**Statistical analysis plan**

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| **Project reference:** | CCU090\_01 |
| **Project title:** | Cardiac rehabilitation following transcatheter aortic valve implantation (TAVI) before, during and after the COVID-19 pandemic: A Whole-Population Study |
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**Title**

Cardiac rehabilitation following transcatheter aortic valve implantation (TAVI) before, during and after the COVID-19 pandemic: A Whole-Population Study.

**Background**

Cardiac rehabilitation (CR) is a multidisciplinary, multicomponent healthcare program, supporting patients make healthy lifestyle changes in cardiovascular disease. It includes clinician consultations, exercise training, physical activity promotion, medication management, health education, psychological support, goal setting, and self-management strategies to maintain a healthy lifestyle (1, 2). These programs are effective, improving risk factor profiles, enhancing quality of life, and reducing hospital readmissions and mortality (1, 3, 4). Thus they are consistently recommended in international guidelines for a wide range of cardiac diagnoses, including acute coronary syndromes (ACS) and heart failure (HF) and following coronary revascularization procedures (percutaneous coronary intervention (PCI)) or coronary artery bypass graft (CABG) surgery(1, 5, 6). They are also helpful to patients with heart valve disease (7).

Despite the well-documented benefits of cardiac rehabilitation (CR), participation rates among post-ACS and heart failure patients remain low (3, 8, 9). Numerous barriers hinder access to CR, including system-level obstacles such as inefficient referral processes and the limited availability of programs, as well as patient-related factors such as time constraints, lack of motivation, and a low perceived need for rehabilitation (1, 10). Many post-ACS patients, being asymptomatic and feeling well after discharge, perceive little need for ongoing care, which contributes to the low participation rates in this population (1, 10). In response, a growing body of research is exploring alternative CR delivery models, such as digitally enabled and home-based programs, to expand access and increase utilization among post-ACS and HF patients (11-13). However, there remains a relative paucity of evidence regarding CR attendance and its benefits for patients with aortic valve stenosis who have undergone transcatheter aortic valve implantation (TAVI) (14).

Surgical aortic valve replacement (sAVR) has historically been the gold standard for treating aortic valve stenosis (15). However, sAVR is not suitable for high-risk patients because it typically involves open-heart surgery to replace the valve (15). TAVI is a relatively new and less invasive procedure for treating aortic valve stenosis, which is performed through a catheter to replace a damaged aortic valve. Therefore, TAVI, being less invasive than sAVR, has revolutionized valvular heart disease treatment by offering a safer option for high-risk, older, and previously inoperable patients (16). The post-discharge management pathway for sAVR typically includes cardiac rehabilitation. While CR has also been recommended for patients following TAVI (7), this is a different scenario, without the acute deterioration of function associated with the hospital stay, chest wound and bypass pump-based injury of SAVR. Perhaps because of these differences, CR remains notably underutilized in TAVI patients, with several possible factors contributing to the very low participation rates (17).

Firstly, although these patients may derive significant benefit from CR, the evidence supporting CR in this population remains limited (14), in contrast to the robust guidelines established for post-ACS and heart failure management. Consequently, no formal guidelines currently exist for the post-discharge management of TAVI patients (18). Secondly, TAVI patients are usually discharged home within a few days of the procedure (some the same day) and thus there is no prolonged hospital stay to recover from. There is an underlying assumption that patients are in stable health, potentially leading to a perception among clinicians that CR may be unnecessary (19). As a result, it is far from the norm for TAVI patients to be referred to CR (20). Third, the drivers of functional impairment in TAVI candidates are more chronic than the acute insults in SAVR patients. Advanced age, frailty, and presence of multiple comorbidities are markers of patients who benefit from CR from an acute deterioration (16, 21), but it is not clear that CR can reverse their effects alone. Fourth, delivering CR to these patients is challenging – they are elderly, often need assistance to attend, and are often not facile with using online resources. In this context, it is not surprising that undergoing TAVI is associated with a lower probability of participating in a CR program (22). Finally, the COVID-19 pandemic imposed substantial challenges on traditional in-person cardiac rehabilitation programs, resulting in the temporary closure of numerous facilities and reduced capacities at those that partially reopened (1). These disruptions compounded pre-existing access barriers and further exacerbated the underutilization of CR (1, 23).

Preliminary analysis of data from HDR UK (NICOR – TAVI and HES-Outpatient) suggests that only 4% to 6% of TAVI patients in the UK have a subsequent outpatient CR admission within 180 days post discharge. Regional variation is notable, with participation rates ranging from 0% in the Northeast, Yorkshire, and The Humber regions to 10% in the Northwest (*unpublished data*). These participation rates are markedly lower than those observed in the United States, where 30.6% of TAVI patients attend CR (20). Significant variation is also seen across US hospitals, with participation rates ranging from 5% to 60% across 24 institutions, even after adjusting for differences in patient case mix (20).

Patient characteristics, clinical practice and policy, and the impact of the COVID-19 pandemic are likely contributing to the low rates of CR attendance among TAVI patients. There is true equipoise regarding the feasibility and value of CR in this setting, and the justification to resource such a service in this challenging group. The lack of sufficient evidence characterizing the current state of CR participation and supporting these associations makes it challenging to drive changes in clinical practice and shape informed policy decisions. Accordingly, the primary objective of this project is to analyse and characterise CR attendance following TAVI procedures across England, both before and after the pandemic. In addition, the study will assess the factors associated with CR participation. Lastly, the project will examine the associated outcomes of exposure to CR in TAVI patients, with the aim of determining whether there is an associated benefit, particularly given their vulnerability, frailty, and higher burden of comorbidities.

**Objectives**

1. **Temporal trends in cardiac rehabilitation attendance post TAVI procedure before and after the Covid-19 pandemic, across England (2018 to 2023):** we will explore the volume and CR rates of TAVI patients, who attended a cardiac rehabilitation program within 180 days post discharge from the TAVI procedure. Quarterly and annual cardiac rehabilitation rates (number who attended cardiac rehabilitation / total number of follow-up time of TAVI patients) from 1 January 2018 and 31 March 2023 (Figure 1 and Figure 2: *Example Templates*).
2. **Characterization of patients hospitalised for a TAVI procedure categorised by participation in cardiac rehabilitation**. We will profileall patients who were hospitalised for a TAVI procedure from 1 January 2018 and 31 March 2023. We will split the profiles into two categories: a) cardiac rehabilitation attendance (defined by: the volume of TAVI patients, who have had a subsequent outpatient appointment with a cardiac rehabilitation specialty within 180 days) and b) no cardiacrehabilitation attendance. Key demographics and clinical characteristics to be summarised are age, sex, ethnicity, socioeconomic status, smoking status, region, body-mass index, New York Heart Association (NYHA) classification, diabetes, clinical frailty scale score, poor mobility, prior myocardial infarction, history of pulmonary disease, liver disease, previous cardiac surgery and previous percutaneous coronary intervention (PCI), number of cardiac rehabilitation appointments attended (Table 1: *Example Template*).
3. **Factors associated with cardiac rehabilitation attendance.** We will quantify the factors associated with cardiac rehabilitation attendance. Specifically patient demographic, socioeconomic, and clinical factors.
4. **Outcomes associated with exposure to cardiac rehabilitation post TAVI.** We will quantify the outcomes associated with cardiac rehabilitation exposure following a TAVI procedure.TAVI patients, who have had a subsequent outpatient appointment with a cardiac rehabilitation specialty within 180 days, will be compared with TAVI patients who did not attend cardiac rehabilitation. The primary outcome will include hospital readmission with HF (in a competing risk analysis with death). Secondary outcomes will include subsequent all-cause mortality, all-cause rehospitalisation and non-CVD rehospitalisation. We will adjust for confounding baseline characteristics that are captured in the TAVI registry.

**Data Sources**

This project will make use of the following data sources within the NHS secure data environment (SDE):

1. National Institute for Cardiovascular Outcomes Research (NICOR) – Transcatheter aortic valve implantation (TAVI)
2. Hospital Episode Statistics for admitted patient care (HES-APC)
3. Hospital Episode Statistics for outpatient appointments (HES-OP)
4. General Practice Extraction Service Extract for Pandemic Planning and Research (GDPPR) primary care data
5. Office for National Statistics (ONS) Civil Registration of Deaths

**Methods**

Study population

The TAVI study population will comprise adults aged 18 years or older who underwent a TAVI procedure coded in the NICOR-TAVI dataset between 1 January 2018 and 31 March 2023 (defined as a ‘known previous TAVI’). This allows a minimum of 1 year follow-up for all TAVI patients in GDPPR/HES APC/HES Outpatients. We will restrict the cohort to patients undergoing first ever TAVI procedure (using the previous TAVI indicator variable in NICOR TAVI dataset). The data set will include one TAVI event per patient in the cohort, which will be each patient’s first ever TAVI.

Intervention population (exposure variable)

TAVI patients who attended cardiac rehabilitation will be identified within the HES-Outpatient (OP) data set via a cardiac rehabilitation ‘Treatment Specialty’ code number 327 (Cardiac Rehabilitation Service). Treatment specialty describes the specialised service within which the patient was treated. Patients with an HES Outpatient appointment with a cardiac rehabilitation specialty code 327 will be used as a proxy for cardiac rehabilitation attendance. Therefore, post TAVI cardiac rehabilitation exposure will be defined as: all TAVI patients from January 2018 to 31 March 2023, AND with a cardiac rehabilitation specialty code (number 327) outpatient appointment identified within 180 days of the index TAVI procedure. The following, cardiac rehabilitation flags will be identified in the data: 1. Binary flag of CR within 6 months; 2. count of appointments within 6 months; 3. number of appointments attended (attendance flag), 4. date of cardiac rehab attendance (defined from the date of 1st cardiac rehabilitation appointment).

Cardiac rehabilitation exposure will be defined from the date of the 1st cardiac rehabilitation appointment and thus having attended at least 1 or more cardiac rehabilitation appointments.

Comparator population

The TAVI study population (adults aged 18 years or older who underwent a TAVI procedure coded in the NICOR-TAVI between 1 January 2018 and 31 March 2023 and at least 1 year of prior medical records in HES-APC, HES-OP, or GDPPR) WITHOUT a cardiac rehabilitation specialty (code 327) outpatient appointment within 180 days of the index TAVI procedure. These patients will be compared via a cox proportional hazards model and adjusting for covariates.

Covariates

We will derive important demographic, clinical and biometric covariates, captured at the time point of the TAVI procedure, from the NICOR-TAVI data set. Covariate selection was informed by the study cardiologist and selected based on clinical relevance and likely influence on outcomes following TAVI. Covariates may include (not limited to); age, sex, ethnic background, BMI, deprivation (LSOA) (from hospital record), poor mobility, Katz score, comorbidity composite (pulmonary disease, severe liver disease, history of neurological disease and extracardiac vasculopathy), NYHA status, diabetes, smoking status, previous MI time, previous cardiac surgery, LV function, mitral regurgitation and TAVI procedure complications (device failure, valve not deployed/malfunction, further valve intervention before discharge, conversion to full sternotomy, tamponade, peri-procedural MI, CVA, vascular access complications and acute kidney injury).

Outcomes

We will assess the following outcomes:

* **Primary outcome**: Unplanned hospital readmission with heart failure.
* **Secondary outcomes**: All-cause mortality, all cause rehospitalization and non-CVD rehospitalization.

Hospitalization outcomes involving secondary care data only (HES-APC) will include only unplanned rehospitalizations for the following causes: HF, all-causes, and for non-cardiovascular causes. Non-CVD readmissions may be investigated as a secondary outcome to capture readmissions due to other causes such as falls and frailty.

Both first and all recurrent events will be considered up to the study period's end date, and hospitalizations with primary ICD-10-coded discharge diagnoses will be included. Patients who do not experience each outcome during the designated follow-up period will be censored at a pre-specified cut-off date.

Mortality outcomes will be defined using data from ONS Civil Registration of Deaths and include all-cause mortality.

**Clinical outcomes which may be assessed in the present study.**

|  |  |
| --- | --- |
| **Category** | **Type** |
| Mortality | All-cause mortality |
| Hospitalisation | Heart failure hospitalisation |
| All-cause hospitalisation |
| Hospitalisation for non-cardiovascular disease |

Timepoints

1st January 2018 to 31 March 2023. This allows a minimum of 1 year follow-up (to 31 March 2024) for all TAVI patients in GDPPR/HES APC/HES-OP.

Statistical analysis

All analyses will be conducted using R statistical software. Descriptive statistics will be used to summarize baseline characteristics of the cohort. Continuous variables will be reported as means and standard deviations or medians and interquartile ranges, depending on distribution. Categorical variables will be summarized using frequencies and percentages.

To examine trends in CR uptake over time, we will calculate quarterly rates of CR participation, expressed per 10,000 person-days of follow-up.

Factors associated with CR participation will be explored using a Cox proportional hazards model, with time to first CR attendance as the outcome. Patients will be censored at the time of death or end of follow-up. This model will identify demographic, clinical, and procedural characteristics associated with CR exposure.

To evaluate the association between CR and clinical outcomes, we will conduct separate Cox proportional hazards regressions for the following endpoints: heart failure rehospitalization, all-cause rehospitalization, non-cardiovascular rehospitalization, and all-cause mortality. Exposure to CR will be defined as any participation within 180 days of TAVI discharge, and the time scale will begin at day 180 post-discharge. We will model the hazard of the outcomes occurring *after* this 180-day window. We will separately estimate the association between CR and heart failure rehospitalization, all-cause rehospitalization, non-cardiovascular rehospitalization, and all-cause mortality. Covariate adjustment will include demographic and clinical variables collected at the time of TAVI: These may include: age at TAVI, sex, ethnicity (5-group classification), socioeconomic deprivation (IMD 2019 quintiles), smoking status, body mass index category, NYHA dyspnea status prior to the procedure, Katz index of functional status, history of poor mobility and diabetes (binary variables), comorbidities (pulmonary, liver, neurological, extracardiac vascular disease), history of myocardial infarction, prior cardiac surgery, left ventricular function, mitral regurgitation, and procedural complications. To adjust for temporal effects (e.g. changes in care delivery during COVID-19), the year of TAVI discharge will be extracted from the discharge date and will also be included as a categorical covariate.

As a sensitivity analysis, we will fit Cox proportional hazards models treating CR participation as a time-varying exposure. This approach allows the exposure status to change over time, better reflecting real-world variation in rehabilitation engagement. The analysis timescale will be based on calendar days from 1 January 2018, enabling alignment with key events such as COVID-19 lockdowns or policy shifts. This approach will allow cardiac rehabilitation status to vary dynamically throughout the observation period, capturing changes in participation that may influence the risk of rehospitalization or mortality, particularly the COVID19 lock down periods and other restrictions that may have impacted standard care during that time.

We will conduct another sensitivity analysis focusing on CR exposure within 90 days of TAVI discharge. We will re-estimate the association between CR and heart failure rehospitalization, restricting the exposure definition to CR attendance within 90 days and modeling hazard of heart failure rehospitalization occurring *after* this 90-day window.

A dose-response analysis will be conducted to examine whether the number of CR sessions attended is associated with clinical outcomes. Attendance will be treated as an ordinal exposure, and separate Cox models will estimate its relationship with heart failure rehospitalization, all-cause rehospitalization, and non-cardiovascular rehospitalization.

Finally, to contextualize outcome incidence, we will calculate crude rates of all-cause rehospitalization, heart failure rehospitalization, non-cardiovascular rehospitalization, and all-cause mortality, expressed per 10,000 person-days of follow-up.

**Projected clinical impact**

This study will conduct a comprehensive and systematic investigation of cardiac rehabilitation exposure following TAVI procedures across England, before, during and after the COVID-19 pandemic. The research aims to describe the current state and temporal trends of CR participation post-TAVI and to identify the key factors influencing attendance. The findings are anticipated to contribute to the development of targeted strategies and policy interventions aimed at enhancing cardiac rehabilitation uptake, particularly in underrepresented groups. Additionally, the study will assess the associated outcomes with exposure to CR in TAVI patients, evaluating whether they derive benefits (similar to those observed in post-ACS patients), given their increased vulnerability, frailty, and comorbidities. This research will generate new evidence to guide the post-discharge management of TAVI patients and lay the foundation for future prospective studies. Leveraging whole-population electronic health records covering 57 million individuals in England, this study will likely be one of the largest investigations into CR following TAVI procedures, with the potential to influence future secondary prevention clinical practices and policy. Moreover, improving CR utilisation is known to enhance patient outcomes, reduce hospital readmissions, and alleviate pressures on the healthcare system. The findings could drive policy changes focused on optimising the allocation of scarce healthcare resources, particularly for older, frail, and vulnerable patients, who are most likely in need of rehabilitation and most likely to benefit from it.

**Template Figures and Tables (dummy data)**

**Objective 1.**

**Figure 1:** Temporal trends in cardiac rehabilitation attendance post TAVI procedure (2018 to 2024) before, during and after the Covid-19 pandemic, across England. *\*\*DUMMY DATA\*\**

**Figure 2:** Rate of TAVI patients who attended cardiac rehabilitation (2018 to 2024) before, during and after the Covid-19 pandemic, across England *\*\*DUMMY DATA\*\**

**Objective 2**

**Table 1:** Characterisation of patients hospitalised for a TAVI procedure split by cardiac rehabilitation participation.

|  |  |  |  |
| --- | --- | --- | --- |
| **Table 1:** Baseline Characteristics by CR Participation Within 180 Days After TAVI Discharge | | | |
|  | **Cardiac Rehabilitation Participation  (n =XYZ)** | **No Cardiac Rehabilitation Participation  (n =XYZ)** | **All TAVI patients  (n=xyz)** |
| **Age, years, mean (SD)** |  |  |  |
| **Sex, no. (%)** |  |  |  |
| Female |  |  |  |
| Male |  |  |  |
| **Ethnicity, no. (%)** |  |  |  |
| White |  |  |  |
| Black |  |  |  |
| Asian |  |  |  |
| Mixed |  |  |  |
| Other |  |  |  |
| Unknown |  |  |  |
| **Socioeconomic status quintile, no. (%)** |  |  |  |
| 1 (most deprived) |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |
| 4 |  |  |  |
| 5 (least deprived) |  |  |  |
| **Smoking status, no. (%)** |  |  |  |
| Current |  |  |  |
| Former |  |  |  |
| Never |  |  |  |
| Missing |  |  |  |
| **Region no. (%)** |  |  |  |
| East Midlands |  |  |  |
| East of England |  |  |  |
| London |  |  |  |
| North East |  |  |  |
| North West |  |  |  |
| South East |  |  |  |
| South West |  |  |  |
| West Midlands |  |  |  |
| Yorkshire and The Humber |  |  |  |
| **Clinical and lifestyle characteristics** |  |  |  |
| Body-mass index, kg/m2 |  |  |  |
| Mean (SD) |  |  |  |
| Missing, no. (%) |  |  |  |
| NYHA class, no. (%) |  |  |  |
| I |  |  |  |
| II |  |  |  |
| III |  |  |  |
| IV |  |  |  |
| Missing |  |  |  |
| Diabetes |  |  |  |
| Mean (SD) |  |  |  |
| Missing, no. (%) |  |  |  |
| **Other clinical characteristics** |  |  |  |
| On dialysis no. (%) |  |  |  |
| Severe liver disease no. (%) |  |  |  |
| Poor mobility no. (%) |  |  |  |
| History of pulmonary disease no. (%) |  |  |  |
| **Previous cardiac procedures** |  |  |  |
| Previous PCI no. (%) |  |  |  |
| Previous MI no. (%) |  |  |  |
| Previous CABG no. (%) |  |  |  |
| Previous valve no. (%) |  |  |  |
| **Index hospital Status** |  |  |  |
| Cardiac rehabilitation appointments Mean (SD) |  | N/A |  |

**Objective 4**

**Supplementary Material 1**

**Cox proportional hazards model with time-varying exposure – model summary and data structure**

The Cox model estimates the hazard of rehospitalization for heart failure (HF) at any time, accounting for the time-varying participation in cardiac rehabilitation. Calendar time (days since 1 January 2018) will be used as the timescale, and the exposure (participation in cardiac rehab) changes dynamically between patients over the observation period.

**Methods**

To model the effect of cardiac rehabilitation (CR) on rehospitalization for HF using a Cox proportional hazards model, we will create two datasets:

**1st data set: Baseline Structure with 1 Row Per Patient**

This dataset captures one row per patient and summarizes the key events in terms of time since 1 January 2018 (Day 0).

|  |  |
| --- | --- |
| **Variable** | **Description** |
| ID | Unique identifier for each patient. |
| TAVI\_time | Days since 1 January 2018 up to the time of the TAVI procedure. |
| Cardiac\_Rehab\_indicator | 0 (not in CR) or 1 (in CR) at the end of follow-up. |
| Rehab\_Time | Days since 1 January 2018 up to the time when the patient started cardiac rehab (if applicable, else NA). |
| Rehospitalization\_indicator | 1 if the patient was rehospitalized for HF during the follow-up, 0 if censored. |
| Rehosp/censoring\_Time | Days since 1 January 2018 up to when rehospitalization for HF occurred or censoring happened. |
| Covariates | Baseline covariates recorded at the time of TAVI: age at TAVI, sex, ethnicity (5-group classification), socioeconomic deprivation (IMD 2019 quintiles), smoking status, body mass index category, NYHA dyspnea status prior to the procedure, Katz index of functional status, history of poor mobility and diabetes (binary variables), comorbidities (pulmonary, liver, neurological, extracardiac vascular disease), history of myocardial infarction, prior cardiac surgery, left ventricular function, mitral regurgitation, and procedural complications. |

**Example Table:**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **ID** | **TAVI\_time** | **Cardiac\_Rehab\_indicator** | **Rehab\_Time** | **Rehospitalization\_indicator** | **Rehosp/censoring\_Time** | **Age** | **Sex** | **Ethnicity** | **Socioeconomic Status** | **…** |
| 1 | 120 | 1 | 180 | 1 | 250 | 70 | M | White | Low | … |
| 2 | 90 | 0 | NA | 0 | 300 | 65 | F | Asian | High | … |
| 3 | 60 | 1 | 100 | 1 | 220 | 80 | M | Black | Medium | … |

**2nd Dataset: Extended Structure with Time-Split Intervals**

This dataset extends the first dataset by splitting each patient's follow-up period into intervals where exposure to cardiac rehabilitation remains constant. This structure is required for fitting a Cox model with time-varying exposure.

|  |  |
| --- | --- |
| **Variable** | **Description** |
| ID | Unique identifier for each patient. |
| Time\_1 | Start time of the interval (in days since 1st January 2018)  *Either TAVI\_time or Rehab\_time (if the patient received rehab)* |
| Time\_2 | End time of the interval (in days since 1st January 2018)  *Either Rehab\_Time or Rehosp/censoring\_Time* |
| Cardiac\_Rehab\_indicator | Binary indicator for cardiac rehab participation (0 = no, 1 = yes) during the interval.  0 (not in CR) or 1 (in CR) during the interval. |
| Rehospitalization\_indicator | Binary indicator for rehospitalization (1 = rehospitalized, 0 = censored).  1 if rehospitalization for HF occurred during the interval, 0 if censored at the end of the interval. |
| Covariates (Baseline patient characteristics captured at the time of TAVI:) | Age at TAVI, sex, ethnicity (5-group classification), socioeconomic deprivation (IMD 2019 quintiles), smoking status, body mass index category, NYHA dyspnea status prior to the procedure, Katz index of functional status, history of poor mobility and diabetes (binary variables), comorbidities (pulmonary, liver, neurological, extracardiac vascular disease), history of myocardial infarction, prior cardiac surgery, left ventricular function, mitral regurgitation, and procedural complications |

**Example Table:**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **ID** | **Time\_1** | **Time\_2** | **Cardiac\_Rehab\_indicator** | **Rehospitalization\_indicator** | **Age** | **Sex** | **Ethnicity** | **Socioeconomic Status** | **...** |
| 1 | 120 | 180 | 0 | 0 | 70 | M | White | Low | ... |
| 1 | 180.1 | 250 | 1 | 1 | 70 | M | White | Low | ... |
| 2 | 90 | 300 | 0 | 0 | 65 | F | Asian | High | ... |
| 3 | 60 | 100 | 0 | 0 | 80 | M | Black | Medium | ... |
| 3 | 100.1 | 220 | 1 | 1 | 80 | M | Black | Medium | ... |

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