



Ethical Medicines Industry Group

Laura McIver, Chief Pharmacist

Supporting better quality health and
social care for everyone in Scotland





Healthcare
Improvement
Scotland

Many parts, one purpose -
better quality health and social care
for everyone in Scotland.

| Advice
on new
medicines

| Advice
on health
technologies

| Standards,
guidelines
and indicators

| Inspections
and reviews

| Enabling health
and social
care improvement

| Death
Certification
Review Service

| Scottish
Patient Safety
Programme

| Improving
antibiotics
use

| Making
the public
voice count

| Global quality
improvement
webinars

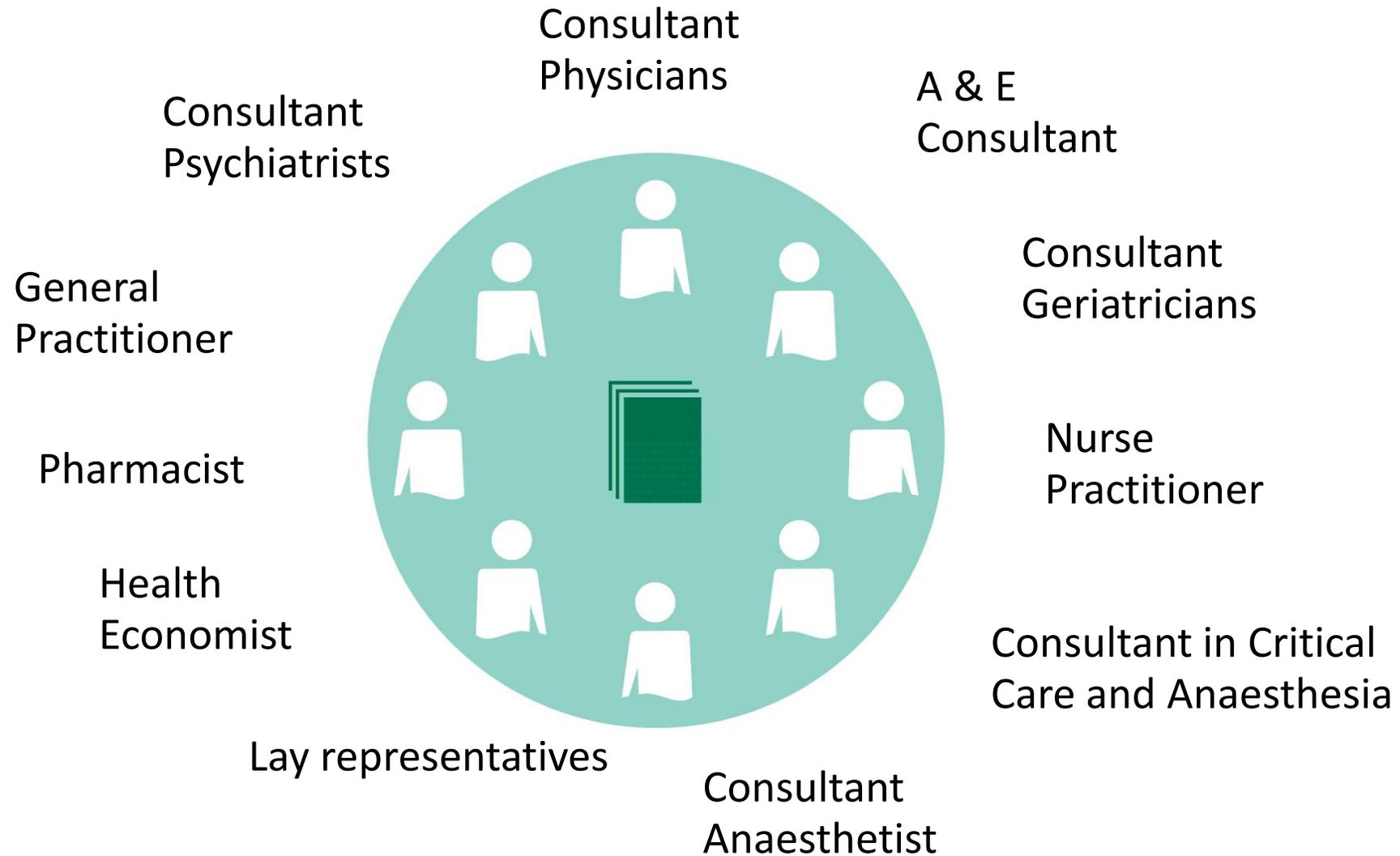
Evidence



- *Scottish Intercollegiate Guideline Group (SIGN)*
- *Scottish Health Technologies group (SHTG)*
- *Scottish Antimicrobial Group (SAPG)*

- Scottish Medicines Consortium (SMC)
- Standards

Delirium guideline development group

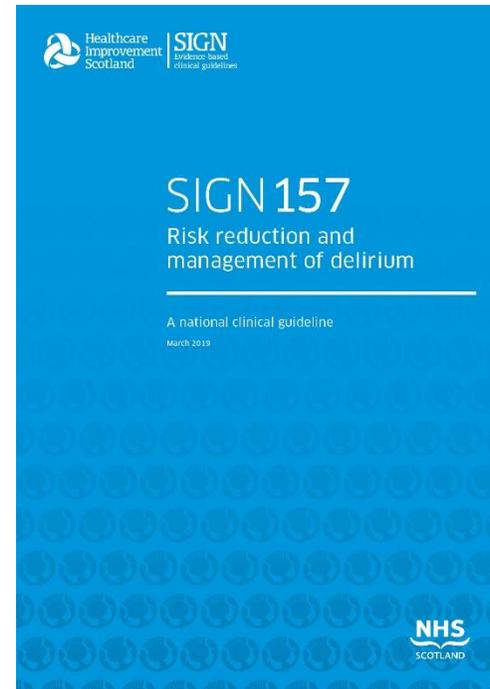


Publication and implementation

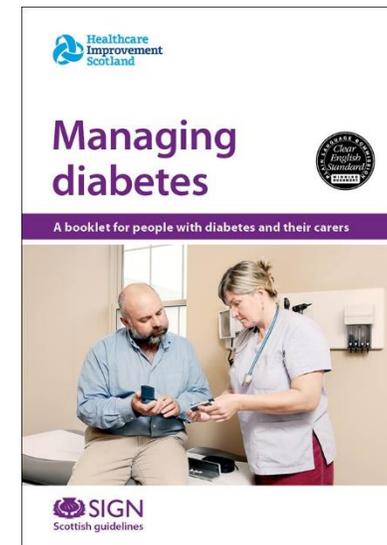


The screenshot shows the SIGN website homepage. At the top left is the Healthcare Improvement Scotland logo and the 'SIGN' brand name. A search bar is located at the top right. Below the header is a navigation menu with links: 'Our guidelines', 'Who we are', 'What we do', 'Patient involvement', and 'Get involved'. The main content area features a featured article titled 'Delirium is among the most common of medical emergencies.' with a sub-headline 'SIGN 157: Risk reduction and management of delirium provides recommendations based on current evidence for best practice in the detection, assessment, treatment and follow up of adults with delirium, as well as reducing the risk of delirium. The guideline applies to all settings: home, long-term care, hospital, and hospice.' To the right of the text is a small image of the SIGN 157 guideline booklet. Below the featured article is a grid of six smaller promotional tiles:

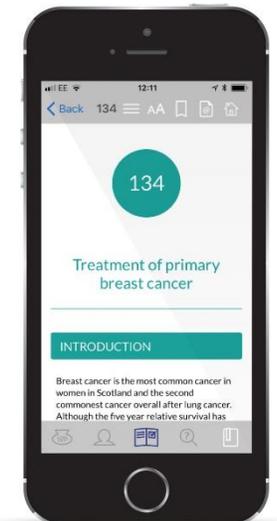
- New guideline published:** SIGN 157: Risk reduction and management of delirium. A national clinical guideline. First guideline on risk reduction and management of delirium for Scotland.
- 25 years of SIGN guidelines:** Celebrating 25 years of improving patient care through SIGN guidelines. View our time line.
- Patient booklet:** Migraine. A booklet for people with migraine and their carers. Read the booklet here.
- Consultation draft:** A small update to SIGN 136: Management of chronic pain is available for consultation. Feedback by 26 April. Feedback required.
- MHRA advice on Valproate:** New advice from MHRA on Valproate. MHRA advice. Affects guidelines SIGN 127 | SIGN 143 | SIGN 155.
- Guideline:** SIGN 156: Children and young people exposed prenatally to alcohol. A national clinical guideline. First UK guideline for diagnosing fetal alcohol spectrum disorder (FASD).



The image shows the front cover of the SIGN 157 guideline booklet. The cover is blue with a repeating pattern of the SIGN logo. The text on the cover reads: 'SIGN 157 Risk reduction and management of delirium. A national clinical guideline. March 2019.' The NHS Scotland logo is in the bottom right corner.



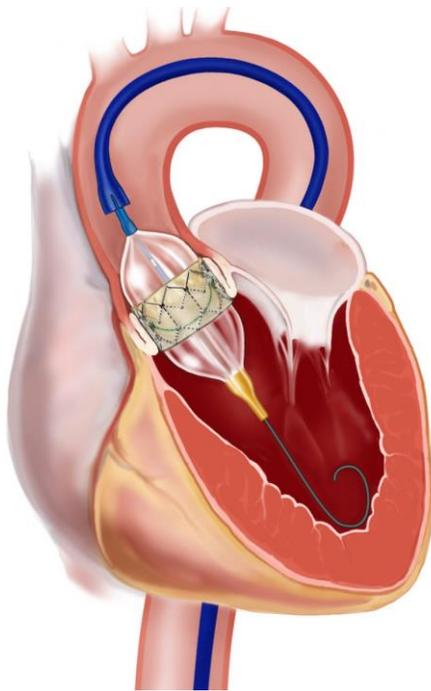
The image shows the front cover of the 'Managing diabetes' patient booklet. The cover is white with a purple header. The text reads: 'Managing diabetes. A booklet for people with diabetes and their carers.' There is a 'Checklist Standard' logo in the top right corner. Below the title is a photograph of a healthcare professional talking to a patient. The SIGN logo is at the bottom.



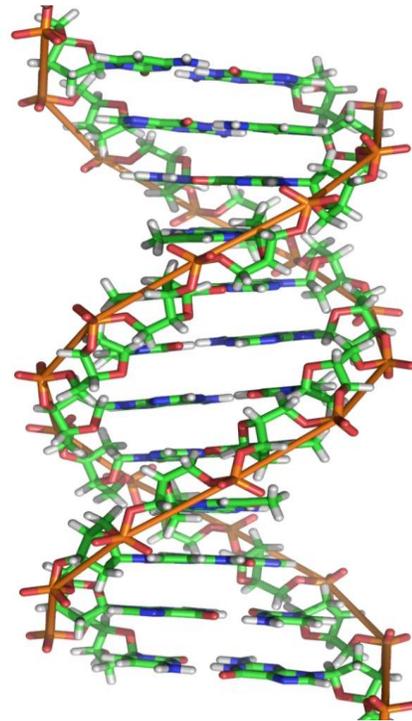
The image shows a smartphone displaying the SIGN 134 app interface. The screen shows the title '134 Treatment of primary breast cancer' and an 'INTRODUCTION' section. Below the introduction, there is a short paragraph: 'Breast cancer is the most common cancer in women in Scotland and the second commonest cancer overall after lung cancer. Although the five year relative survival has...'. The app interface includes a back button, a menu icon, and a search icon.

www.sign.ac.
uk

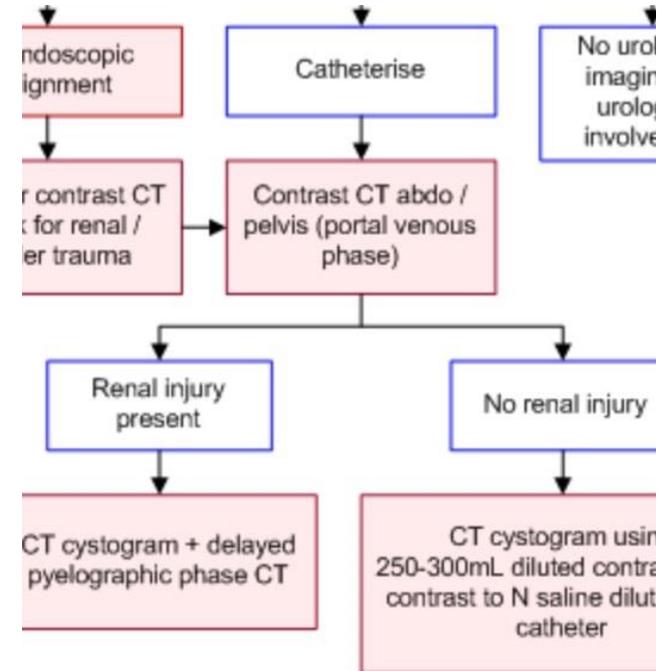
Health Technologies



Devices

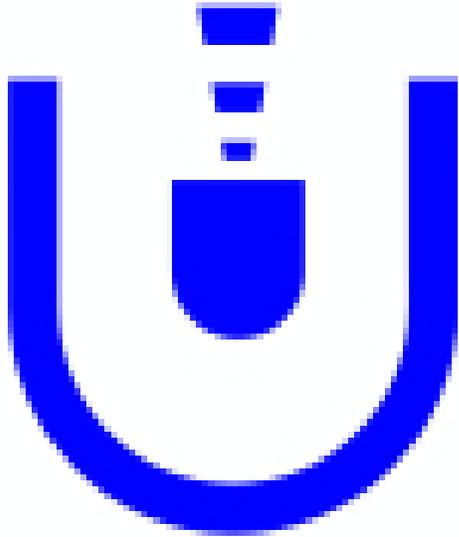


Diagnostics



Pathways

Boundaries



Social

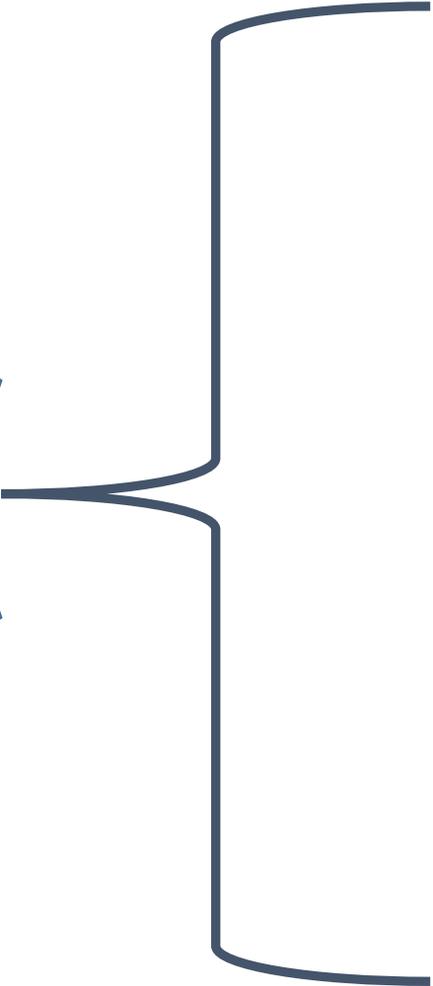


Health Technologies



Medicines

Regenerative Therapies



Cell therapies

Gene therapies

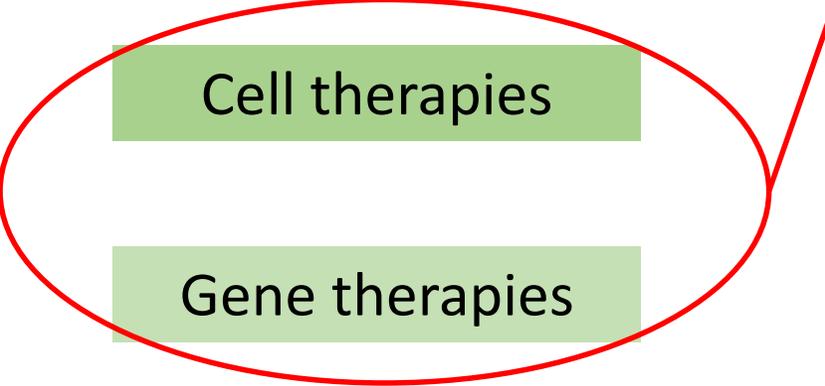
Tissue Engineering

Bio Engineering

Biologics

Devices

ATMP



Challenges



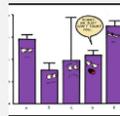
High upfront cost – current financial mechanisms



Different evidence standards – greater uncertainty



Decision making: One off decision large investment



Long-term data collection



Non "ATMP" interventions; identification and assessment



HM Government

Contained and controlled

The UK's 20-year vision for antimicrobial resistance

Published 24 January 2019



HM Government

Tackling antimicrobial resistance 2019–2024

The UK's five-year national action plan

Published 24 January 2019

Tackling antimicrobial resistance 2019–2024

Executive summary

Antimicrobial resistance (AMR) is a global problem that impacts all countries and all people, regardless of their wealth or status. The scale of the AMR threat, and the need to contain and control it, is widely acknowledged by country governments, international agencies, researchers and private companies alike.

This document sets out the UK's 2019–2024 national action plan to tackle AMR within and beyond our own borders. Developed in consultation with a broad range of stakeholders across different sectors, it builds on the achievements of our last strategy (2013–2018), and is aligned with global plans and frameworks for action.

The plan has ultimately been designed to ensure progress towards our 20-year vision on AMR, in which resistance is effectively contained and controlled. It focuses on three key ways of tackling AMR:

- reducing need for, and unintentional exposure to, antimicrobials;
- optimising use of antimicrobials; and
- investing in innovation, supply and access.

Impact of SAPG work - key highlights from latest HPS report

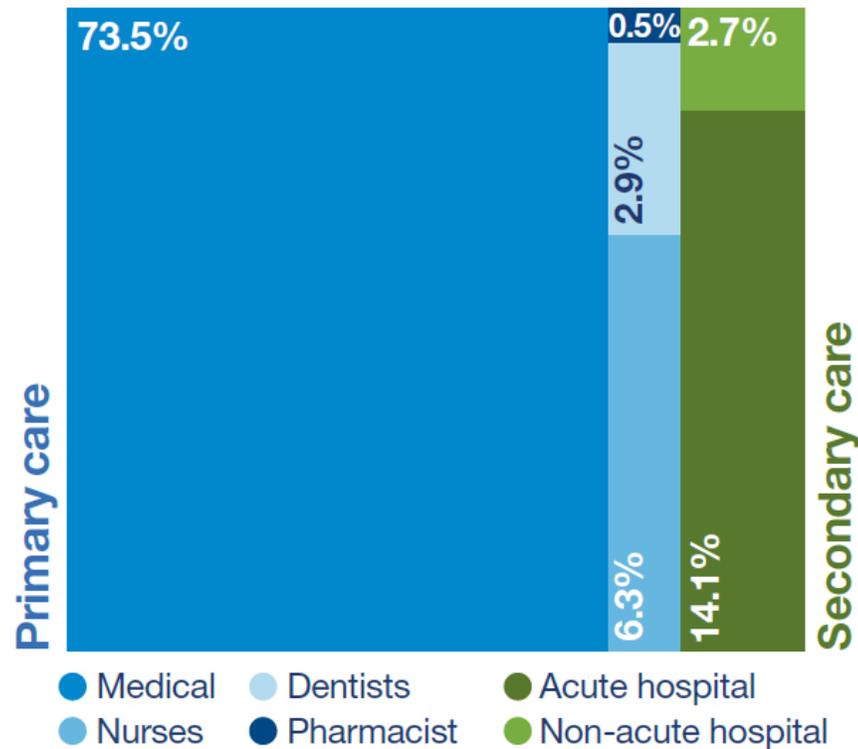
Total antibiotic use

There has been a **6.2%** decrease in antibiotic use between 2014 and 2018

58.5% of antibiotics use in humans were Access (first line) antibiotics

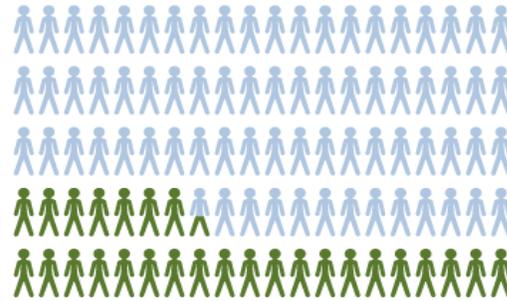
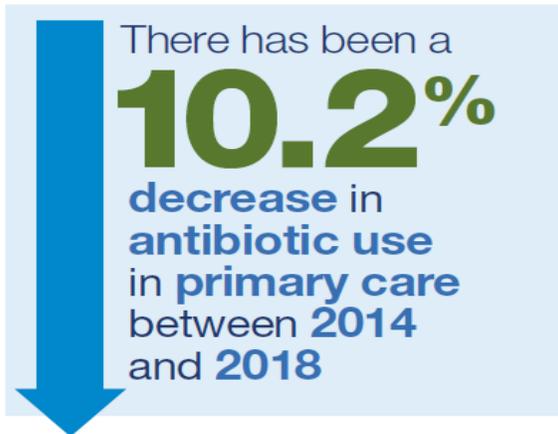


Total breakdown of antibiotic use in humans in 2018

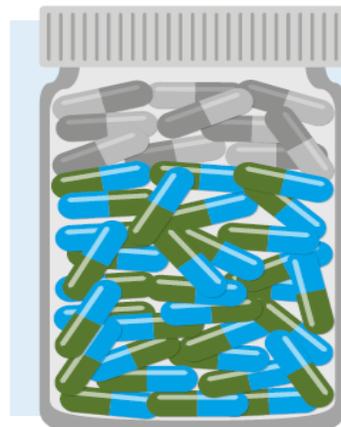
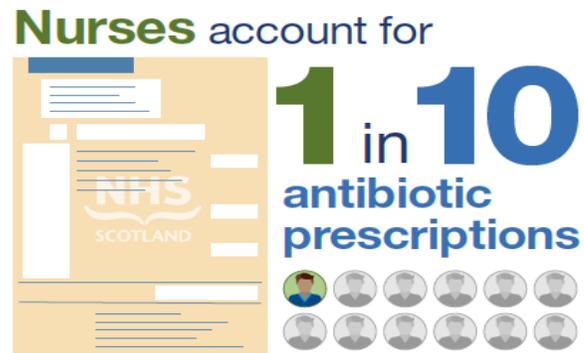


Impact of SAPG work – improvements in antibiotic use in primary care

Antibiotic use in primary care



27.3% of the Scottish population had at least one course of antibiotics in 2018



Over **75%** of antibiotic prescriptions were Access (first line) antibiotic items

Example from hospital practice

Gentamicin and vancomycin

National guidance

Updated and restructured to make it easier to follow

Educational resource

Existing educational resources collated to inform a national resource comprising a series of case studies covering practical and clinical issues accessed via an online learning platform

Standardised documentation

Prescription charts for both gentamicin and vancomycin.

On-line calculator

Previous calculators for gentamicin and vancomycin were updated and validated plus new gentamicin Hartford calculator developed and made available via app

ADULT PARENTERAL GENTAMICIN (GGC): PRESCRIBING, ADMINISTRATION & MONITORING CHART
NHS SCOTLAND

Use for patients prescribed intravenous gentamicin as per the GGC dosing guidance. Not for prophylactic indication or where gentamicin doses (usually in adult patients) are being used. Refer to full guidance for information on EXCLUSIONS and Exemptions / Contra-indications to gentamicin.

Patient name: _____ Age: _____ Sex: M / F / I Initial Gentamicin Dose* _____
Date of birth: _____ Weight: _____ Predicted Frequency* _____
OF no: _____

PROMPT ADMINISTRATION
within 1 hour of recognition of sepsis reduces mortality

SIGNS OF GENTAMICIN TOXICITY
RENAL: ↓ urine output/oliguria or ↑ creatinine
OTO: N/VW tinnitus, dizziness, poor balance.
VESTIBULAR: hearing loss, oscillating vision.
Toxicity may occur irrespective of gentamicin concentration.

TOXICITY
Before prescribing each dose check:
Renal & Oto-vestibular function

Step 1: Calculate and prescribe the first dose of gentamicin (see overview for more details)
• If creatinine is known - use the online gentamicin dose calculator.
• If creatinine is not known - give 5 mg/kg gentamicin (maximum 400 mg) or, if CKD 5, give 2.5 mg/kg (maximum 100 mg) on advice of senior medical staff.
• Prescribe gentamicin 'as per chart' on the medication chart (barcode). AVOID specifying dose or administration time on the barcode.
• Prescribe individual doses in the prescription record section below, specifying the date and time the dose should be given.
Step 2: Monitor creatinine and gentamicin concentration and reassess the dosage regimen
• Check gentamicin concentration after the first dose and then at least every 2 days (see overview for more details).
• Monitor creatinine daily. Seek advice if renal function is unstable (e.g. a change in creatinine of >1.20%).
Step 3: Assess daily - the ongoing need for gentamicin, signs of toxicity
• Consider an alternative agent if creatinine is increasing or the patient becomes oliguric.
• If gentamicin continues for >7 days, suggest referral to microbiology for assessment.
• Refer to guidelines or clinical pharmacist for further advice on prescribing, monitoring and administration.

TOXICITY	Gentamicin Prescription Record	Administration Record	Monitoring Record
Complete each time a dose is to be given (ensuring gentamicin is prescribed 'as per chart' on the barcode).	Complete each time a dose is to be given (ensuring gentamicin is prescribed 'as per chart' on the barcode).	Complete each time gentamicin is administered (in addition to the barcode).	Record all sample dates/times accurately below. See overview for monitoring advice.
Time to be given: 24 hours	Time to be given: 24 hours	Time of sample: 24 hours	Time of sample: 24 hours
Time to be given: 24 hours	Time to be given: 24 hours	Time of sample: 24 hours	Time of sample: 24 hours
Time to be given: 24 hours	Time to be given: 24 hours	Time of sample: 24 hours	Time of sample: 24 hours
Time to be given: 24 hours	Time to be given: 24 hours	Time of sample: 24 hours	Time of sample: 24 hours

learnPro NHS

Home Profile Resources Help Logout

HOME LEARN GAV

MSL GAV - Gentamicin (GGC) and Vancomycin

More Learning

This item is broken down into Topics. Please select a Topic from the list below.

- GAV Gentamicin GGC Infusion
- GAV Vancomycin Continuous Infusion
- GAV Vancomycin Intermittent Infusion
- GAV Vancomycin Intermittent Infusion
- GAV Vancomycin Intermittent Infusion

To return to the full list of learning click LEARN.

GENTAMICIN CALCULATOR (HARTFORD REGIMEN) FOR ADULT PATIENTS

Type in the data shown in blue and press 'calculate'. Recommended dose is shown in black below.

GENTAMICIN 7 mg/kg (HARTFORD) DOSAGE REGIMEN	
Dose	400 mg
Duration of infusion	60 mins
Sampling time	Take a sample 6-14 hours after the first dose and refer to Hartford programme for dosing interval.
REVIEW ANTIBIOTIC THERAPY DAILY	
Seek advice from microbiology if gentamicin is required beyond 3-4 days	

Print Calculator Record

Gentamicin dose is based on Actual Body Weight or Corrected Body Weight if 'obese' (> 30% above Ideal Body Weight)
Developed and validated by Stephen Owen, Dundee Health Partnership, Dundee, 04/01/2016, Version 1.0
Adapted by Mike McKeown, Aberdeen Health Partnership, Aberdeen, 04/01/2016, Version 1.1
Digitally signed by Mike McKeown, DN: cn=Mike McKeown, o=Health Partnership, ou=Pharmacy, email=mmc@hpa.gov.uk

Current SAPG projects to optimise prescribing

Hospital Antibiotic Review Programme

A quality improvement toolkit to support clinical teams in **reliable reviews of IV antibiotics** and documentation of duration for oral antibiotics

Penicillin allergy de-labelling

A risk algorithm and communication tools to support **assessment of penicillin allergy** in patients whose history suggests that previous reaction to penicillin was not allergic in nature so that their allergy label can be removed.

Antibiotic use towards the end of life antibiotics

Good practice recommendations on **when and when not to use antibiotics in patients during their last days and weeks of life** to prevent harmful antibiotic-associated side effects and complications which may impact on quality of life.

Improvement



- Prototyping
- Shared learning networks
- Improvement Collaboratives

Area Drug and Therapeutics Committee Collaborative (ADTCC)

- Policy context – Achieving excellence in Pharmaceutical care, Access to medicines and Realistic Medicines
- To provide professional and clinical advice and leadership to NHS board ADTCs to support safe, clinically effective, cost effective and patient-centered use of medicines
- Maximise opportunities for NHS Boards by consideration and delivery on a Once for Scotland approach
- Maintaining a forum for learning and sharing of good practice between ADTCs via quarterly webex events and newsletters

Prescribing Framework



A Competency Framework for all Prescribers

Publication date: July 2016
Review date: July 2020



NICE has accredited the process used by the Royal Pharmaceutical Society to produce its professional guidance and standards. Accreditation is valid for 5 years from 17 February 2017.
For full details on NICE accreditation visit www.nice.org.uk/accreditation



Medicines and Healthcare products Regulatory Agency (MHRA): Early Access to Medicines Scheme (EAMS)

Summary of operational arrangements for EAMS medicine avelumab, in combination with axitinib, for first-line treatment of advanced renal cell carcinoma in NHS Scotland (EAMS No: 11648/0002).

The aim of the MHRA Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed and 'off label' medicines to UK patients that have a high unmet clinical need. The medicinal products included in the scheme are those that are intended to treat, diagnose or prevent seriously debilitating or life threatening conditions where there are no adequate treatment options. More information about the scheme can be found here: <http://www.mhra.gov.uk/howweregulate/innovation/EarlyaccesstomedicinesschemeEAMS/index.htm>

EAMS medicine avelumab, in combination with axitinib, is made available free of charge for patients via EAMS during the EAMS period. This document summarises how the medicine can be used in Scotland.

Medicine

- Avelumab 20mg/ml vials, each 10ml vial containing 200mg avelumab for dilution for infusion
- Axitinib (Inlyta®) 5mg tablets and 1mg tablets

Indication and patient population

Avelumab in combination with axitinib is indicated for the first line treatment of adult patients with advanced renal cell carcinoma (RCC)

Dosing and enrolment information

Patients will be identified as eligible for this EAMS by their physician who will then contact Merck/Pfizer. Patients with advanced RCC meeting the eligibility criteria will then be enrolled at participating sites via an online portal. Instructions for using the portal are as follows:

Patients will be enrolled via an online portal, which is managed by Inceptua, as per instructions below:

Step 1: Registering on the Imap portal (<https://portal.inceptua.com>) via the 'Not registered?' link.

Step 2: Qualification process

- You will need your professional qualification documentation.

Email for all EAMS related correspondence between pharmaceutical company and ADTC collaborative: hcs.eams@nhs.net



Area Drug and Therapeutics Committee Collaborative

Newsletter October 2019

Welcome to the October edition of the Area Drug and Therapeutics Committee (ADTC) Collaborative newsletter. In this edition, we'd like to share with you some of our current work with ADTCs.

Previous editions of our newsletters are still available on the Healthcare Improvement Scotland website [here](http://hcs.scot.nhs.uk).

If you have any comments on the new look or if you have issues viewing the newsletter, please contact us at hcs.adtc.collaborative@nhs.net



EU Exit: Action to Maintain Continuity of Supply of Medicines

The UK Government has overall responsibility for EU exit contingency planning and for entry and any customs control at the UK border. Since August 2018, the Department of Health and Social Care (DHSC) has been leading on UK-wide contingency plans to secure supplies of medicines, medical devices and clinical consumables in the event of a 'no deal' exit from the EU.



User Groups eg JAC

HEPMA Oversight group (reporting to ePharmacy Board)

HEPMA
Consistently achieved improved clinical care and outcomes for

Shared learning system (HIS)

Safer Implementation

HIS Good Practice Guide and FV learning (published)
Resources: Staff change management and implementation (local business cases)
Learning system (commission awaited)

Funding

National Business Case and Funding
Local business case funding plus recurring

Safe IT System

Operational Requirement

3 Day Clinical Evaluation and site visit

Contract (NSS)

System optimisation (AA leading plus live sites)

Pharmacist profession/team optimisation (skill mix, capacity, plans, etc)

Data harvest

Benefits Realisation

Off Label Use of Cancer Medicines: Evidence into practice

Policy commitment:

- SGHD Beating Cancer: Ambition and Action - “assess what improvements can be made to maximise opportunities for access to ‘off-patent medicines.’”

Work programme:

- Two year programme with SGHD funding
- Test principles and methodology
- Measure and evaluate the effectiveness of the programme
- Business case to operationalise programme

Anticipated benefits:

- Service efficiency – ‘once for NHS Scotland’
- Improved medicines governance
- Reduce unwarranted variation
- Improved patient outcomes
- Improved equity of access

Assurance



- Quality of Care Framework
- Intelligence led service reviews
- Responding to concerns
- **Regulator for Independent Healthcare**
- Inspection for Health Care in Prisons

Independent Health Care

- Private Hospitals (4)
- Hospices
- Independent health care clinics eg aesthetics, botox, dental, slimming clinics “lifestyle”

Potential safety risks

- not linked to a patient’s NHS GP or regular healthcare provider
- there may be limited access to a patient’s medical records.

Issues include

- Standards consistent with NHS
- Non compliance with NHS arrangements eg SMC advice, SIGN guidance.

On line Primary Care

- Sexual health e.g. STI treatment/testing
- Men's health e.g. erectile dysfunction
- Women's health e.g. OCP, cystitis treatment
- Travel health
- Chronic e.g. repeat supplies for diabetes, asthma,

Potential safety risks

- not linked to a patient's NHS GP or regular healthcare provider
- there may be limited access to a patient's medical records.

Issues include

- increased attempts to gain access to medicines which can cause serious harm
- the need to ensure safe ongoing monitoring of those with long term conditions.



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Any Questions?