Measuring implementation of a national COVID-19 therapeutic alert following PRINCIPLE trial using OpenSAFELY

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A national NHS COVID-19 therapeutic alert was issued in April 2021 regarding use of inhaled budesonide for patients with COVID-19 and high risk of complications[1] following prepublication of results[2] from the PRINCIPLE trial. During COVID-19 our team has built OpenSAFELY, a secure open source platform executing code across NHS patients' full electronic health records in situ in near-real-time. Using this platform, we find that implementation of the PRINCIPLE trial findings has been minimal.

With NHS England approval, we analysed 24 million people's electronic health records managed by TPP, a GP software provider, linked to death data provided by the Office of National Statistics, SARS-CoV-2 test data from Public Health England, and Admitted Patient Care and Emergency Care Data Set provided by NHS Digital. We identified eligible patients based on their age, positive SARS-CoV-2 PCR test, lack of COVID-19-related hospital admission, COVID-19 complication risk[3], and lack of recent corticosteroid prescription. We then identified budesonide prescriptions within two weeks of positive SARS-CoV-2 test from the NHS alert until July 31st 2021. All code for the platform and analysis is shared under open licenses[4].

Of 11,748 eligible patients, only 43 (0.37%) received inhaled budesonide prescriptions issued by 25 practices (Table 1). There were striking geographic differences, with the South West region having 72% of prescriptions, and 64% of prescribing practices, but only 11% of the eligible population.

We also recognise some limitations. Our data, although large, may not be fully representative and does not include all data from settings such as “out of hours” clinics or COVID-19 treatment centres where different software may be used. However we have assessed open NHS dispensing data and there does not appear to be any substantial increase in budesonide prescription in these settings[4].

Following final publication of PRINCIPLE[5], we will now further monitor changes. More broadly, OpenSAFELY can now execute code securely across 58 million patients’ full electronic health records, and opens the possibility of monitoring implementation of critical new guidance and evidence in near-real-time using fine-grained data covering almost the entire population while preserving patients’ privacy.

Table 1: *Counts of inhaled budesonide prescriptions issued to eligible patients within two weeks of positive PCR test for COVID-19*

Cohort	**Number of budesonide prescriptions in 2 weeks following positive test**	**Count of Patients** *(numbers <10 suppressed)*
All	0	11,748
	1	43
	2	-
Aged 50-64 with COVID-19 Complication Risk	0	2593
	1	13
Aged 65+	0	9,209
	1	30
	2	-

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Conflicts of Interest

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