The Impact of Pediatric-Specific Vancomycin Dosing Guidelines: A Quality Improvement Initiative

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BACKGROUND AND OBJECTIVES: There are limited data guiding vancomycin dosing practices in the pediatric population to target the goal troughs recommended by national vancomycin guidelines. In this study, we sought to improve adherence to guideline trough targets through a quality improvement intervention.

METHODS: A retrospective analysis was first conducted to assess baseline performance. A multidisciplinary team then developed and implemented a standardized dosing algorithm recommending 15 mg/kg per dose for mild and moderate infections (goal trough: 10–15 µg/mL) and 20 mg/kg per dose for severe infections (goal trough: 15–20 µg/mL), both delivered every 6 hours (maximum single dose: 750 mg). The impact of the intervention was evaluated prospectively using standard statistics and quality improvement methodology. The outcome measures included the percentage of patients with an initial therapeutic trough and the time to therapeutic trough.

RESULTS: A total of 116 patients (49 preintervention, 67 postintervention) were included. Postintervention, there was a significant increase in the percentage of patients with an initial therapeutic trough (6.1% to 20.9%, \( P = .03 \)) and in the percentage of patients with initial troughs between 10 and 20 µg/mL (8.2% to 40.3%, \( P < .001 \)). The time to therapeutic trough decreased from 2.78 to 1.56 days (\( P = .001 \)), with the process control chart showing improved control postintervention. Vancomycin-related toxicity was unchanged by the intervention (6.1% versus 4.5%; \( P = .70 \)).

CONCLUSIONS: Using quality improvement methodology with standardized higher initial vancomycin doses, we demonstrated improved adherence to national trough guidelines without noted safety detriment.

Vancomycin is an antibiotic commonly used to treat Gram-positive infections in hospitalized patients, particularly infections caused by methicillin-resistant Staphylococcus aureus (MRSA). The most recent American Society of Health-System Pharmacists (ASHP) and Infectious Diseases Society of America (IDSA) consensus guidelines suggest a goal trough of 15 to 20 µg/mL in serious or invasive infections, significantly higher than previously used, to enhance treatment efficacy and decrease antibiotic resistance.1,2 These higher troughs are generally used as a surrogate marker to target an area under the curve/minimum inhibitory concentration (AUC/MIC) ratio of \( \geq 400 \), which has been shown to correlate with improved clinical effectiveness in patients infected with S. aureus with an MIC \( \leq 1 \) mg/L.1 To achieve this trough goal, the dose recommended...
was 15 mg/kg every 6 hours for pediatric patients. It is unclear, however, if the high trough goal can be reliably attained by using the suggested dosing and if the use of higher doses will improve target attainment within a clinically appropriate time interval.

Similar to previous reports, we have observed disparate and inconsistent dosing practices at our institution as well as frequent subtherapeutic initial troughs and lengthy time intervals for patients to reach therapeutic levels. For many prescribers, the fear of causing renal damage may overshadow the concern for underdosing of patients.

Consequently, we conducted a quality improvement (QI) project to optimize vancomycin practices at our institution in line with national guidelines. Our specific aims were threefold: (1) study which vancomycin doses would more reliably lead to desired troughs; (2) based on this information, develop new standardized dosing guidelines for pediatric patients; and (3) improve adherence to the IDSA/ASHP recommended trough goals through the application of the new guidelines.

**METHODS**

A multidisciplinary team comprised of 3 physicians, an attending nurse, and a pediatric pharmacist was assembled to conduct this QI project. The study consisted of 3 phases: (1) a baseline diagnostic chart review; (2) development, approval, and implementation of standardized pediatric vancomycin dosing guidelines; and (3) postintervention prospective monitoring and data analysis. This project was undertaken as a QI initiative and, as such, was not formally supervised by the institutional review board per its policies.

**Phase 1: Diagnostic Data and Baseline Performance**

In phase 1, we performed a retrospective chart review to evaluate vancomycin prescribing practices at our institution and to determine the relationship between the initial dose used and the resultant trough. Over a 4-year period (2010 to 2013), patients who were 1 month to 18 years old, admitted to the pediatric floors or the PICU, treated with at least 3 similar and uninterrupted doses of vancomycin, and who had an appropriately timed trough obtained at steady-state (defined as within 1 hour before the fourth or fifth dose) were included. Patients were excluded if they had an acute kidney injury, chronic kidney disease or renal transplant, cystic fibrosis, or if they were on vasopressors for cardiovascular instability, or aminoglycoside therapy while being treated with vancomycin. The abstracted data included patient demographics, medical history, presumptive and confirmed diagnosis, details of each vancomycin dose and frequency, serum vancomycin trough levels, serum creatinine levels if obtained, concomitant use of nonsteroidal antiinflammatory agents, intravenous contrast, or aminoglycoside antibiotics, as well as all-cause adverse events. Nephrotoxicity was defined as ≥2 consecutive serum creatinine levels of 0.5 mg/dL above the patient’s baseline or ≥50% of the patient’s baseline, whichever was greater.

Mild to moderate infections were assigned a trough target of 10 to 15 µg/mL, whereas severe infections, including those caused by MRSA, were assigned a trough target of 15 to 20 µg/mL, as per IDSA/ASHP guidelines. We first evaluated the relationship between the initial dose prescribed and the resultant trough level. Two additional variables were also analyzed: (1) the percentage of patients with an initial therapeutic trough (PITT), as defined by the severity of infection and target trough combination above; and (2) the time to therapeutic trough (TTT), which represented the length of time needed to reach a therapeutic trough, including the time spent for a dose adjustment when needed.

**Phase 2: Development of the Guidelines and Implementation of the Intervention**

In phase 2, based on diagnostic data and baseline performance, we created standardized vancomycin dosing guidelines with the input of local subject matter experts. The guidelines proposed that patients with mild/moderate infections receive 15 mg/kg per dose every 6 hours (maximum: 750 mg/dose) and those with severe infections, including MRSA, receive 20 mg/kg per dose every 6 hours (maximum: 750 mg/dose). Goal troughs remained the same as detailed in phase 1. Monitoring parameters were also included in the guidelines. After additional refinement with frontline users, including nurses and pharmacists, and approval by our institution’s medication education safety and approval committee, the guidelines (Fig 1) were implemented on January 1, 2015. Implementation included dissemination to the pediatric inpatient units and the PICU and postings in the resident work rooms, nursing stations, pharmacy, and on the hospital’s central policies and procedures Web site. Residents and nurses were introduced to the guidelines at dedicated conferences and through periodic e-mail communications. House staff received laminated cards to attach to their identification badges to enable quick access to the guidelines when needed.

**Phase 3: Surveillance and Analysis**

In phase 3, we conducted prospective postintervention active surveillance of vancomycin use over a 14-month period (January 2015 to February 2016), which was a QI initiative and, as such, was not formally supervised by the institutional review board per its policies.
Vancomycin Dosing and Monitoring Guidelines in Pediatric Patients

Patient population

- Age: 1 month – 18 years old
- Healthy at baseline
- Absence of:
  - cardiovascular instability requiring pressor support at the start of vancomycin therapy
  - acute kidney injury, chronic kidney disease or renal transplant
  - concomitant use of other nephrotoxic antibiotics (e.g. aminoglycosides)
  - prior intolerance to vancomycin (excluding Red Man Syndrome)

Recommended dosing

<table>
<thead>
<tr>
<th>Indication for treatment/ Empiric coverage</th>
<th>Starting dose</th>
<th>Goal trough (draw 5-6 hours after the 3rd dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild/Moderate infection, such as: cellulitis +/- abscess, fever/neutropenia, CA-pneumonia</td>
<td>15 mg/kg IV every 6 hours (max 750 mg/dose)</td>
<td>10-15 mg/L</td>
</tr>
<tr>
<td>Severe infection, such as: MRSA infection, osteomyelitis, sepsis, meningitis</td>
<td>20 mg/kg IV every 6 hours (max 750 mg/dose)</td>
<td>15-20 mg/L</td>
</tr>
</tbody>
</table>

Safety and monitoring

- Monitor strict I/O and ensure patient remains well hydrated during therapy
- Renal monitoring:
  - Obtain baseline BUN/Cr then every 3-5 days
  - Monitor more frequently if concern for nephrotoxicity, sepsis/severe infection, concomitant nephrotoxic agents
- Vancomycin levels:
  - Initial trough – obtain 5-6 hours after start of 3rd dose
  - Repeat levels should be obtained:
    - for any change in dosing – obtain 5-6 hours after start of 3rd new dose
    - every 3-5 days once therapeutic, or sooner if change in renal function or concomitant nephrotoxic agents
- Consults:
  - Infectious Disease consultation for severe/invasive infections
  - Nephrology consultation if concern for nephrotoxicity
- Pharmacy Pager: ######


FIGURE 1
The MGHc vancomycin guidelines (adapted from the original document for the purposes of this manuscript). BUN/Cr, blood urea nitrogen/creatinine; CA-pneumonia, community-acquired pneumonia; I/O, input/output; IV, intravenous; max, maximum.
All patients who received vancomycin were screened. The inclusion and the exclusion criteria were identical to those used in phase 1. Data abstraction was completed from the charts of all patients who met inclusion criteria. To monitor potential adverse effects of the guidelines in real time, 4 team members received daily vancomycin trough levels for pediatric patients from the previous 24 hours. When a supratherapeutic level was identified, a team member investigated the specific circumstances within 8 hours of the report, directly communicated with the patient’s clinical care team, and then discussed the case with the other vancomycin team members. All data abstracted in phase 3 were similarly analyzed as in phase 1.

**Statistical Analyses**

Statistical analyses were done by using both standard statistics as well as QI methods. Simple descriptive statistics were used to characterize the pre- and postintervention study populations. One continuous variable (TTT) and 3 dichotomous variables (PITT, patients with first vancomycin trough at 10–20 µg/mL, and patients with vancomycin-related toxicity) were identified for clinical relevance and compared in pre- and postguideline data sets. For continuous variables, diagnostics for normality were applied. The t test was used for normally distributed data sets, and the Mann–Whitney nonparametric test was used for data sets that did not pass normality testing. For each dichotomous variable, a 2 × 2 table was constructed, and odds ratios, confidence intervals (CIs), and P values were calculated by using the \( \chi^2 \) test. If \( \geq 1 \) cell in a table had \( \leq 5 \) measurements, the Fisher’s exact test was used instead of \( \chi^2 \), because it calculates P values with better accuracy for small sample sizes.

For this QI project, the process measure was the application of the Massachusetts General Hospital for Children (MGHfC) vancomycin guidelines. The outcome measures were PITT, patients with first trough between 10 and 20 µg/mL, and TTT. Vancomycin-related toxicities, including nephrotoxicity, were the balance measures. The quality control methods used for analyses included process control charts with 3-σ control limits and special cause rules based on the Institute for Healthcare Improvement.

We compared the preguideline patient population and the postguideline, compliant patient population. We also compared the preguideline population and all evaluable postguideline patients regardless of compliance with the guidelines. Noncompliance was defined as those patients who met inclusion criteria, but were prescribed vancomycin in doses and/or intervals different than those proposed by the guidelines, or patients who were prescribed vancomycin appropriately, but had incorrectly timed doses or incorrectly timed troughs.

In addition, we combined both pre- and postintervention data sets and calculated the means and 95% CIs of the initial troughs when the doses of 15 mg/kg per dose every 6 hours and 20 mg/kg per dose every 6 hours were used.

Standard statistical analyses were performed by using the Prism software package (version 7.02; GraphPad Software, Inc, La Jolla, CA) and a statistical process control chart was completed through QI Macros for Excel (KnowWare International, Inc, Denver, CO). Significance tests were all 2-tailed at \( P < .05 \).

**RESULTS**

A total of 116 patients were included. In phase 1, 49 patients met inclusion criteria over the 4-year retrospective review period, out of a total of 506 patients screened (9.7%). Patient accrual was hindered by the high number of patients who had a change in dose before initial trough measurement and/or incorrectly timed troughs. In this preintervention group, there was significant heterogeneity in the doses and intervals prescribed (Fig 2A) with an overall trend of higher total daily doses yielding higher average troughs (Fig 2B). This provided the rationale for recommending higher initial doses in the subsequent guidelines. In the postintervention phase, 127 patients out of 305 patients screened (41.6%) met inclusion criteria, but only 67 patients were treated according to the recommended guidelines, with an overall compliance rate of 52.8% (67 out of 127 patients) (Fig 3). Of the 60 noncompliant patients, only 8 had interpretable troughs.

The preguideline population and the postguideline, compliant patient population were comparable overall (Table 1). Younger patients predominated in both groups, along with boys. A large but comparable proportion of both groups were patients admitted to the PICU, likely reflective of the comparatively sicker population in need of vancomycin therapy while hospitalized. The proportion of patients who achieved a therapeutic trough during their hospitalization was not significantly different between both groups.

The impact of the intervention is illustrated in Table 2 and Fig 4. There was a significant increase in the percentage of PITT (6.1% vs 20.9%, \( P = .03 \)) as well as a significant decrease in the TTT (2.78 days vs 1.56 days, \( P = .001 \)) (Table 2). The percentage of patients with first trough between 10 and 20 µg/mL rose from 8.2% in phase 1 to 40.3% in phase 3 (\( P < .001 \)) (Table 2), indicating a significant proportion of patients at or close to the therapeutic target. In the statistical process
FIGURE 2
Prescribing and monitoring outcomes in the preintervention population. A, Distribution of dosing frequencies in the preintervention population. B, Relationship between initial dose and average initial trough in the preintervention population. *The actual doses are equal to or within 10% of the dose listed. Q6H, every 6 hours; Q8H, every 8 hours; Q12H, every 12 hours.
control chart (XmR chart) (Fig 4), the baseline period revealed wide variability in TTT. Postintervention, all data points were within tighter control limits, indicating a process in more control with improved TTT.

When comparing the preguideline population ($N = 49$) to all postguideline patients who met inclusion criteria and had interpretable troughs ($N = 75$; 67 patients who were guideline compliant and 8 patients who were noncompliant and had interpretable troughs), a similar trend was noted. The percentage of patients with first trough between 10 and 20 µg/mL was improved by the guidelines (8.2% vs 37.3%, $P < .001$). There was a trend for improvement for percentage of PITT (6.1% vs 18.4%, $P = .06$). TTT and toxicity calculations were similar to those calculated when preguideline and postguideline, compliant patients were compared, because the 8 noncompliant patients with interpretable troughs had no vancomycin-associated kidney injury and none achieved therapeutic levels while hospitalized.

When patients from both pre- and postintervention data sets were combined, the average initial trough was 7.49 µg/mL in 49 patients who

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**FIGURE 3**

Flowchart of the postintervention patient population. a Overall compliance rate with the guidelines was 52.8% (67 patients out of 127 patients who met inclusion criteria). b Noncompliance was defined as those patients who met inclusion criteria but were prescribed vancomycin in doses and/or intervals different than those proposed by the guidelines, or patients who were prescribed vancomycin appropriately, but had incorrectly timed doses or incorrectly timed troughs.
were dosed at 15 mg/kg per dose every 6 hours (95% CI: 6.45–8.39) and 12.7 µg/mL in 31 patients who received 20 mg/kg per dose every 6 hours (95% CI: 10.54–15.09).

Although limited by the relatively small numbers of patient encounters per group, the observed proportion of vancomycin-related toxicities was low in both study groups and unchanged by the intervention (Table 2). In each phase 1 and phase 3 patient cohorts, 3 patients developed vancomycin-related acute kidney injury, all of whom recovered.

### DISCUSSION

The most recent vancomycin guidelines recommend dosing of 15 mg/kg every 6 to 12 hours to achieve goal troughs of 15 to 20 µg/mL for serious and invasive infections. The results of recent studies, however, suggest that it is difficult to reliably attain troughs in this range by using the recommended dose and interval. The principal goal of this QI project was to improve adherence to the national guidelines with timely and consistent attainment of the recommended trough levels through the use of higher, illness severity-specific initial doses. Although previous research has suggested using higher doses, this is the first study to implement this in pediatric clinical practice and prospectively analyze its impact.

The development of the MGH/C guidelines relied on 2 premises: higher initial daily doses and a fixed interval between doses. Higher dosing was supported by the preintervention results (Fig 2B), as well as by previous research. In studies using 15 mg/kg every 6 hours, only 6.76% or 13% had troughs between 15 and 20 µg/mL, and the average resultant trough was 10.7 µg/mL. Another retrospective review by Geerlof and Boucher found that only 31.7% of pediatric patients treated with 60 mg/kg per day had troughs between 10 and 20 µg/mL. Larger doses >60 mg/kg per day have therefore been proposed because low troughs may contribute to treatment failures and increased bacterial resistance.

A dosing equation by Eiland et al predicted that, for patients with uncomplicated infections, 70 mg/kg per day should yield a trough of 10 µg/mL and 85 mg/kg per day should yield a trough of 15 µg/mL. Although cognizant of the potential risk of dose-related vancomycin nephrotoxicity, the aggregate of the above results, as well as our support the need to use higher vancomycin doses to meet the IDSA-recommended goal troughs of 15 to 20 µg/mL for serious infections.

The fixed interval of every 6 hours between doses was chosen for 2 reasons. First, it provided an earlier opportunity for trough measurement and dose adjustment as well as evaluation of toxicity in comparison with a dosing schedule of every 8 or 12 hours. Second, it minimized the number of variables in dose adjustments for frontline users by only allowing changes in individual dose versus potentially changing the dose and the interval. The doses

### Table 1

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Preguideline Population (N = 49)</th>
<th>Postguideline Compliant Population (N = 67)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (y)</td>
<td>5.66</td>
<td>5.18</td>
<td>.83a</td>
</tr>
<tr>
<td>Age distribution, y, N (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;2</td>
<td>20 (40.8)</td>
<td>27 (40.3)</td>
<td>.96b</td>
</tr>
<tr>
<td>2–6</td>
<td>15 (26.5)</td>
<td>20 (29.8)</td>
<td>.70b</td>
</tr>
<tr>
<td>6–12</td>
<td>6 (12.2)</td>
<td>7 (10.4)</td>
<td>.76b</td>
</tr>
<tr>
<td>12–18</td>
<td>10 (20.4)</td>
<td>13 (19.4)</td>
<td>.89b</td>
</tr>
<tr>
<td>Sex, N (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Girl</td>
<td>17 (34.7)</td>
<td>30 (44.8)</td>
<td>.27b</td>
</tr>
<tr>
<td>Boy</td>
<td>32 (65.3)</td>
<td>37 (55.2)</td>
<td>.27b</td>
</tr>
<tr>
<td>Mean weight (kg)</td>
<td>25.29</td>
<td>20.57</td>
<td>.57a</td>
</tr>
<tr>
<td>Patients who achieved a therapeutic trough, N (%)</td>
<td>20 (40.8)</td>
<td>25 (34.3)</td>
<td>.47b</td>
</tr>
<tr>
<td>Patients who achieved a therapeutic trough, N (%)</td>
<td>18 (36.7)</td>
<td>31 (46.3)</td>
<td>.40b</td>
</tr>
</tbody>
</table>

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* Mann-Whitney test.
* *X2*.

### Table 2

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Preguideline Population (N = 49)</th>
<th>Postguideline Compliant Population (N = 67)</th>
<th>Relative Risk (Effect Size)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>PITT, %</td>
<td>6.1 (N = 3)</td>
<td>20.9 (N = 14)</td>
<td>2.63</td>
<td>.03b*</td>
</tr>
<tr>
<td>Patients with first trough 10–20 µg/mL, %</td>
<td>8.2 (N = 4)</td>
<td>40.3 (N = 27)</td>
<td>4.10</td>
<td>&lt;.001c*</td>
</tr>
</tbody>
</table>
| TTT mean d (µg/mL)                               | 2.78b (1.99–3.56)                | 1.58b (1.22–1.89)                           | N/A                        | .001d*
| Patients with vancomycin-related toxicity, %     | 6.1 (N = 3)                      | 4.5 (N = 3)                                 | 0.84                       | .70b|

**PITT:** 10–15 µg/mL for patients with mild/moderate infections and 15–20 µg/mL for patients with MRSA/severe infections.
* Fisher’s exact test.
* In 18 patients who achieved a therapeutic trough during hospitalization.
* In 31 patients who achieved a therapeutic trough during hospitalization.
* Excluding red man syndrome. All toxicities documented were vancomycin-related acute kidney injury.
* P < .05.
and interval used in our guidelines were ultimately devised to balance the higher doses needed for goal trough attainment and the potential risk of dose-related vancomycin nephrotoxicity.

Although the preintervention results demonstrated inconsistent and largely ineffective practices (Fig 2, Table 2), the postintervention analysis of patients compliant with the guidelines (N = 67) showed an in-control process (Fig 4) with a substantial improvement in trough measurements and a decrease in TTT by 29.3 hours (Table 2). When the preguideline population (N = 49) was compared with all postguideline patients who met inclusion criteria and had interpretable troughs (N = 75), similar results were noted. However, the percentage of PITT became only marginally significant (P = .06), essentially highlighting the need for improved compliance with the guidelines. The intervention also allowed streamlining of practices with an effective study accrual of 67 patients out of 305 patients screened (22.0%) (Fig 3) compared with 49 patients out of 506 patients screened (9.7%) preintervention (P < .001).

Although the numbers of patients evaluated were relatively small in both study groups, we did not observe a significant increase in vancomycin-related toxicities. All documented toxicities were reversible kidney injury. The guidelines emphasize careful attention to fluid balance while on therapy and more frequent laboratory monitoring in ill patients or those with concomitant use of nephrotoxic agents. It is our opinion that more emphasis should be placed on ensuring optimal pharmacodynamic vancomycin exposure to improve drug efficacy and avoid the development of resistance, rather than on the prevention of infrequent and largely reversible toxicities. These guidelines continue to be our hospital’s routine clinical practice and are also now being implemented at our community hospital sites.

Despite these noted improvements, the MGH/C guidelines failed to consistently produce therapeutic troughs in all patients. Higher or perhaps more age-specific doses are needed. It may also be that trough measurement is not the optimal approach to monitoring vancomycin efficacy and safety. There is poor correlation between vancomycin trough levels and clinical outcomes in the therapy of S. aureus infections. The AUC/MIC pharmacodynamic index is best predictive of vancomycin efficacy, and trough
The vancomycin prescribing guidelines suggested in this study offer a relatively simple and safe approach to better conform to the IDSA and ASHP trough targets. The intervention was relatively low effort to implement at a minimum cost. In dynamic hospital environments, there are frequent opportunities for education and reinforcement of such policies, making our project sustainable and fully applicable to other institutions. Future areas of interest include the impact of these guidelines and the shortened TTT on direct clinical, microbiological, economic and safety outcomes. Other research efforts should evaluate the utility of other dosing schema in pediatric populations, such as loading doses or continuous infusions in comparison with intermittent doses, and the AUC/MIC methodology in comparison with trough measurements.

**ACKNOWLEDGMENTS**

We thank the MGH/C Quality and Safety Committee for their support of this work.

**ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASHP</td>
<td>American Society of Health-System Pharmacists</td>
</tr>
<tr>
<td>AUC/MIC</td>
<td>area under the curve/minimum inhibitory concentration</td>
</tr>
<tr>
<td>CI</td>
<td>confidence interval</td>
</tr>
<tr>
<td>IDSA</td>
<td>Infectious Diseases Society of America</td>
</tr>
<tr>
<td>MGH/C</td>
<td>Massachusetts General Hospital for Children</td>
</tr>
<tr>
<td>MRSA</td>
<td>methicillin-resistant Staphylococcus aureus</td>
</tr>
<tr>
<td>PITT</td>
<td>patients with initial trough at therapeutic level</td>
</tr>
<tr>
<td>QI</td>
<td>quality improvement</td>
</tr>
<tr>
<td>TTT</td>
<td>time to therapeutic trough</td>
</tr>
</tbody>
</table>

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