECHNICAL REPORT

DISMEVAL

Developing and validating disease management evaluation methods for European healthcare systems

Final report

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Prepared for the European Commission
on behalf of the DISMEVAL Consortium

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Summary

The DISMEVAL project was funded under the European Commission's Seventh Framework Programme (grant agreement 223277). DISMEVAL's three-year programme of work was developed around a set of key objectives, which include **(1) to review current approaches** to chronic care and their evaluations, as implemented by EU Member States at national and regional levels, **(2) to explore the policy context** for chronic disease management in European countries, **(3) to develop and validate disease management evaluation methods** using data from existing programmes and approaches through employing a range of evaluation designs and assessing the sensitivity of findings to selected methods, and **(4) to formulate recommendations** for scientifically sound yet operationally feasible evaluation approaches for chronic disease management that are relevant to planned and ongoing policies at the EU and wider European level as well as internationally. This final report presents the overall findings of the work carried out within the project. The learning from these various work streams led to the formulation of recommendations for the evaluation of chronic disease management. We report these recommendations in the form of a separate guidebook, which is published alongside this final report.

Chronic disease management in Europe

We reviewed the policy context for, and approaches to, chronic disease management in 13 European countries. We found that fragmentation between ambulatory/primary care and hospital/secondary care, and between the health and social care sector remains a key concern in most healthcare systems. Countries have sought to create a regulatory and policy framework to respond to chronic disease during recent years. These generally aim to promote approaches that better integrate care and improve coordination between sectors and levels of care but countries differ with regard to their vision towards controlling and managing chronic disease.

Approaches to chronic disease management vary in scope and nature across Europe

While our review did not attempt to present a comprehensive inventory of all approaches being implemented in a given country, some of the key observations were that:

- the majority of countries tend to focus on care models for populations with defined conditions, most frequently diabetes type 2, and involve some form of GP-led care coordination
- nurse-led approaches are becoming more common although there are differences in the degree to which nurses can operate independently

- patient access is typically granted in line with access to usual care although many approaches are being implemented in selected geographical regions so potentially limiting access to defined population groups
- the majority provide some form of patient self-management support although the level and scope of support offered varies
- the overall use of clinical information systems for chronic disease management tends to be the least developed strategy in most approaches.

Existing approaches to evaluating chronic disease management in Europe are diverse

Most chronic disease management initiatives reviewed here had undergone some form of evaluation or had evaluation plans in place. However, the nature and scope of evaluations varied, with differences in objectives, design, the performance metrics used, the length of observation and approaches to data collection. We identified a range of challenges posed to the more systematic use of evaluation of complex healthcare interventions such as disease management in European health systems, such as a perceived lack of an evaluation culture in some settings, alongside lack of financial and human resources to conduct systematic evaluation. We note that evaluation of approaches to disease management reviewed would likely benefit analytically from increased use of sophisticated statistical techniques, but also conceptually from drawing more explicitly on one of the many possible theories of behaviour change to better link the choice of performance measures to the goals of the intervention (and of the evaluation). There may also be scope to more systematically draw in mixed-methods approaches to help place observed quantitative findings into the context within which the intervention under evaluation is embedded. More information is needed about the characteristics of the intervention and its intended populations, requiring greater specification of the wider context so as to improve comparisons and potential transferability across settings and countries in Europe.

There remain considerable challenges towards the development of a policy framework for providing a strategic response to chronic disease

Interviews with key informants in a sample of countries highlighted a series of continued challenges to arrive at a more comprehensive or strategic response to chronic disease. These included a continued focus of chronic care on complications management, with some movement towards more systematic disease management, and an overall lack of coordination between levels; failure to integrate risk minimisation and disease prevention with other components along the care spectrum; misalignment of financial incentives that tend to reward 'aggressive' treatment of complications rather than management to maintain functioning and reduce risk of complications; and a disjoint between intent, at national level, to enhance coordination and integration, and ability at regional or local level to translate these ambitions into practice. While perhaps not specific to chronic care as such, these observations emphasise the need for the development of a coherent response to chronic disease that takes account of the various tiers in the system and along the care continuum, with involvement of professionals forming a crucial component for achieving sustainable change.

Testing and validation of methods and metrics for the evaluation of chronic disease management

The testing and validation of disease management evaluation methods comprised studies carried out in six countries and using data from existing interventions. These were: disease management programmes for diabetes type 2 in Austria and Germany, diabetes care groups in the Netherlands, provider networks for diabetes and for cancer in France, an interdisciplinary and -sectoral rehabilitation programme for people with chronic obstructive pulmonary disease and for diabetes in Denmark, and a nurse-led intervention targeting a working-age population at risk of cardiovascular disease in Spain. All interventions were implemented in a non-experimental setting; the only exception was the diabetes disease management programme in Salzburg, Austria, which was implemented as a pragmatic cluster-randomised controlled study.

As interventions and the setting in which they were implemented varied, so did their approaches to testing and validating approaches to evaluation. Thus, country studies aimed to:

- quantify differences in effect sizes of structured care within a diabetes disease management programme using randomised and non-randomised controlled and non-experimental designs (Austria)
- test different approaches to identify treatment-control matches in non-experimental settings and quantify the likely impact on the effect estimate of an interdisciplinary and -sectoral intervention for patients with chronic obstructive pulmonary disease or diabetes (Denmark)
- compare different methods to adjust for confounding in a non-experimental setting using routine data to assess intervention effect of a diabetes disease management programme (Germany)
- test for selection bias for participating in a structure care programme for diabetes (Germany, France)
- employ advanced methods of disease management evaluation in non-experimental settings to better understand differential effects of structured care components on sub-populations (Netherlands, Spain).

Secondary goals of each analysis further included evaluating the effects of the intervention under study on patient outcomes more generally (all countries), alongside better understanding of the usefulness of current approaches to evaluation in the context of intervention practice (France, Netherlands) and to derive recommendations for further development of interventions and evaluation practice.

Evaluating the diabetes disease management programme in Austria using an uncontrolled design overestimates treatment effect

In Austria, the evaluation of the effect of the diabetes disease management programme ‘Therapie Aktiv’, using a randomised controlled design, found a reduction in HbA1c levels of 0.13 percent after one year. This effect was not statistically significant while measures of process quality such as regular eye and foot examination and patient education improved significantly. In contrast, using an uncontrolled before-after design, treatment effect was estimated as a significant reduction in HbA1c levels of 0.41 percent in the intervention group. Extrapolating these findings to clinically relevant endpoints such as number needed

to treat to avoid one case of myocardial infarction or one diabetes complication over a period of ten years, the uncontrolled before-after design overestimated treatment effect by a factor of three. These findings support the general notion that use of a randomised controlled design should be considered as the main means for evaluating treatment effect of a structured care intervention. Cluster randomisation as applied in the case of Austria can be seen to provide a pragmatic approach to DMP evaluation where a randomised controlled design is not feasible.

Different approaches used to identify treatment-control matches in a non-experimental intersectoral intervention for patients with chronic obstructive pulmonary disease in Denmark provide different estimates of treatment effect

In Denmark, the evaluation of the effect of an interdisciplinary and intersectoral rehabilitation programme for patients with chronic obstructive pulmonary disease (COPD) used three different methods: (i) pre-post analysis to assess changes in the intervention group over time; (ii) intervention-control analysis in the post-period to assess actual differences between intervention and control patients at the point of the evaluation; and (iii) difference-in-difference analysis to assess the impact of the intervention in a particular context and time. The analysis found effect sizes to vary with the method of constructing control groups for the intervention-control and the difference-in-difference analysis. For example, propensity score matched sampling lowered the magnitude of the predicted intervention effect for COPD-specific hospital bed days when compared with controls created by random sampling. Likewise, control groups not matched by disease severity overestimated the effects of pulmonary rehabilitation on COPD-specific hospital contacts and bed days.

The study considered the method of control group construction and matching using propensity scoring and the use of difference-in-difference analyses to assess intervention effect to be optimal for evaluating the impact of interventions in a non-experimental setting. As for the impact of the overall programme, the case study provided evidence that the intervention might have decreased the pace of disease progression in the intervention group, which was reflected in a non-significant increase in COPD hospital contacts, bed days, ambulatory visits and emergency room visits in the intervention group, while these indicators significantly increased in the entire sample.

Different methods to adjust for baseline differences in a non-experimental setting using routine data to assess intervention effect of a diabetes disease management programme in Germany result in similar effect measures

In Germany, the evaluation of intervention effect of a diabetes disease management programme (DMP) in a non-experimental setting applied different approaches to adjust for baseline differences between DMP and the control group created from routine data. The main finding was that all matching and/or weighting methods used resulted in similar effect measures for the outcome variables analysed. However, applicability of available statistical methods and tools to perform a sound evaluation of programme effects is conditional on the availability of real baseline data prior to enrolment in the intervention, so enabling adjustment of differences between intervention and control group. Therefore, effort should be made to ensure a thorough collection of detailed and valid data to maximise the usefulness of routine data for evaluation.

As for the impact of the overall programme, the case study confirmed the findings of other studies that participation in the diabetes DMP improved process parameters in diabetes care, especially those related to the monitoring of the disease. However, intensified care in the programme was accompanied by higher overall costs, primarily because of higher prescription costs. In order to draw valid conclusions about DMP effects on clinical endpoints such as mortality or micro- and macro-vascular complications, a longer study period consistent with what is known about the time course of the disease should be chosen.

Patient selection for participating in a structured care programme for diabetes in Germany and France leads to misestimation of findings of the effect of the intervention

The evaluation of the diabetes disease management programme in Germany also observed a significant reduction of mortality in the intervention group. This effect was largest in the first year following enrolment in the programme, but then decreased. Such an observation is counterintuitive since an effect attributable to a given intervention would be expected to increase rather than decline. It is therefore more likely that GPs systematically excluded patients from joining the programme who were more likely to die in the near future. Adjusting for baseline variables reduced this effect compared with the unadjusted analysis. Future analyses should include further adjustment for variables suited to predict short-term mortality risk. Furthermore, a longer observation period would be required to assess whether the mortality difference diminishes over the years.

Evidence of patient selection into the intervention was also observed in the case study for France, which examined patient characteristics of those enrolled with a diabetes provider network. These patients were found to be of younger age, whose diabetes was diagnosed more recently but who showed evidence of worse glycaemic control than patients in the reference population. By comparing a standard uncontrolled pre-post evaluation design with a pre-post design after calibration with the reference population at baseline, the analysis further showed that the uncontrolled evaluation design overestimated the intervention effect on a number of clinical outcomes, including improvements in HbA1c levels and body mass index while underestimating deterioration in renal function in diabetic patients.

Advanced methods of disease management evaluation in non-experimental settings help understand the differential effects of care components on sub-populations and so inform further development of structured care approaches

Most randomised controlled trials are conducted in academic settings and provide limited insight into the impact of disease management in the everyday practice of healthcare. In the Netherlands, the evaluation of integrally financed, regional disease management programmes for diabetes therefore used different approaches to better understand the effects of the programmes. It found that applying methods that permit for sub-group analyses provide important new insights into differential component effects. Thus, while the overall analysis of intervention effect found only modest impacts of the care programmes on the health status of patients with diabetes type 2, sub-group analyses revealed disease management to be considerably more effective for patients with poor baseline clinical values. As the vast majority of patients included in the analyses had good baseline values of most clinical endpoints, this differentiation provided a plausible

explanation for the modest overall effects of the intervention. This suggests that further development of the intervention should move towards a more tailored approach to diabetes care, in which the characteristics of patients directly determine the processes of diabetes care, including self-management support. However, such a move will require improvements in the current systems for data registration to provide valid and reliable information on patients' health status to determine care intensity. Similarly, in assessing the effect of a nurse-led intervention targeting a working-age population at risk of cardiovascular disease in Spain, the use of advanced methodological approaches that permit for sub-group analysis in a non-experimental setting provided important new insights into the effects of the intervention.

Continued challenges and lessons learned

The DISMEVAL project set out to enhance our understanding of the use of various approaches to the evaluation of disease management in Europe. It further aimed to identify examples of best practice and lessons learned and to provide evidence-based recommendations to policymakers, programme operators and researchers on evaluation approaches that may be most useful in a given context.

The Austrian case study in DISMEVAL has illustrated how it can be feasible to employ a randomised design in routine settings where the context allows for such a design to be applied. However, use of an experimental design may not be possible (or desirable) for population-wide disease management interventions, which are frequently implemented in an operational setting and do not usually have a control group available, such as those implemented in Germany and the Netherlands. Here, observational study designs are more suitable, keeping their methodological limitations in mind. Given that disease management is essentially a population-based care strategy, advancing observational study designs is therefore crucial to inform on how to best target sub-groups of chronically ill patients in daily healthcare practice.

The DISMEVAL project has identified and tested a wide range of methods that can be employed in situations where randomisation is not possible, emphasising that rigorous evaluation is still possible where baseline or predefined control groups are not available and how advanced designs can help better understand how different (combinations of) care components and processes might be effective for managing chronic disease in patients with different characteristics. Future evaluation work drawing on such approaches can provide insight into what works for whom in the area of disease management, a question that randomised trials have thus far been unable to answer. Project work further highlighted, through the introduction of statistical controls for selection or statistical matching, how findings were substantially different from simple comparisons of patients receiving a given disease management intervention and those who do not. Thus, the DISMEVAL project has shown how the use of randomisation or other methods of control is necessary to accurately assess the impact of such interventions. It also identified a range of methods that can be employed successfully to implement such controls.

The findings from these different work streams led to the development of a set of recommendations for the evaluation of chronic disease management. This has been published as a separate report alongside this final report.