The Dutch CISOE-A framework for cytology reporting increases efficacy of screening upon standardisation since 1996

S Bulk, F J van Kemenade, L Rozendaal, C J L M Meijer

**Aim:** To describe the effect of introducing the CISOE-A framework for reporting cervical cytology results, including changes in repeat and referral advice in the Netherlands, on the efficacy of the screening programme. Changes in the distribution of cytological results, the detection rate of cervical intraepithelial neoplasia (CIN) lesions, and the detection rate of squamous cervical carcinoma are reported.

**Methods:** The results of all gynaecology cytological and histological examinations, as registered in the nationwide database for histopathology and cytopathology (PALGA) from 1990 to 2000, were retrieved from seven laboratories in the greater Amsterdam area.

**Results:** After the introduction of the CISOE-A classification, cytological results with equivocal diagnoses decreased significantly from 11.3% to 2.6%, without an increase in the percentages of moderate dyskaryosis or worse. During the study period, the detection rate of histologically diagnosed high grade CIN lesions increased significantly from 4.1 to 6.4/1000 smears, whereas there was no change in the detection rates of low grade lesions or invasive cervical cancer.

**Conclusions:** The introduction of the new CISOE-A classification system resulted in a substantial decrease of equivocal results and repeat recommendations, without a decrease in the detection rate of high grade lesions, making the screening programme more efficacious.

Screening for cervical cancer and its precursor lesions as a method to reduce cervical cancer morbidity and mortality has been gradually introduced in the Netherlands since 1970. Nationwide cervical screening was introduced in 1988. However, the lack of a uniform and reproducible reporting procedure for cytomorphological findings resulted in a considerable number of repeat smears, based on equivocal cytological results—that is, smears coded as borderline or mild dyskaryosis (BMD). In particular, the interpretation of smears with inflammation as “borderline dyskaryosis” resulted in an extremely high percentage (14%) of equivocal results. This led to a high number of repeat and referral smears, burdening both preclinical and clinical capacities. To increase the efficacy of the programme, the new CISOE-A classification introduced in 1996 uniformly described cytomorphological results. Simultaneously, the nationwide screening programme was restructured to provide general practitioners and gynaecologists with clear guidelines and unambiguous repeat and referral advice; in addition, the age range of women invited for screening was extended.

“The lack of a uniform and reproducible reporting procedure for cytomorphological findings resulted in a considerable number of repeat smears”

In our paper, we describe the effect of the introduction of the CISOE-A classification by evaluating the percentage of equivocal results and by assessing the effectiveness of the screening programme to detect squamous (pre)malignant lesions of the cervix. We used routinely collected data in the greater Amsterdam area of the Netherlands to compare the first five years of monitoring after the introduction of the CISOE-A classification in 1996 with the period preceding its introduction. Because the screening programme is aimed at the detection of squamous lesions, we excluded glandular lesions from our study.

**METHODS**

The Dutch screening programme and coding of cervical cytology

Before 1996, women between the ages of 34 and 55 years were invited every three years, and from 1996 onwards women between the ages of 30 and 60 years were invited every five years. To be invited for screening, women have to reach the targeted age during that calendar year, meaning that the first screening round at age 30 included women of both 29 and 30 years of age. From 1988, when nationwide screening was introduced, until 1996, repeat recommendations or referral for further diagnostic evaluation were based on the Pap classification of smears. The CISOE-A classification, as introduced in 1996, has been described previously. Criteria were distributed throughout all the laboratories during 1996 and 1997 on CD-ROM, with clear images representing all the different grades of the CISOE-A nomenclature. Briefly, the CISOE-A classification interprets smears using a rating system including information on specimen composition, inflammatory characteristics, and adequacy of the smear. The letters C (composition), I (inflammation), S (squamous), O (other and endometrium), and E (endocervical cylindrical epithelium) are used to indicate the composition and morphology of the smears (table 1). The letter A (adequacy) is used to indicate the adequacy of the smear (three tiered grading system) and, except for inadequate smears (A3), does not affect the advice.

**Abbreviations:** BMD, borderline or mild dyskaryosis; CIN, cervical intraepithelial neoplasia; PALGA, nationwide network and registry of histopathology and cytopathology; SCC, squamous cell carcinoma
CISOE-A for reporting cervical cytology

The laboratories (Cervical Registration and Information computer application of the local systems was introduced in introduction of the CISOE-A classification, a dedicated diagnosis as equivocal (figs 1 and 2). In conjunction with the neoplastic), whereas previously these changes were often induced by inflammation, are diagnosed as normal (non-neoplastic), whereas previously these changes were often diagnosed as equivocal (figs 1 and 2). In conjunction with the introduction of the CISOE-A classification, a dedicated computer application of the local systems was introduced in the laboratories (Cervical Registration and Information System version 3) to ensure uniform registration into local laboratory databases and to prevent “illogical” CISOE-A combinations in the report. Description of the smears is performed by entering the CISOE-A scores in the program, which generates a report automatically (automated report, fig 3) with a clear conclusion concerning the advice for the clinician (for convenience, the Pap score is included). Thus, CISOE-A interpretations can be “translated” into Pap classifications or the Bethesda classification (table 3).4 5

Data collection
Excerpts of all cervical smears and histological diagnoses are stored in the nationwide network and registry of histopathology and cytopathology (PALGA). We investigated cervical screening data from seven laboratories in the greater

Table 1 Overview of the CISOE-A classification

<table>
<thead>
<tr>
<th>Score</th>
<th>CISOE-A classification</th>
<th>I Inflammation</th>
<th>S Squamous epithelium</th>
<th>O Other, and endometrium</th>
<th>E Endocervical columnar epithelium</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Inadequate</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1</td>
<td>Endocervical epithelium</td>
<td>Viral infection</td>
<td>Normal</td>
<td>No other abnormalities</td>
<td>Normal</td>
</tr>
<tr>
<td>2</td>
<td>Squamous metaplastic cells</td>
<td>Trichomonas vaginalis</td>
<td>Abnormal squamous epithelial cells</td>
<td>Epithelial atrophy</td>
<td>No endocervical cells present</td>
</tr>
<tr>
<td>3</td>
<td>Endometrium</td>
<td>Bacterial infection</td>
<td>Atypical squamous metaplasia</td>
<td>Mild dyskaryosis</td>
<td>Atypical repair reaction</td>
</tr>
<tr>
<td>4</td>
<td>Endocervical epithelium and squamous metaplastic cells</td>
<td>Candida albicans</td>
<td>Mild endometrium</td>
<td>Moderately atypical endometrium</td>
<td>Some atypical endocervical epitheli um</td>
</tr>
<tr>
<td>5</td>
<td>Endocervical epithelium and endometrium</td>
<td>Haemophilus vaginalis</td>
<td>Severe dyskaryosis</td>
<td>SeVERELY atypical endometrium</td>
<td>Severely atypical endocervical epithelium</td>
</tr>
<tr>
<td>6</td>
<td>Squamous metaplastic cells and endometrium</td>
<td>Haemophilus vaginalis</td>
<td>Moderate dyskaryosis</td>
<td>Moderately atypical endometrium</td>
<td>Moderately atypical endocervical epithelium</td>
</tr>
<tr>
<td>7</td>
<td>Endocervical epithelium, squamous metaplastic cells, and endometrium</td>
<td>Actinomycetas</td>
<td>Atypical squamous metaplasia</td>
<td>Atypical repair reaction</td>
<td>Atypical repair reaction</td>
</tr>
<tr>
<td>8</td>
<td>Solely squamous epithelium</td>
<td>Chlamydia</td>
<td>Atypical repair reaction</td>
<td>Atypical repair reaction</td>
<td>Atypical repair reaction</td>
</tr>
<tr>
<td>9</td>
<td>Not applicable</td>
<td>Non-specific inflammation</td>
<td>Invasive squamous carcinoma</td>
<td>Normal</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

The smears are examined for five different aspects of the composition of the smear, and a score is assigned leading to the CISOE code. “A” indicates adequacy of the smear, which is graded as 1–3; 1, adequate; 2, adequate but suboptimal (reason specified by cytotechnologist); 3, inadequate.

Table 2 Comparison of referral and repeat schedules before and after 1996 in the Netherlands

<table>
<thead>
<tr>
<th>Description</th>
<th>Pap</th>
<th>Advice</th>
<th>Pap</th>
<th>Advice</th>
<th>Equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Pap 1</td>
<td>Default screening advice: repeat after 3 years</td>
<td>Pap 1</td>
<td>Default screening advice: repeat after 5 years</td>
<td>Normal</td>
</tr>
<tr>
<td>Borderline</td>
<td>Pap 2</td>
<td>Repeat at 12 and 24 months</td>
<td>Pap 2</td>
<td>Repeat at 6 and 18 months</td>
<td>BMD</td>
</tr>
<tr>
<td>Mild/moderate dyskaryosis</td>
<td>Pap 3a</td>
<td>Repeat at 3 and 12 months</td>
<td>Pap 3a1</td>
<td>Moderate dyskaryosis</td>
<td></td>
</tr>
<tr>
<td>Severe dyskaryosis, carcinoma in situ, carcinoma</td>
<td>Pap 3b</td>
<td>CarpoBx</td>
<td>Pap 3b</td>
<td>CarpoBx</td>
<td></td>
</tr>
</tbody>
</table>

*Moderate dyskaryosis had no separate advice before 1996.
BMD: borderline or mild dyskaryosis; CarpoBx, colposcopy and/or colposcopically directed biopsies.
Amsterdam area. From these laboratories, we included all cervical smears registered from 1 January 1990 to 31 December 2000 inclusive, as stored in PALGA, without separating “indication” from “opportunistic” (that is, outside the national screening programme) because registration of these categories for smear taking was either absent (before 1996) or not consistently reported (after 1996).6 We included laboratories from the region that were connected with central PALGA for the entire duration of the study period, had examined a minimum of 5000 cervical smears yearly, and had consistently participated in the follow up procedure of the quality assurance procedures. The selected laboratories covered approximately 90% of all screening smears performed in the region. Throughout the study period, there were no changes in the population referred to these laboratories for screening.

Because we retrieved data on all gynaecological cytology results from PALGA, more than one smear from one woman could be retrieved. We included all smears, unless a smear was taken for opportunistic reasons (that is, smear taken at an age not invited for screening). Repeat smears were excluded from the analysis whenever taken within a two year period after a smear included in the analysis. All histological reports of mild to high grade cervical intraepithelial lesions (CIN1–3) and squamous cell carcinoma (SCC) were included. Adenocarcinoma and its precursor lesions were excluded, because the changes in the classification aimed at improving the diagnosis of squamous lesions.

Figure 1 Pap smear diagnosed as “Pap 2” before the introduction of CISOE-A, showing reactive atypia caused by infection. The CISOE-A scores would be 8 for composition (on the basis of cells in this picture), 9 for inflammation, and 1, 1, and 1 for normal squamous cells, other cells, and endocervical cells (not visible in this picture), respectively. Conclusion: Pap 1, no abnormal epithelial cells present. Advice: repeat after five years.

Figure 2 Pap smear diagnosed as “Pap 2” after the introduction of CISOE-A, showing abnormal squamous cells. The CISOE-A scores would be 8 for composition (on the basis of cells in this picture), 2 for infection (trichomonal), 2 for abnormal squamous cells (enlarged nucleus with irregular contours), 1 for normal other cells, and 1 for normal endocervical cells (not visible in this picture). Conclusion: Pap 2, abnormal epithelial cells present. Advice: repeat after six months.

Figure 3 Dedicated software ensures automated reporting with minimal dataset as required for proper CISOE-A reports. Both the descriptive part and the conclusive part of the diagnosis are prompted (shown right) on the basis of the CISOE-A score (shown left). All language in Dutch (the acronym CISOE-A is KOPAC-B in Dutch; the two last sentences in the conclusion were for research purpose only and are outside CISOE-A).
Between 1990 and 2000, there was a significant decrease in the percentage of equivocal results, from 11.3% in 1990 to 2.6% in 2000 (p < 0.001), and this difference was present in all age categories (table 4; fig 4). The contribution of results worse than BMD did not change over time. Inversely related to the decrease in BMD results, the percentage of normal smears increased significantly over time, from 87.1% in 1990 to 95.3% in 2000 (p < 0.001). The category of inadequate smears showed a small increase from 0.7% to 1.2% (p = 0.004).

During the study period, the total number of smears decreased from over 100 000 to approximately 80 000 smears.

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**Table 3** The CISOE-A classification compared with the Bethesda 2001 and Pap classifications

<table>
<thead>
<tr>
<th>S</th>
<th>O</th>
<th>E</th>
<th>Pap</th>
<th>Description</th>
<th>Bethesda 2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Inadequate</td>
<td>Unsatisfactory for evaluation</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>Normal</td>
<td>Negative for intraepithelial lesion or malignancy</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>Normal</td>
<td>Atrophy, negative for intraepithelial lesion or malignancy</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>Borderline dyskaryosis</td>
<td>ASC-US/ASH</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>Mild dyskaryosis</td>
<td>ASC-H/LSIL</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>3</td>
<td>2</td>
<td>Moderate dyskaryosis</td>
<td>HSIL</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>3</td>
<td>1</td>
<td>Severe dyskaryosis</td>
<td>AGC</td>
</tr>
<tr>
<td>7</td>
<td>7</td>
<td>4</td>
<td>1</td>
<td>Carcinoma in situ</td>
<td>AIS</td>
</tr>
<tr>
<td>8-9</td>
<td>9-5</td>
<td>5</td>
<td>1</td>
<td>Carcinoma</td>
<td>Adenocarcinoma</td>
</tr>
</tbody>
</table>

AGC, atypical glandular cells; AIS, endocervical adenocarcinoma in situ; ASC-H, atypical squamous cells cannot exclude HSIL; ASC-US, atypical squamous cells of undetermined significance; CIN, cervical intraepithelial neoplasia; HSIL, high grade squamous intraepithelial lesion, encompassing CIN2–3; ISIL, low grade squamous intraepithelial lesion, encompassing CIN1.

**Table 4** Cytological diagnoses of cervical smears and trends, 1990–2000

<table>
<thead>
<tr>
<th>Year</th>
<th>Pap O N (%)</th>
<th>Pap 1 N (%)</th>
<th>Pap 2 N (%)</th>
<th>Pap 3a1 N (%)</th>
<th>Pap 3a2 N (%)</th>
<th>Total N</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>818 (0.7)</td>
<td>96 929 (87.1)</td>
<td>10 875 (9.8)</td>
<td>1693 (1.5)</td>
<td>959 (0.9)</td>
<td>111 274</td>
</tr>
<tr>
<td>1991</td>
<td>843 (0.8)</td>
<td>94 768 (86.6)</td>
<td>11 199 (10.2)</td>
<td>1723 (1.6)</td>
<td>975 (0.9)</td>
<td>109 428</td>
</tr>
<tr>
<td>1992</td>
<td>922 (0.8)</td>
<td>95 935 (85.2)</td>
<td>12 555 (11.3)</td>
<td>1898 (1.7)</td>
<td>1093 (1.0)</td>
<td>114 925</td>
</tr>
<tr>
<td>1993</td>
<td>878 (0.8)</td>
<td>95 222 (85.1)</td>
<td>12 797 (11.4)</td>
<td>1994 (1.8)</td>
<td>111 910</td>
<td></td>
</tr>
<tr>
<td>1994</td>
<td>921 (0.8)</td>
<td>98 681 (85.9)</td>
<td>12 367 (10.8)</td>
<td>1918 (1.7)</td>
<td>114 925</td>
<td></td>
</tr>
<tr>
<td>1995</td>
<td>947 (0.9)</td>
<td>90 272 (87.0)</td>
<td>9801 (9.5)</td>
<td>1704 (1.6)</td>
<td>103 714</td>
<td></td>
</tr>
<tr>
<td>1996*</td>
<td>951 (0.8)</td>
<td>100 668 (89.5)</td>
<td>8452 (7.5)</td>
<td>1480 (1.3)</td>
<td>976 (0.9)</td>
<td>112 518</td>
</tr>
<tr>
<td>1997</td>
<td>879 (0.8)</td>
<td>105 821 (91.4)</td>
<td>6747 (5.8)</td>
<td>1305 (1.1)</td>
<td>1028 (0.9)</td>
<td>111 780</td>
</tr>
<tr>
<td>1998</td>
<td>888 (0.9)</td>
<td>93 038 (94.7)</td>
<td>2531 (2.6)</td>
<td>960 (1.0)</td>
<td>875 (0.9)</td>
<td>105 821</td>
</tr>
<tr>
<td>1999</td>
<td>912 (1.0)</td>
<td>83 875 (95.2)</td>
<td>1881 (2.1)</td>
<td>718 (0.8)</td>
<td>764 (0.9)</td>
<td>88 150</td>
</tr>
<tr>
<td>2000</td>
<td>956 (1.2)</td>
<td>74 477 (95.3)</td>
<td>1506 (1.9)</td>
<td>537 (0.7)</td>
<td>694 (0.9)</td>
<td>78 178</td>
</tr>
</tbody>
</table>

p Value = 0.001, <i>*</i>

**Figure 4** Decrease of cumulative percentages of equivocal cervical smear results. The arrow denotes the introduction and implementation of the CISOE-A classification and transition from a three year interval between screening to a five year screening interval.

**Statistical analysis**

For the analyses, CISOE-A cytology results were categorised as "inadequate" (A3), "normal" (S1, O1–2, E1–2), "equivocal" or borderline (S2–3, O3, E3), mild dyskaryosis (S4, E4, A4), and moderate dyskaryosis or worse (S≥5, O≥5, E≥5). To evaluate the effects of age on the efficacy of screening, we categorised age as follows: women who were never screened (<28 years), women who were screened only after 1996 (age 29–33 and 54–61), women who were screened in both schedules (34–53 years), and mature women screened in either of the schedules (≥62 years). Data on cervical histology were divided into CIN1, CIN2–3, and SCC. Detection rates of histological lesions were calculated for each 1000 smears. Data were analysed for linear trends over time by linear regression analysis and p values of 0.05 or less were considered significant. All analyses were performed using SPSS 9.0 for Windows.

**RESULTS**

Between 1990 and 2000, there was a significant decrease in the percentage of equivocal results, from 11.3% in 1990 to 2.6% in 2000 (p < 0.001), and this difference was present in all age categories (table 4; fig 4). The contribution of results worse than BMD did not change over time. Inversely related to the decrease in BMD results, the percentage of normal smears increased significantly over time, from 87.1% in 1990 to 95.3% in 2000 (p < 0.001). The category of inadequate smears showed a small increase from 0.7% to 1.2% (p = 0.004).

During the study period, the total number of smears decreased from over 100 000 to approximately 80 000 smears.
or 62 years and over, except for a significant decrease in the detection rates of lesion in age categories 54–61 years.

The detection rate of SCC (p = 0.449). There were no obvious linear trends increased significantly from 1.2/1000 smears to 5.0/1000 smears (p = 0.001), with an increased detection rate of CIN1 lesions (p < 0.001). In women aged 54–61 years, the detection rate of CIN2–3 lesions increased significantly from 1.2/1000 smears to 5.0/1000 smears (p = 0.001), also with an increased detection rate of CIN1 lesions (p = 0.449).

We found no obvious linear trends in the detection rates of lesions in age categories 54–61 years or 62 years and over, except for a significant decrease in the detection rate of SCC of 1.3/1000 smears to 0.5/1000 smears in women aged 54–61 years (p = 0.008).

DISCUSSION

Our data show that as a result of the introduction of a uniform classification system, the number of cytological BMD results decreased substantially, without decreasing the detection rate of high grade CIN lesions or worse in the cervical cancer screening programme. The new repeat and referral schedule that was introduced in conjunction with the CISOE-A classification in 1996 strongly influenced the number of smears taken. One of the aims of the new schedule was to decrease the number of opportunistic smears. Outside the screened ages 29–61 years, the number of smears decreased substantially. Even though the decrease was present throughout the entire period studied, it was particularly impressive in the youngest age category of women under 29 years of age. In addition, within the screened age range, the number of smears decreased in women aged 29–33 and 34–53 years. In mature women screened, the number of smears more than doubled after 1996. Spontaneous screening is associated with a decreased participation rate in mature women. Thus, the introduction of the new schedule has led to a substantially increased coverage of mature women in the cervical cancer screening programme in our region.

The efficacy of the screening programme, as measured by the detection rate of high grade lesions, did not decrease during our study period. In contrast, upon restructuring the
The national screening programme in 1996, detection rates of high grade lesions increased significantly, from 1.5/1000 smears to 5.4/1000 smears. This shift towards higher rates was noted not only in the group that was screened throughout 1990 to 2000, but also in women below the age of 29 (who were never in the official screening programme) and women aged 29–33 (who only entered the programme after 1996). We propose several explanations for the increased detection rates of CIN2–3. First, the detection rates of high grade lesions increased because the efficacy of the screening programme increased as a result of the more consistent application of the CISOE-A classification and its translation into repeat and referral advice. Because the CISOE-A classification and its referral policies were applied for cytology in younger ages also, it may have contributed to higher detection rates in the younger group too. Second, the observed increases in detection rates may be related to a true rise in the incidence of premalignant cervical lesions, irrespective of the new classification and referral policy. However, we detected no significant rises in the incidence of carcinoma in any of the age groups (table 6). The most plausible explanation for a rise of high grade lesions in the young category only is based on an increased prevalence of human papillomavirus infection caused by changes in sexual behaviour. Third, an increase in the detection rate of CIN2–3 may be a spurious finding caused by length-time bias, as the repeat and referral schedule changed. Because the interval between normal smears increased from three to five years, high grade CIN lesions have more time to develop and thus be diagnosed. These CIN lesions could be progressive, but also regressive. Several studies indicate that regressive CIN lesions are more frequent in younger women.10–12

Again, the stable detection rates of SCCs argue against the option of increased detection of progressive CIN lesions.

We have no evidence to favour the second and third mechanisms as explanations for the observed rise in high grade CIN lesions. However, because high grade CIN lesions precede invasive cervical carcinoma by several years, and a more efficient cervical cancer screening programme will only lead to a decrease in cervical cancer incidence many years later,13 it may be too early to conclude that there is no effect on the detection rates of SCC. The women in the mature age group (54–61 years) have been screened for a large part of their adult life, and therefore precursor lesions of invasive cervical cancer will have been diagnosed and treated more often than in the younger age categories. Thus, in this age group, a decrease in the SCC detection rate may be a consequence of successful screening. Although these results should be treated with caution because of the small numbers of SCC cases involved, support for this theory comes from data on the incidence of cervical cancer in the Netherlands because the strongest decrease in incidence is seen in mature women, who have been screened throughout most of their adult life (S Bulk et al, unpublished data, 2003).

Take home messages

- The introduction of the new CISOE-A classification system resulted in a substantial decrease of equivocal results and repeat recommendations
- In addition, this effect was not accompanied by a decrease in the detection rate of high grade lesions—the detection rate of histological high grade cervical intraepithelial neoplasia increased in all age groups
- These results point to the greater efficacy of this new classification system

‘The introduction of the new schedule has led to a substantially increased coverage of mature women in the cervical cancer screening programme in our region’

In conclusion, the introduction of the CISOE-A classification, together with clear guidelines for its use, have caused a substantial decrease in the proportion of equivocal results, thereby resulting in a substantial decrease in the number of repeat recommendations. At the same time, this effect has not been paralleled by a decrease in the detection rate of histological high grade CIN lesions, as might be expected in an inefficient screening programme. In contrast, the detection rate of histological high grade CIN lesions increased in all age categories, indicating the efficacy of the screening programme.

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