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Included patients and integrated clinical treatment trials

EDITORIAL

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Healthcare policy makers are in agreement, and the medical professions are supportive. We nevertheless risk failing to achieve the target of 5 % of patients in the specialist health service participating in clinical trials in 2025.

Photo: Sturlason

Clinical trials are not sufficiently integrated into patient treatment, patients do not have adequate access to trials, and many health trust boards give too little attention to research. Such was the conclusion of the report by the Office of the Auditor General of Norway in 2021 on clinical treatment trials in the various health trusts (1).

The *National action plan for clinical trials 2021–2025* was published simultaneously. It stated that clinical research should be an integral part of all clinical practice and patient treatment (2). The primary objectives were to double the number of clinical trials, and for one in twenty patients in the specialist health service to participate in clinical trials. The Auditor General's criticism and a political solution were therefore formulated in parallel, and their descriptions of the situation were by and large similar.

How do things look now, one year before the 5 % target deadline? The figures for 2019–23 point in the right direction (3). In 2023, a total of 22 506 patients (compared to 13 783 in 2019) were included in clinical treatment trials, equivalent to 3.57 % of the patients in the specialist health service. Northern Norway Regional Health Authority is best in class and last year included 4.17 % of the patients in the region, an increase from 1.77 % the previous year.

However, there is no corresponding increase in clinical trials that are ongoing or for which applications have been submitted (4). That is not such good news in terms of the goal of doubling the number of trials. From the patients' perspective, however, it may be more important to gain access to high-quality clinical trials than to have access to more trials.

The increased demand for healthcare services is expected to continue. Patient inflow is not a limiting factor for trials in the health trusts and neither will it be one in the future. Patient treatments increased by 12 % from 2012 to 2019, and treatment in somatic hospitals increased by 2 % from 2022 to 2023 alone (5, 6).

> ***«The notion that an increase in patient inflow will result in more research is wishful thinking. Rather, when scarce resources are distributed, patient treatment takes precedence over other legally mandated tasks»***

The notion that an increase in patient inflow will result in more research is wishful thinking. Rather, when scarce resources are distributed, whether it be health trust spending or healthcare professionals' time, patient treatment takes precedence over other legally mandated tasks. The opposite is difficult to envisage. Tasks such as specialist training, patient education and clinical research are inextricably linked to patient treatment, but this interdependency is neither balanced nor mutual: patient treatment can stand alone – while other tasks are put on hold. With the number of doctors and nurses expected to decrease in the coming years, a committed investment is needed to achieve the goals in the action plan. Services must receive earmarked funding as well as clear guidelines on the prioritisation of tasks.

The authorities have addressed this by introducing an indicator for clinical treatment trials (the KBS indicator) and a points system (7). Its purpose is to maintain an overview of new patients who are included, and to use this for 'management and prioritisation and as an (economic) incentive to develop a good provision for patient participation' in clinical trials (8). The KBS indicator and KBS points are part of a new national system for measuring research and innovation activity in the health trusts and national competence centres(7). The indicator serves as a measurable factor that can be weighted in prioritisations at health trust level, while national coordination of the health trusts' annual reporting on the indicator has been assigned to Sikt – Norwegian Agency for Shared Services in Education and Research (4).

> ***«It is to be hoped that the system does not come at the expense of patient treatment that has a low relevance for treatment trials»***

It is to be hoped that the system does not come at the expense of patient treatment that has a low relevance for clinical treatment trials. Beyond the statement that the action plan shall not change 'the prioritisation criteria that shall form the basis for the patient treatment', it is difficult to discern how the health trusts will prioritise research in relation to other commitments when the shortage of qualified personnel is expected to increase (2).

The university hospitals are in a unique position when it comes to contributing to the objectives of the action plan, not least through the six NorTrials centres that receive annual funding from the state budget (9). However, since many of us live outside the catchment areas of the university hospitals, it is unclear to what extent the investment will benefit the population as a whole.

The fact that a growing number of patients are being included in clinical trials can be interpreted to mean that the action plan has served as a worthwhile goal to pursue. But why has the target been set at 5%? As pointed out in consultation responses, neither the baseline percentage nor the denominator was known, nor how this was to be measured (10).

It may, therefore, be difficult to measure any increase. With the introduction of the KBS indicator and 2019 as the first year counting, changes can now be monitored that were previously difficult to measure nationally and regionally.

In the period covered by the action plan, 60 % of clinical trials applied for had a commercial sponsor, and that proportion appears to be stable (4). If we rely on the pharmaceutical industry to be responsible for the lion's share of the trials. This will be a violation of the principle of equal access to health services.

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