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Measuring the cost of a pediatric vaccine administration in the UK

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ABSTRACT

The administration of a vaccine dose involves a series of activities prior to and on the day of vaccine delivery. Total vaccination cost should include the cost of each activity, which is often not done or poorly reported.

To calculate those costs a field study was performed in 6 United Kingdom (UK) sites (General Practitioner (GP) practices) during a 4-month period (April–June 2015). First, a workflow map of all the relevant vaccine-related activities per site was obtained through interviews. Second, time estimates for activities happening prior to the vaccination day were obtained through interviews and associated costs were calculated. A prospective, non-interventional study using Time & Motion (T&M) methodology was used to measure time for activities happening on the day of vaccination. Consumables, wastage, and guardian time were also collected. Third, the time for each task and for all tasks combined during the T&M study was analyzed using a random intercept model to account for site effect.

Hundred and twenty-three T&M observations with approximately 20 per site were collected and were equally stratified by vaccination visit during the first year of a baby's life. Total cost per visit was £11.9 (site range: £8.6–£17.0) when supply cost and time for activities prior to the vaccination day were included. Time per dose administrated was 7.1 min (site range: 5.7–9.2) and the associated cost was £4.3 (site range: £3.1–£6.2).

The study demonstrates an accurate reflection of the time and cost involved in a vaccine dose administration in a pediatric setting in the UK. The amount measured is consistent with the current National Health Services fee schedule.

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1. Introduction

Cost of vaccine dose administration has been poorly reported. It is often considered marginal in the developed world as compared with the cost of the vaccine. As pediatric vaccination schemes are getting dense, assessing the time and cost impact of introducing new vaccines with extended dose schemes could become critical. Decision-makers may want to know the marginal cost incurred

Abbreviations: AN, auxiliary nurse; CDP, central data platform; CI, confidence interval; CRF, case report form; GP, general practitioner; HCP, healthcare professional; IEC, independent ethics committee; NHS, National Health Service; RN, registered nurse; SAS, statistical analysis software; T&M, time and motion; UK, United Kingdom; US, United States.

per vaccination visit and per single vaccination dose. This information is necessary to assess the cost implications of introducing a new vaccine in the most cost-efficient way [1].

Time for a vaccine dose administration has previously been reported in the range of 17.3 min in the United States (US) (activities prior to and on vaccination day) [2] and 23.8 min in New Zealand [3] based on diaries and questionnaires. Both studies highlighted that the sample size and the self-reported time estimates led to large variations in the results. Objective observations of time measured by third party individuals should help circumvent those issues.

In the absence of precise cost data on pediatric vaccine dose administration in the United Kingdom (UK), a field study was set up that includes Time & Motion methodology to define the workflow process and to quantify the time spent on completing the different activities identified. T&M is well-established in measuring time especially in production settings [4,5]. In healthcare the aim has often been to measure the dynamics of staff movement and

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the utilization of healthcare resources [6,7]. The method consists in decomposing a process into essential activities and involves the repeated measurement of each pre-specified activity by trained observers using a stopwatch. The study here aimed at calculating the time and cost dedicated by healthcare professionals (HCPs) to the activities of a vaccine dose administration in young children (first year of life). The study also quantifies the consumable usage, the vaccine wastage, and the caregiver time associated with the vaccine administration visit.

2. Methods

2.1. Study design

The workflow of pediatric vaccine administration in the UK was first identified during a feasibility evaluation by interviewing 3 nurses with field experience. A workflow map was then generated listing pre-specified activities prior to and during vaccination day (Fig. 1). Subsequently, a Case Report Form (CRF) was developed with start- and stop-points for those pre-specified activities.

A field study, consisting of two phases, was then conducted in 6 United Kingdom (UK) sites. First, information on time usage for activities performed prior to the vaccination day was collected through an interview at each site. Second, accurate time measurements for activities performed on vaccination day were performed through a T&M study. To remain representative for the UK, site stratification was introduced according to geographical area (north, south, and middle) and population density (rural, urban). Other selection criteria were the General Practitioner (GP) practice's experience in clinical research, the availability of local observers, and interest to participate. Selection of English sites only was

adopted to simplify the Independent Ethics Committee (IEC) approval obtained from each participating site and from the National Research Ethics Service. All participants signed an informed consent.

2.2. Data collection

In each site the head nurse was interviewed to collect information about site characteristics (number of subjects, vaccinations, and visits), vaccination-related activities taking place prior to and on vaccination day with start- and stop- points, the main performer of each activity, and their estimated time. Adjustments to the generic CRF were proposed to accurately reflect each site's practice.

Activities occurring prior to the vaccination day were not using the T&M technique because they occur infrequently, pertain to more than one subject, and may not follow a standardized process.

Time for activities occurring on vaccination day for child visits at 2, 3, 4 and 12–13 months [8] was measured using T&M. All vaccines were delivered via intramuscular (IM) injection with the exception of rotavirus vaccine being delivered orally. Eleven vaccine doses are given during the first year of life during those 4 visits resulting in 2.75 doses on average per visit. Observers at each site received training to measure the time of each activity by identifying the start- and stop-points and to record time onto site-specific CRFs.

Completed CRFs were sent to the Study Coordinating Centre (SCC) on an ongoing basis and status updates were sent in weekly. The SCC issued data clarification forms for missing data, out-of-range values, and illegible or inconsistent responses.

The study outcomes were the HCP time per pre-specified activity measured with a stopwatch (minutes and seconds), total HCP

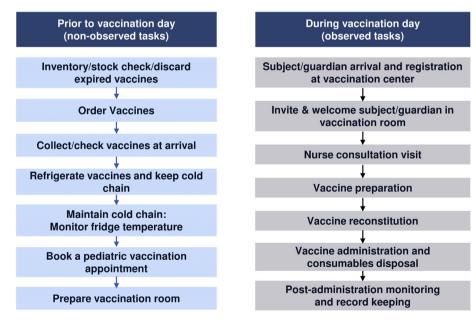


Fig. 1. Chronological listing of pediatric vaccination activities.

Table 1
HCP staff unit cost.

Staff Type	Gross Annual Salary	Other Employer Expenses (Training, Social Security, Contributions, etc.)	Full Loaded Salary Cost	Hours per Annum	Unit Cost (£/min)
Registered nurse	£25,847 [10]	149% [10]	£64,254	1575	0.68
Auxiliary nurse (support staff)	£16,282 [10]	118% [10]	£35,566	1575	0.38

Table 2
Unit costs for consumables

Consumable	Unit cost [11]
Kidney dish	£0.12
Syringe (if not included in vaccine package)	£0.19
Blue needle (if not included in vaccine package)	£0.07
Cotton wool	£0.02
Plaster	£0.05
Gloves (pair)	£0.06
Micropore	£0.05
Paper towel	£0.01
Tissue	£0.05

Source: Supplies costs. www.amazon.co.uk [accessed 05.06.15] [11].

time calculated as the sum of time for each pre-specified activity, and the calculated costs from the perspective of the health care site. The time and cost per vaccine dose administered was obtained by dividing the outcome per vaccination visit by the mean number of vaccine doses administered per visit. Additional outcomes were the guardian time in the GP surgery and the observed quantity and cost of consumables used and wasted vaccine vials.

The study was descriptive and the sample size was based on convenience. The target sample size was set to 20 observations per site, equally distributed across the first four vaccination visits (i.e., 5 observations per visit), for a total target sample of 120 observations. Eventually, 123 observations were performed during April-June 2015.

2.3. Data analysis

For the non-observed activities prior to vaccination day, the time estimate per activity came from the interviews with each head nurse. An estimated time expressed in minutes devoted per month per activity type and with a proportional distribution per HCP type was communicated. That value was divided by the mean number of vaccination visits per month at the site to get an estimated time per visit.

For the observed activities with time collected through the T&M methodology, each time value was chronologically measured and recorded per pre-specified activity. A data point with no value was considered missing; when the site ascertained that the activity did not occur, a 0 time value was set. For activities that occurred but with missing time measurements, imputation was performed using the mean result of available data collected from the observations at the site, if at least 50% of the observations at the site was non-missing. Data were entered in an MS Excel workbook and, after database lock, data were transferred to Statistical Analysis Software (SAS) 9.2.

A random intercept model with site as the second level random effect was used to analyze each time outcome (each pre-specified activity and total HCP time) to correct for site-effect [9]. The model assumed a normal distribution for the random effect as well as for the random error.

Using all the time data across all the sites goodness-of-fit tests (Kolmogorov-Smirnov and the Anderson-Darling test) were conducted to determine the best fitted distribution, which for all time variables was the gamma-distribution. Mean time and corresponding 95% confidence interval (CI) for each site were then calculated. Descriptive statistics for consumables are reported with mean, median, minimum, and maximum.

Cost of HCP time was calculated by multiplying the time with the fully loaded salary cost (Table 1) including gross salary (i.e., before withholding income tax and employee social security contributions) and on-costs (covers all fringe benefits, overtime, shift differential, employer pension plan contributions, etc.). Four HCP types were involved in the process: registered nurse (RN), auxiliary nurse (AN), receptionist (RE), and administrative staff (AS). For AN and other GP surgery support staff a similar salary level as a clinical support worker nursing (community) was assumed. On-costs were estimated between 118% (AS) and 149% (RN). Annual fully loaded salary costs were divided by 1575 working hours per year ([42 w $eeks \times 5 days \times 7.5 h$ per day) to yield a cost per minute of £0.68 and £0.38 for RN and for AN, respectively (Table 1). For each consumable, the mean number was multiplied with the corresponding unit cost taken from publicly available sources [11] (Table 2).

Table 3Site characteristics and time related to activities prior to vaccination day.

	UK-01	UK-02	UK-03	UK-04	UK-05	UK-06
NHS-managed	No	Yes	No	No	Yes	Yes
Number of registered subjects	12,535	11,848	8030	16,950	19,443	13,392
Number of pediatric vaccinations per month (year)	39 (468)	45 (550)	35 (420)	90 (880)	128 (1536)	71 (868)
Frequency of vaccination visits	Clinic once per week	Randomly during the week	Clinic once per week	Clinic twice per week	Clinic once per week	Clinic twice per week
Approximate size of vaccination room; ft ² (m ²)	106.5 (9.9)	140 (13)	100 (9.3)	131 (12.2)	129 (12)	161.5 (15)
Automated self-check in (GP arrival and registration)	Yes	Yes (solely)	Yes	No	Yes (solely)	No
Activities prior to vaccination day (estimated time per mor	nth (HCP responsibl	(e))				
Inventory/stock check/discard expired vaccines	20 min (RN)	195 min (RN)	120 min (RN)	30 min (RN)	65 min (AN)	12 min (RN)
Vaccines and clinical waste disposal	20 min (RN)	30 min (RN)	30 min (RN) 40 min (AN)	30 min (AN)	2 min (RN) 2 min (AN)	20 min (RN)
Ordering vaccines	15 min (RN)	87 min (RN)	40 min (RN)	40 min (RE)	65 min (AN)	65 min (AS)
Vaccines collection/check vaccines at arrival	60 min (RN)	29 min (RN)	20 min (RN)	15 min (RN)	43 min (AN)	20 min (AS)
		23 min (RE)			22 min (RE)	10 min (RE)
Storage of vaccines/keeping cold chain	4 min (RN)	98 min (RN) 3 min (RE)	10 min (RN)	20 min (RN)	22 min (AN)	9 min (AS) 9 min (RE)
Maintain cold chain/monitor fridge temperature	44 min (RN)	76 min (RN)	43 min (RN)	22 min (RN)	108 min (AN)	22 min (RN)
			43 min (AN)	65 min (AN)		22 min (RE
Booking pediatric vaccination appointments	90 min (RE)	99 min (RN)	70 min (RE)	300 min (RE)	448 min (RE)	240 min (RN)
		54 min (RE)				27 min (RE)
Prepare vaccination room on vaccination day, per day (prior to guardian arrival)	10 min (RN)	5 min (RN)	30 min (RN)	5 min (RN)	15 min (RN)	5 min (RN)
Estimated average time per visit	7. 6 min	13.9 min	15.6 min	7.1 min	6.6 min	9.8 min

^{*}UNK, Unknown; RN, Registered Nurse; AN, Auxiliary Nurse; RE, Receptionist; AS, Administrative Staff; NHS, National Health Service; GP, General Practitioner; HCP, Healthcare Professional.

Table 4Active HCP time by activity per single vaccine administration process (pooled and per site, corrected for site effect).

Time spent by HCP per activity per visit (minutes)	Pooled	UK-01	UK-02	UK-03	UK-04	UK-05	UK-06
Guardian/subject arrival and registration at GP surgery	0.3	0.8	0.0	0.4	0.3	0.0	0.5
Invite and welcome guardian/subject in the vaccination (consultation) room	0.4	0.6	1.1	0.0	0.5	0.0	0.4
Nurse consultation visit	3.1	2.9	3.2	2.2	3.2	3.0	3.9
Vaccine preparation	0.5	0.5	0.7	0.5	0.4	0.5	0.4
Vaccine reconstitution	1.0	1.2	1.5	0.7	0.8	0.9	1.1
Vaccine (s) administration and consumables disposal	1.4	0.9	2.2	1.0	1.3	1.5	1.3
Record keeping and post-administration monitoring	2.8	1.9	2.6	2.2	2.0	4.4	3.7
Total active HCP time	9.5	8.8	11.3	7.0	8.5	10.3	11.3
Lower 95% CI	7.7	8.2	9.9	6.1	7.4	9.5	9.9
Higher 95% CI	11.3	9.4	12.8	7.9	9.6	11.0	12.6
Total time spent by HCP type (min)							
RN & AN	8.6	8.0	11.3	6.6	8.2	5.7	10.7
RE/AS	0.9	0.8	0.0	0.4	0.3	4.5	0.6

AN: Auxiliary Nurse; AS: Administrative Staff; CI: Confidence Intervals; GP: General Practitioner; HCP: Health Care Professional; RE: Receptionist; RN: Registered Nurse; UK: United Kingdom.

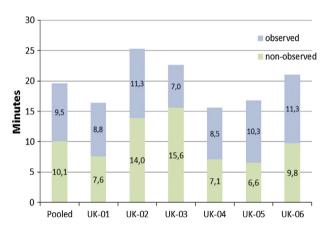


Fig. 2. Total HCP time per single vaccine administration process (observed and non-observed time; pooled and per site). UK, United Kingdom.

3. Results

3.1. Site characteristics and activities prior to the vaccination day

Information obtained from head nurses per site is summarized in Table 3. Half the participating GP surgeries were NHS-managed. The others operated as independent contractors. The number of pediatric vaccinations per month ranged between 35 (UK-03) and 128 (UK-05).

Mean time for activities prior to the vaccination day was 10.1 min per visit (site range: 6.5 to 15.6 min). 5.4 min (57%) were attributable to the RN and 4.7 min (43%) to the AN and other staff.

3.2. Activities on vaccination day

Mean observed HCP time, adjusted for site-effect, was 9.5 min per visit (site range: 7.0 to 11.3 min; 95% CI: 7.7–11.3). The HCP time per activity is shown in Table 4 (pooled and per site). 8.6 min (90%) was attributable to the RN and 0.9 min (10%) to the AN (see Table 4).

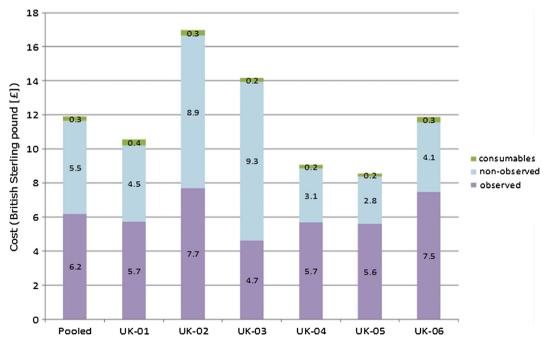


Fig. 3. Total cost per single vaccine administration process (pooled and per site). UK, United Kingdom.

3.3. Total HCP time and additional time information

Total mean HCP time was 19.6 min, with 9.5 min for activities taking place on vaccination day and 10.1 min for activities prior to the vaccination day (site range: 15.6 to 25.3 min) (see Fig. 2). Total mean time per dose administrated was 7.1 min (site range: 5.7 to 9.2 min).

Mean guardian time in the GP surgery, including waiting time, was 23.9 min (site range: 17.2 to 30.1 min). Mean guardian time in the vaccination room was 8.4 min (site range: 5.7 and 12.7 min).

The consumables usage was similar and standardized among sites. Mean consumables usage consisted of 0.7 kidney dishes, 0.9 blue needles, 1.7 cotton wool balls, 1.4 plasters, 0.4 micropore plasters, and 0.4 paper towels. Wastage of 1 vial during the 123 observations was reported; the vaccine was denied on religious grounds (i.e., the measles, mumps, and rubella vaccine contains porcine gelatin).

3.4. Cost per pediatric vaccine administration and per dose

The total cost for a pediatric vaccination process, excluding the cost of the vaccine and wastage, was £11.9 (site range: £8.6 to £17.0), including supplies (£0.3) and preparation time prior to the vaccination day (£5.5) (Fig. 3). The HCP cost for a vaccination process based on T&M data alone was £6.2 (site range: £4.7 to £7.7). The cost per pediatric administration dose, assuming 2.75 doses per visit, was £4.3 (site range: £3.1 to £6.2).

4. Discussion

This field study in 6 GP surgeries across England showed that total time per vaccine administration visit was 19.6 min (9.5 min observed time and 10.1 min non-observed time) or 7.1 min per dose administered, resulting in a cost per vaccination visit of £11.9 and a cost per dose of £4.3. The results should be interpreted with caution as half the time estimate is based on interviews which could be considered less robust information (see further).

The T&M study also showed that the mean guardian time in the GP surgery was 23.9 min with 8.4 min spent in the vaccination room. In most sites all vaccination-related activities took place in the vaccination room with the guardian being present. One site (UK-04) organized the vaccine administration flow differently: only two activities (nurse consultation visit and vaccine(s) administration/consumables disposal) took place with the guardian in the vaccination room resulting in a shorter stay. Guardian time in the waiting area was subject to individual site organization policies. For instance, UK-03 booked multiple appointments for the same timeslot to mitigate an observed high rate of missed appointments: the appointee attending at the same time had therefore a prolonged waiting time.

The study aimed at generating results reflective of GP surgeries across the county. As site characteristics may be important predictors of process flow and time, the site sample was balanced by including different geographical areas (3 South-England, 1 Midlands, and 2 North-England), equal numbers of urban and rural settings (3 each), and equal distribution between NHS-managed and non-NHS-managed sites (3 each). This enabled reducing expected inter-site variability. As all participating GP surgeries were located in England, the sample cannot be considered to be fully representative for the UK. However, expecting that vaccination schemes and management practices are similar across the UK, the results serve in making inferences for England and could be relevant for the wider UK setting as well [12]. Finally, we applied a random intercept model as it was deemed the most suitable method to

adjust for the assumed site-effect and to obtain more precise estimates and confidence intervals.

Process workflow and time outcomes could also be highly variable within sites due to other characteristics such as patient age, vaccination visit sequence, guardian specificities (e.g., religious beliefs), and process measurement (i.e. person being observed and the observer measuring time). We mitigated these potential biases by stratifying each site sample to achieve an equal number of 5 observations per vaccination visit, defining clear start- and stop-points for each activity, performing standardized observer training, and offering ongoing support throughout data collection.

Workflow mapping at each site is critical to understand how the whole process is being organized. During those interviews, differences in the way GP practices organize their pediatric vaccination programs became apparent and the CRFs were customized accordingly. Overall, vaccine administration processes seemed harmonized among sites for activity distribution. HCP staff involvement, and total time dedicated to those activities. Our study focused on the pooled results by design, and did not explore individual site results. During the workflow mapping, various covariates were identified that may impact both workflow and time, including visit sequence, number of reconstitutions, and number of IM vaccine administrations. The impact of each covariate on time was assessed as part of exploratory analyses and results are shown in the Appendix. Nurse consultation duration was significantly higher for a first visit. Adding a reconstitution (one to two) or an IM administration (two to three) significantly increased reconstitution duration and vaccine administration duration, respectively. However, the overall time spent by a subject/guardian is the factor determining the daily activity volume of a GP surgery. Dose administration time and any required reconstitution do not affect the overall time spent per visit as much.

Following a micro-costing approach, time was transferred to cost by using national unit values. Consumables costs associated with the vaccination process were also added. The wastage cost of one unused vial has not been included in the analysis as it represented less than 0.3% (1/338) of the vaccines being administered. The cost of cold-chain equipment (fridges) has not been included either. First, equipment is typically used for various purposes and it is complex to precisely apportion equipment cost to vaccines. Second, equipment costs are depreciated over a number of years, which may be variable by site which further complicates its estimation.

The total cost for a pediatric vaccination process, excluding the cost of the vaccine, was estimated at £11.9 or £4.3 per single vaccine dose, which is consistent with earlier findings in the UK [13,14]. These findings may be of interest to various stakeholders. National payers and Health Technology Assessment bodies may want to understand how a new intervention impacts HCP workload within busy GP practices, and how it affects overall health care delivery efficiency. Regional payers or commissioners may be interested in how modifications to the immunization scheme impact payments. Healthcare providers on the other hand may focus on the impact of changes in the immunization schedule on their workload (e.g. adding a new vaccine to an existing visit, or adding an extra vaccine visit), and also look to balance income/revenue stream with the costs of running their GP practices.

The present study has some limitations. As this is a descriptive study, no sample size calculation was performed but a convenience sampling approach was adopted, which was partly driven by budget limitations. However, the sample was stratified by expected predictors of time (geography, setting, ownership, and vaccine visit sequence) to reduce the inter- and intra-site variability and to generate more precise results that are reflective of a heterogeneous population. Indeed, the narrow 95% CI for the total active HCP time (7.7–11.3) suggests a good precision of the estimate. Another lim-

itation is the combination of opinion-based and observed results to yield total estimated HCP time. The T&M study only collected time for standardized, well-defined activities that took place during vaccination day and were directly attributable to an individual child. Many other activities associated with vaccination and happening prior to vaccination day are typically performed with lower frequency and/or for multiple children (e.g. inventory and ordering) that could not be included in the observational study. Our results revealed that potentially 50% of the total time could be associated with those non-observed activities. It is well-known that opinionbased estimates may not offer a realistic reflection of time dedicated to activities in the real world and therefore need to be interpreted with caution. However, non-observed time should be considered if the aim is to obtain an estimate that covers all vaccination-related activities. Finally, the estimated cost per minute per staffing level was based on assumptions around the fixed costs associated with employment. In real life, salary costs vary depending on experience, years of service, and geographic location. Therefore, the cost results presented here are mere point values and should therefore be interpreted with caution.

5. Conclusion

Pooled data from 6 GP surgeries in the UK showed that the mean HCP time for a vaccine administration visit was 19.6 min (observed and non-observed data). Apportioning total time equally across the mean number of doses given per visit (2.75) yielded a time per dose administered of 7.1 min, with an associated cost of £4.3, excluding the vaccine acquisition cost. This cost is in line with the current fees allocated per administration of a vaccine dose, when co-administered with other vaccines during the same visit. However, the already busy immunization scheme in the UK may not allow for a new vaccine to be added on top of the existing schedule. If a new vaccine were to require a new visit on a new day, the associated costs would be more substantial. But if an existing vaccine could be switched to an equally effective alternative with a lower dose scheme, this may become an attractive option for pediatric immunization as it lowers the overall vaccine administration cost whilst freeing up time for a new vaccine introduction.

Conflict of interest

EDC and SM were employees of UBC: An Express Scripts Company at the time when the research was conducted. UBC: An Express Scripts Company received funding from the GSK group of companies to complete the work disclosed in this manuscript, and from Novartis, outside of the submitted work. BS is an employee of the GSK group of companies and holds shares in the GSK group of companies. XL was an employee of the GSK group of companies at the time the study was conducted.

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data. GSK Biologicals SA also covered all costs associated with the development and publication of this manuscript.

Contributorship

BS, EDC, SM conceptualized and designed the study; BS, EDC, and SM developed the model and acquired the data, and BS, EDC, SM and XL analyzed the data; BS drafted the manuscript.

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Appendix A. Supplementary material

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.vaccine.2017.11.042.

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