

CO-GENT: Clinical Outcomes in Gentamicin Prescribing and Monitoring, a National Audit

Guide to Patient Selection and Data Entry

This guide is intended to answer questions on how to randomly select your 20 patients whilst minimising sampling bias, and enter data in parts of the datasheet where it may not be clear what exact data is required. For ease of reading, we have not included every question, as many of them are self-explanatory (for example, patient age). We also provide the rationale for some of the data requested. We hope that this will help to standardise data entry across multiple centres and aid data clean-up and analysis.

The data is to be collected retrospectively and will require access to patient notes, blood results and drug charts.

Any 30-day period can be chosen from the start of May 2021 onwards. Several secondary outcomes are at 30 days from the first dose of gentamicin. We therefore recommend selecting a 30 day period that ends at least 30 days before the date you begin data collection at your Trust.

Please note that all data within the audit tool in all four tabs are compulsory, except for columns BV (blood culture organism, if positive) and BW (blood culture date flagged positive) in tab A.

Patients must not be contacted to obtain data. GP records may be accessed remotely.

Please store patient identifier data locally at your Trust, and omit patient identifying data when submitting.

If you have any queries, please don't hesitate to contact the Project Team, by emailing any of the project leads:

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Patient Selection

For selecting the 20 patients, we recommend obtaining a list of gentamicin levels from your local biochemistry or microbiology department over any 30-day period from the start of May 2021 onwards. We recommend that you contact your local audit and/or Microbiology / infectious diseases department, who will often work with staff with IT expertise to generate lists of patients or other outputs for local audits.

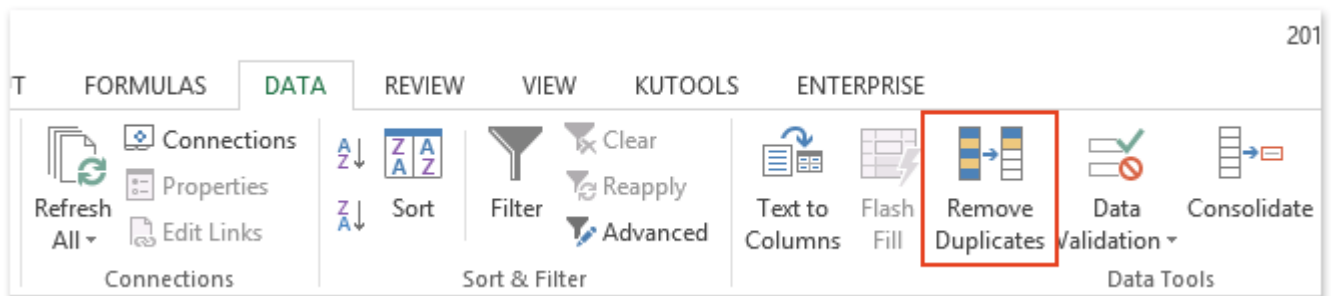
We suggest that you request the list of gentamicin levels to be in MS Excel format. If you receive the list in another format, we recommend that you either convert into an Excel file or copy and paste into Excel, as the remainder of this guide to random sampling is designed for use in Excel.

Sampling bias will be introduced if patients are randomly selected from your list of gentamicin levels without first removing duplicate entries, for patients who have had more than one level taken. Therefore duplicate entries must be removed before your 20 patients are randomly selected. These duplicate entries can easily be removed in MS excel:

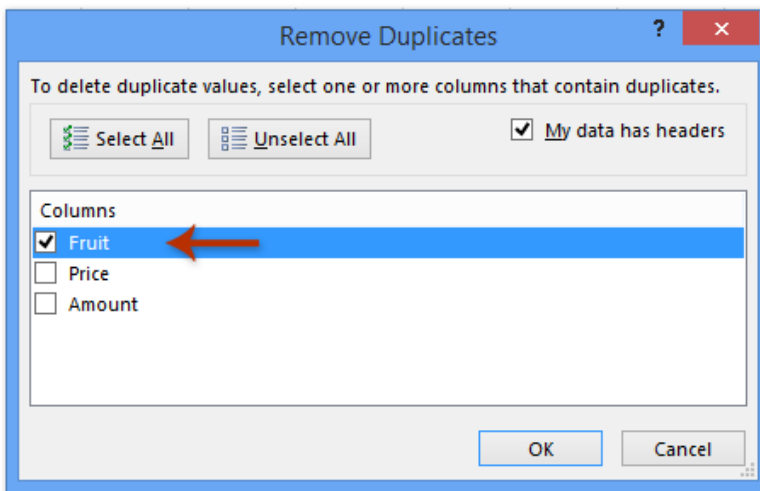
Remove Duplicates

This method will introduce the **Remove Duplicates** feature to remove entire rows based on duplicates in one column easily in Excel.

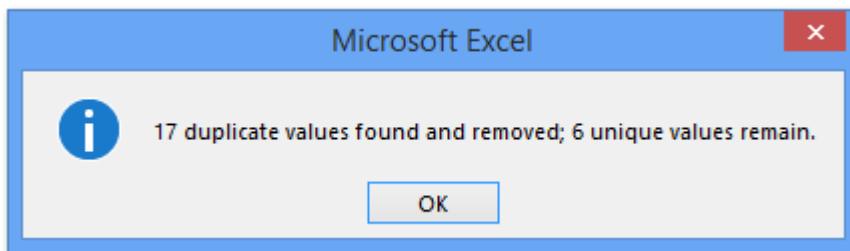
1. Select the range you will delete rows based on duplicates in one column, and then click **Data > Remove Duplicates**.



2. In the popping up Remove Duplicates dialog box, please only check the Column whose duplicate values you will remove entire rows based on, and click the **OK** button. See screenshot:




3. And then a dialog box will come out and show how many duplicate values have been found and removed. Click the **OK** button to close it.



And now entire rows are deleted based on the duplicate values in the specified column. See screenshot:

| | A | B | C |
|----|-----------|-------|--------|
| 1 | Fruit | Price | Amount |
| 2 | Orange | 7.9 | 734.7 |
| 3 | Raspberry | 2.9 | 165.3 |
| 4 | Raspberry | 2.6 | 176.8 |
| 5 | Mango | 7.1 | 539.6 |
| 6 | Apple | 8.4 | 613.2 |
| 7 | Lemon | 7.9 | 734.7 |
| 8 | Raspberry | 6.1 | 359.9 |
| 9 | Lemon | 7.9 | 734.7 |
| 10 | Mango | 5 | 270 |
| 11 | Orange | 2.6 | 176.8 |
| 12 | Lemon | 6.7 | 656.6 |
| 13 | Peach | 2.6 | 176.8 |
| 14 | Orange | 7.1 | 660.3 |
| 15 | Mango | 0.4 | 32.4 |
| 16 | Apple | 5 | 270 |
| 17 | Raspberry | 5 | 270 |
| 18 | Raspberry | 5.3 | 492.9 |
| 19 | Orange | 8.2 | 492 |
| 20 | Peach | 9.2 | 542.8 |
| 21 | Raspberry | 5 | 270 |
| 22 | Peach | 6.3 | 598.5 |
| 23 | Apple | 6.2 | 341 |
| 24 | Peach | 4.6 | 161 |



| | A | B | C |
|---|-----------|-------|--------|
| 1 | Fruit | Price | Amount |
| 2 | Orange | 7.9 | 734.7 |
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| 4 | Mango | 7.1 | 539.6 |
| 5 | Apple | 8.4 | 613.2 |
| 6 | Lemon | 7.9 | 734.7 |
| 7 | Peach | 2.6 | 176.8 |

In your list of gentamicin levels, the column of interest for the Remove Duplicates feature will be Hospital or NHS numbers. Once the duplicates have been removed, record the rows remaining. In the above example, this would be row 2 to row 7. These rows will then be the ones from which you randomly select your 20 patients. The next section of this guide explains how to randomly select the patients, now that the duplicates have been removed.

If you have any queries about this stage, please don't hesitate to contact the Project Team.

Random Selection

Once duplicate rows have been removed from your list of gentamicin levels for patients who have had more than one level taken, you are ready to randomly select your 20 patients. Remember, these duplicates **must** be removed prior to patient selection, in order to remove sampling bias.

We have written this section in order to standardise random selection of your 20 patients across all registered centres. To randomly select patients:

1. Please visit <https://www.random.org/> - this is a site that generates random numbers within a chosen lower and upper limit, with a greater degree of 'randomness' than most pseudorandom number generators available online, or the one built into MS excel itself. It has been used in CQUINs and will suffice for the purposes of this project.
2. Enter your lower limit 'Min' as the row number for the first patient on your list of gentamicin levels
3. Enter your upper limit 'Max' as the row number for the final patient on your list of gentamicin levels
4. Click 'Generate' and record the outputs, until you have 20 different numbers. These are the patients you have now selected.

Once you have your list of 20 patients, you will need to request their paper notes from archives in order to begin data entry.

If you have any queries about this stage, please don't hesitate to contact the Project Team.

The next section provides details on some aspects of entering data into the data collection tool.

Guide to Data Entry

Tab A – Patient Baseline, Gentamicin Dosing and Monitoring Data, Clinical Outcome Data

Please note that column A and row 2 in this tab are locked and cannot be edited.

Column D – Patient location at the time of first dose of gentamicin

The drop-down menu includes the commonest types of inpatient locations. **Please note that patients already in critical care prior to receiving their first dose of gentamicin are not included in the audit.** This is because ICU inpatients may have significant changes in their volume of distribution, which can affect gentamicin pharmacokinetics. This means that we are also recording whether and when the patient was admitted to ICU, if this occurred during their course of gentamicin, in columns AY and AZ.

Column E – Indication for Gentamicin

The drop-down menu includes the commonest indications. If the indication is recorded in the notes, and the recorded indication is not present in the drop-down menu, please select 'Other.' **Please note that patients with infective endocarditis are not included in the audit.**

Column F, G – Height and Weight

If these were not recorded at admission, height and weight from later in the same admission can be recorded. If this is not possible, please use GP records and state in 'Freetext comments' (column BX) that GP records were used and give the date these were recorded. If there is no admission or GP record, please select 'Not recorded.'

Column H, I, J, K – Renal function at the time of 1st dose of gentamicin

These columns are for the patient's renal function at the time the 1st dose was given.

If the patient was in A&E, enter the results from the time the patient had bloods taken in A&E. If the patient did not have bloods taken in A&E, enter the renal function from the time and date closest to the time of the first dose of gentamicin.

If the patient was an inpatient at the time of starting gentamicin, give the renal function from the time and date closest to the time of the first dose of gentamicin. This should preferentially be a U&E taken in the 24 hours before the first dose, rather than after.

Some Trusts use an upper limit cut-off of 60ml/min/1.73m² for eGFR. We have therefore listed an option of '>60' for these Trusts.

For any queries or clarification, please contact the project team.

Columns L to R – Baseline renal function

These columns are for up to three previous creatinine results that best reflect a current estimate of the patient's renal function. This is required to accurately record AKI outcomes in our dataset. There is currently no standardised method of calculating baseline creatinine and we leave this to the discretion of local investigators, who have access to full records of previous U&E results.

Please do not leave blank for columns L, N and P (the creatinine estimates). Check previous hospital results. If there are no hospital results on record, check GP records if possible.

If there are no previous hospital records **and** you cannot access GP records, enter 'Unknown.'

If you are able to access both hospital and GP records and there are no previous creatinine results on record, enter 'No record.' Columns M, O and Q are the dates of each of the previous creatinines you are entering – you can leave these blank if there are no previous results to enter. For any queries or clarification, please contact the project team.

Column S, T – CRP (C-reactive protein) and EWS (early warning score)

This is to have some idea of how unwell the patient was at the time gentamicin was given, which we may examine during analysis in relation to AKI rates. Please use a CRP result closest to the time the 1st dose was given, ideally on the same day as the 1st dose and before the dose was given. If there is no recent CRP (within 24 hours before the dose) before gentamicin was given, use the first CRP taken after the gentamicin dose. For EWS, use the closest one taken to the dose of gentamicin being given (preferably before the dose).

Column U, V, W – Diabetes and Hypertension

If there is no mention of either diagnosis in the patient's notes, please check GP records. If you cannot access the GP records, check the admission medicines reconciliation for antihypertensives or hypoglycaemic agents. If you cannot access the GP records or med rec, enter 'Unknown.' For any queries or clarification, please contact the project team.

Column X, Y – nephrotoxic medications

Please review the admission drug charts and medicines reconciliation to determine whether the patient was on any nephrotoxic medications, given between 24 hours before the 1st dose, and 24 hours after the final dose of gentamicin. These may contribute to AKI if one developed, and will aid data analysis of AKI rates. We have not asked for data on whether the nephrotoxic medications were stopped at any point during the course of gentamicin, as there is no easy way of ascertaining whether the AKI was caused by nephrotoxics or gentamicin, regardless of whether they were stopped.

Column Z, AA – urinary tract obstruction and cause

This records whether the patient was diagnosed with a urinary tract obstruction at any point whilst on gentamicin (between 24 hours before the 1st dose, and 24 hours after the final dose of gentamicin) and will aid data analysis of AKI rates. **Please note that single doses of gentamicin for routine urinary catheter changes are excluded from the audit.**

Columns AB to BH – quantities, dates and times of levels and doses

For all second and third doses and corresponding gentamicin levels, enter data ONLY if the patient had these.

Please note dates can only be inputted in the format DD/MM/YYYY and times in 24 hour in the format HH:MM – other formats will generate an error message.

Some instances will arise where more than one level was taken between any two doses of gentamicin. This is more common for centres using pre-dose monitoring, though can happen for other approaches to monitoring. We have therefore included extra columns for details of additional levels between any two doses from dose 1 to dose 4. If an additional level was not taken, enter 'N' for the column asking whether an additional level was taken, and leave blank the corresponding columns asking for details of an additional level.

We do not include any doses or levels from the 4th dose onwards for detailed analysis, but we do ask for the total numbers of gentamicin doses and levels that the patient had for this episode of infection.

Columns BK to BM – diagnosis of AKI

Did the patient develop a rise in serum creatinine from baseline meeting criteria for a diagnosis of AKI? **This applies to any time point ranging from the date of the first dose of gentamicin, up to 7 days after the final dose of gentamicin.** We use only a change in serum creatinine as per the KDIGO criteria. The KDIGO criteria include diagnosis of AKI using urine output. As the data collection in this project is retrospective and urine output generally not well recorded, we use only the change in serum creatinine for AKI diagnosis in our dataset.

| Stage | Serum creatinine |
|--------------|--|
| 1 | 1.5–1.9 times baseline OR ≥0.3 mg/dl (≥26.5 μmol/l) increase |
| 2 | 2.0–2.9 times baseline |
| 3 | 3.0 times baseline OR Increase in serum creatinine to ≥4.0 mg/dl (≥353.6 μmol/l) OR Initiation of renal replacement therapy OR, In patients <18 years, decrease in eGFR to <35 ml/min per 1.73 m ² |

Column BP – duration of antibiotics

Specify total duration of any other antibiotics used in conjunction with gentamicin whilst it was given, including duration of any oral switches used as a stepdown from gentamicin as part of the total duration, for this episode of infection. If antibiotics were escalated for new or worsening infection after completing the course of gentamicin, or a new course was given within a week of stopping antibiotics, please specify in the last column ('Freetext comments' in column BX).

Column BQ – date of patient discharge

Enter date of discharge (DD/MM/YYYY). If patient not discharged on date of data submission to project team, or if patient deceased, please leave blank

Column BR – was gentamicin stopped early due to AKI

Include this only if there is documentation stating that this was the case, in the patient's notes or in the drug chart. Otherwise input 'Not recorded.'

Column BS – mortality data

DO NOT attempt to call or contact patients! This data should be attainable through GP records or by hospital notifications – contact your local ward administrators or secretaries for help if needed. For any queries or clarification, please contact the project team.

Column BT and BU – ototoxicity data

We are recording these as a secondary outcome given the large size of this national dataset, given a lack of data on gentamicin ototoxicity. In the majority of cases, it is likely the patient notes make no mention of these outcomes. However, if they are documented, please input data accordingly.

For cochleotoxicity – did the patient have new hearing loss or tinnitus at any time up to 30 days from 1st dose of gentamicin? Enter 'Not recorded' if not recorded in notes.

For vestibulotoxicity – did the patient have positive head thrust test or other evidence of vestibulotoxicity, at any time up to 30 days from 1st dose of gentamicin? Enter 'Not recorded' if not recorded in notes. For details of the head thrust test, see

https://www.uptodate.com/contents/evaluation-of-the-patient-with-vertigo?search=head%20thrust%20test§ionRank=1&usage_type=default&anchor=H19188844&source=machineLearning&selectedTitle=1~8&display_rank=1#H19188844

Column BX – freetext

This column is for any notes that might be relevant to the data for this patient, for any scenarios not covered in the data sheet or any other issues arising. This column may also be helpful for writing notes for yourself to come back to prior to data submission.

Tab B – Audit Data

Column D – first level

Please note – this applies only to the very first level taken, not to any additional levels taken before the 2nd dose

For any queries or clarification on questions in Tabs C and D, please contact the project team.