BHRCCGs and BHRuT NHS Trust Shared Care Guidelines

METHOTREXATE

Psoriasis, Crohn's Disease & Ulcerative Colitis, Pulmonary Sarcoidosis, Rheumatoid Arthritis, Psoriatic Arthritis

DOCUMENT TO BE SCANNED INTO ELECTRONIC RECORDS AND FILED IN NOTES-

Patient Full Name:	**NHS No:**
Date of Birth: `	**Hospital Number:**
Name of Referring Consultant:	**Contact number:**

INTRODUCTION – Indication, Licensing and Presentations used

Oral: 2.5mg tablets
Subcutaneous: 7.5mg, 10mg, 12.5mg, 15mg, 17.5mg, 20mg, 22.5mg and 25mg pre-filled syringes

- Both oral and subcutaneous doses should only be given weekly
- Subcutaneous injections are for patients, who are intolerant of oral medication or have incomplete response to oral therapy.
- Switching from oral to subcutaneous administration, use the same dose or the nearest lower dose that matches the strengths of the available pre-filled syringes.
- Methotrexate is a disease-modifying agent that is licensed to induce and maintain remission in severe psoriasis.
- Methotrexate is used in inflammatory bowel disease (Crohn's disease and Ulcerative colitis).
- Methotrexate is recommended (BTS Interstitial Lung Disease guidelines) for Pulmonary Sarcoidosis when corticosteroids are not controlling the disease or side effects are intolerable. *Oral* methotrexate, typically as a maintenance 10-15mg per week is advocated.
- Methotrexate is licenced for the treatment of Rheumatoid Arthritis
- Methotrexate is recommended and routinely used for the treatment of moderate and severe Psoriatic Arthritis

  - In Dermatology, methotrexate is only licenced to treat psoriasis, but is commonly used to treat many other dermatological conditions, of which are unlicensed indications. These include atopic dermatitis, Systemic sclerosis, Bullous disorders, Lupus erythematosus, dermatomyositis and pyoderma gangrenosum

PATIENT PATHWAY

Clinical Speciality / Indication	Prescribing Initiated by	Prescribing Continued by	Monitored by	Duration of treatment
Gastroenterology	Gastroenterology Consultant or registrar	By GP for patients who are in a stable condition and who have been on methotrexate for at least 3 months and on a steady dose and require blood monitoring at monthly intervals	Hospital clinician until dose and monitoring stable for 6 weeks, thereafter monthly until the dose and disease is stable for a year. Frequency of monitoring can then be reduced to every 2-3 months based on clinical judgement and following discussion with specialist.	Long term
Dermatology	Dermatology Consultant or registrar			
Respiratory	Respiratory Consultant or Registrar			
Rheumatology	Rheumatology			

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	Consultant or Registrar		Additionally for: a. Dermatology- Procollagen 3 peptide (P3P) b. Gastroenterology - CRP to be monitored every three months, though not critical. ESR not required	

ORAL DOSE AND ADMINISTRATION

Methotrexate is given only ONCE a week

Initial dose:
Psoriasis: 10mg ONCE A WEEK
Crohn's Disease/ Ulcerative Colitis: 25mg ONCE A WEEK
Pulmonary Sarcoidosis: 5mg ONCE A WEEK
Rheumatoid Arthritis / Psoriatic Arthritis: 2.5 – 15mg ONCE A WEEK

Dermatology: 10mg once a week increasing by 2.5mg per week every 2 weeks up to a **maximum of 25mg per week** depending on response and side effects

Gastroenterology: 25mg once weekly for 12 weeks, **then reduce to** 15mg once weekly thereafter, depending on response an side-effects. **Maximum 25mg per week**

Respiratory: 5mg once a week increasing by 2.5mg per week every 2 weeks up to a maximum of 15mg per week depending on response and side effects

Rheumatology: 2.5-15mg once weekly increasing by 2.5-10mg every month to a maximum of 25mg per week depending on response and side effects

In patients *over 65 years of age and those with impaired renal excretion (eGFR <50mls / min)* it is advised that Methotrexate escalation is slower and that the maximum dose is reduced

All communications (letter, patient held record books), discharge prescriptions and FP10s should normally include the following details:

1. Methotrexate Weekly dose: ONCE A WEEK

2. Day of the week dose taken: Always same day each week

3. Strength of tablet/ injection the patient takes

Folic Acid Supplements

Folic Acid 5mg once weekly is co-prescribed with Methotrexate to counteract its anti-folate side-effects, preferably on a different day to Methotrexate. If necessary the folic acid may be increased to 5mg daily.

Time to respond

6 weeks to 3 months

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Contra-indications

- **Severe/ significant renal impairment** - Patients with impaired renal function with an **eGFR below 20mls / min.**
- **Severe liver impairment** - Known liver disease and excessive alcohol intake. However patients with active rheumatoid arthritis may have elevated liver enzymes and these should be monitored when methotrexate is started. Diclofenac can also cause abnormal liver enzymes in 2% of patients and a switch to an alternative NSAID may be advised.
- **Severe haematological disorders or profound deterioration**
- **Pregnancy, conception and breast-feeding-** Methotrexate is teratogenic. Female patients of childbearing age should be prescribed or offered contraception. Both **male and female** patients should wait 6 months after stopping methotrexate before trying to conceive a child.
- **Methotrexate Hypersensitivity**
- **Severe acute or chronic infections such as tuberculosis, HIV or hepatitis B or C**
- **Active gastrointestinal ulcer disease**
- **Concurrent vaccination with live vaccines** such as oral polio, MMR, BCG and yellow fever
- **Immunodeficiency syndromes**
- **Concomitant administration of folate antagonists such as**. Septrin (co-trimoxazole and trimethoprim), phenytoin can result in acute megaloblastic pancytopenia. Hence concomitant use with Methotrexate should be avoided.
- **If pneumonitis suspected.**
- **If stomatitis develops.**

Cautions

- Moderate to severe renal impairment - As methotrexate is renally excreted it may accumulate in patients with renal impairment. Caution needs to be exercised with patients over 65 years of age or if there is impaired renal function with an eGFR below 50mls / min.
- Patients should avoid contact with people who have active chickenpox or shingles and should report any such contact urgently to their GP or specialist.
- Alcohol consumption in moderation, e.g. the occasional glass of wine, is not contra-indicated.
- Over the counter NSAID and aspirin use to be avoided unless agreed with clinician
- Avoid excessive caffeine intake
- Concurrent use with leflunomide, advise to be monitored by secondary care
- Concurrent use with retinoids such as acitretin or etretinate.
- Concomitant administration of drugs that can cause bone marrow depression chloramphenicol/clozapine.

Interactions

- Methotrexate is extensively protein bound and can be displaced by certain drugs such as salicylates, phenytoin, tetracyclines and hypoglycaemics
- Severe bone marrow depression has been reported following the concurrent use of methotrexate and co-trimoxazole or trimethoprim. Concurrent use should probably be avoided
- Renal elimination is reduced by loop diuretics, penicillins, ciprofloxacin, glycopeptides, probenecid, omeprazole, pantoprazole and NSAIDs and will require closer monitoring.
- See BNF, Appendix 1, for further drug interactions

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KEY ADVERSE EFFECTS & ACTIONS

- **Hepatotoxicity** (necrosis, cirrhosis, fibrosis)
- **Pulmonary toxicity** (interstitial pneumonitis often associated with eosinophilia, causing **dry unproductive cough, dyspnoea and fever**, rarely pulmonary fibrosis. Can occur in first year of treatment and later.
- **Gastrointestinal disturbances** (ulcerative stomatitis, dyspepsia, anorexia, nausea, diarrhoea and vomiting, rarely gastrointestinal ulceration)
- **Bone marrow suppression** (leucopoenia, thrombocytopenia, anaemia)
- **CNS disturbances** (headache, tiredness, drowsiness, blurred vision)
- **Hypersensitivity reactions** (fever, rigors, rash, pruritus)
- Rarely alopecia, visual disturbances, myalgia and osteoporosis
- In the event of an overdose, early treatment may be lifesaving. Consult the National Poisons Unit for information

In the following situations, <u>withhold</u> methotrexate until discussed with the specialist team:

- WBC < 3.5 $x10^9$ /l
- Neutrophils < 2.0 $x10^9$/l (<1.6 for Rheumatology patients, as baseline may be lower)
- Platelets <150 $x10^9$ /l (<140 for Rheumatology patients)
- Eosinophils>0.5 $x10^9$ /l
- At least 2 fold rise in AST, ALT (from the upper limit of reference range) (ALT / AST > 100, or clinically significant increasing trend) for Rheumatology patients)
- Albumin-Unexplained fall (in absence of active disease)
- Rash, abnormal bruising, severe sore throat, oral ulceration, nausea & vomiting or diarrhoea
- New or increasing dyspnoea or dry cough
- Renal function- Clinically significant deterioration
- If pre-treatment P3P levels > 4.2 mcg/ L but < 8 mcg/ L: Can commence on methotrexate
- If pre-treatment P3P is > 8 mcg/ L on two occasions or if 3 measurements are > 4.2 mcg/ L in a 12-month period or if > 10 mcg/ L on one occasion should prompt further hepatic investigations (except children and patients with psoriatic arthritis)

N.B. A rapid rise/fall or consistent upward/downward trend in any value should prompt caution and extra vigilance.

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MONITORING STANDARDS FOR METHOTREXATE AT BHRUT NHS TRUST

The following standards have been agreed for the monitoring of methotrexate in gastroenterology & dermatology and Rheumatology patients at BHRUT NHS Trust.

Treatment Monitoring & Responsibility	Indication	Monitoring parameters & When
Pre-treatment **by Hospital Team**	Psoriasis, Crohn's Disease, Ulcerative Colitis, Pulmonary Sarcoidosis, Rheumatoid Arthritis, Psoriatic Arthritis	***FBC, U&E, LFTs, P3P, CXR (unless within 6 months)*** Varicella status – record history of chickenpox or VZV IgG immunity status in patient booklet. Where serology is negative, the patient should be considered for the varicella zoster vaccination. Please follow The Department of Health guidance on this. Pulmonary Function Tests in selective high risk cases. If a patient has known interstitial lung disease, MTX should only be considered after agreement with the respiratory physicians. Hepatitis B and C, and HIV serology ***Note:*** P3P not routinely performed for Rheumatology conditions prior to treatment
Initiation to stabilisation **By Hospital Team**		FBC, U&E and LFTs **7 days after first dose** and **every two weeks** for four weeks, then **monthly** until methotrexate dose is stable. **Note: *For Gastroenterology conditions***, ESR and/or CRP monthly to assess response to treatment ***Note:*** **For Rheumatology Conditions,** FBC, U&E, LFT 2 weekly for 6 weeks and then monthly for 3 months. After dose escalation FBC, U&E, LFT 2 weekly for 6 weeks and then return to routine monitoring.
Ongoing **Monitoring by GP**		FBC & LFTs monitor 3 monthly ***Note:*** **For *Gastroenterology conditions,*** ESR and/or CRP monthly to assess response to treatment***.*** *U&E's 6 monthly once stabilised* ***Note:*** **For *Dermatology condition,*** U&E's: 3 monthly ***Note:*** **For Rheumatology Conditions,** also check U+E, ESR and CRP 3 monthly

Record all blood results in the methotrexate patient held record book, issued by the hospital

If the GP has taken over the prescribing of the methotrexate, but not the monitoring responsibility, the hospital specialist (nurse or doctor) must annotate the blood test request form with "Send to GP giving the GPs name and ideally their drop code.

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Actions for GPs on monitoring patient's blood results & symptoms

Please see recommendations table below for general medical management of a patient presenting with the following blood results & symptoms:

Adverse effects	Symptoms/ signs	Actions
Liver toxicity (ALT rises 3 times above normal upper limit)	Fever, malaise, sore throat, mouth ulcers and abnormal bruising	Order immediate/ urgent FBC Stop Methotrexate and repeat liver function tests every 2 weeks until levels fall and then consider restarting Methotrexate at a lower dose and or with higher doses of folic acid **Discuss with specialist team**
Respiratory toxicity	Dyspnoea, non-productive cough and fever symptoms	Stop methotrexate and a chest x-ray and lung function test ordered. If methotrexate lung toxicity is confirmed patient should not be recommenced on methotrexate. **Discuss urgently with specialist team**
Blood count abnormalities	Falling white cell count particularly neutropenia, falling platelet count or a macrocytic anaemia	Stop methotrexate and look for folate and B12 deficiency, TFT and impaired renal function and restart Methotrexate at a lower dose and with higher doses of folic acid once the blood count returns to normal. **Discuss with specialist team**.

The hospital must update the patient held monitoring book at each visit
If the hospital has the monitoring responsibility it is responsible for contacting the patient if any action is required

This only lists the key important adverse drug reactions- For comprehensive information on cautions, contra-indications and interactions, please refer to the current British National Formulary and Summary of Product Characteristics.

PREGNANCY AND BREAST FEEDING

Methotrexate is teratogenic. Female patients of childbearing age should be prescribed or offered contraception. Both male and female patients should wait 6 months after stopping methotrexate before trying to conceive a child

It is recommended that the patient should not become pregnant whilst on Methotrexate a statement that both men and women will be counselled about contraception and what to do if pregnancy occurs. The counselling should be documented in the patient notes.

For comprehensive information please refer to the current British National Formulary and Summary of Product Characteristics

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SHARED CARE

Shared care guideline*:* is a document which provides information allowing patients to be managed safely by primary care, secondary care and across the interface. It assumes a partnership and an agreement between a hospital specialist, GP and the patient and also sets out responsibilities for each party. The intention to shared care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. Intrinsic in the shared care agreement is that the prescribing doctor should be appropriately supported by a system of communication and cooperation in the management of patients.

The doctor who prescribes the medicine has the clinical responsibility for the drug and the consequence of its use.

SHARED CARE RESPONSIBILITIES

Consultant

1. Ensure that the patient/carer is an informed recipient in therapy.
2. Ensure that patients understand their treatment regimen and any monitoring or follow up that is required (using advocacy if appropriate). Issue any local patient information leaflets where appropriate.
3. Ensure baseline investigations are normal before commencing treatment. Give the patient a patient held booklet for result monitoring if appropriate.
4. Initiate treatment and prescribe until the GP formally agrees to share care (as a minimum, supply the first month of treatment or until patient is stabilised).
5. Send a letter to the GP requesting shared care for this patient.
6. Clinical and laboratory supervision of the patient by blood monitoring and routine clinic follow-up on a regular basis.
7. Send a letter/results notification to the GP after each clinic attendance ensuring current dose, most recent blood results and frequency of monitoring are stated (unless otherwise covered by letter e.g. from Rheumatology Clinical Nurse Specialist or Pharmacy Drug Monitoring Service).
8. Where the GP is not performing the phlebotomy, the blood test form MUST be annotated to request that blood results are also copied to the GP
9. Evaluation of any reported adverse effects by GP or patient.
10. Advise GP on review, duration or discontinuation of treatment where necessary. Where urgent action is required following tests the hospital team will telephone the patient and inform GP.
11. Inform GP of patients who do not attend clinic appointments.
12. Counsel the patient on contraception and what to do if pregnancy occurs. Document in the notes.
13. Ensure that backup advice is available at all times.
14. Ensure, where timing is appropriate, that the patient has received a flu vaccine prior to commencing treatment that is likely to cause immunosuppression. Document this in the patient notes and inform the GP it has been given

General Practitioner

1. Reinforce the patient's understanding of the nature, effect and potential side effects of the drug before prescribing it as part of the shared care programme and contact the specialist for clarification where appropriate.
2. Monitor patient's overall health and well-being.
3. Report any adverse events to the consultant, where appropriate.
4. Report any adverse events to the **CSM,** where appropriate.
5. Help in monitoring the progression of disease
6. Maintain a patient held monitoring booklet where used
7. Prescribe the drug treatment as described.

CCG

1. To provide feedback to the Trust via the Trust Medicines Optimisation Committee..
2. To support GPs to make the decision whether or not to accept clinical responsibility for prescribing.
3. To support the Trust in resolving issues that may arise as a result of shared care.

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Patient/ Carer

1. Report any adverse effects to their GP and/or specialist
2. Ensure they have a clear understanding of their treatment.
3. Report any changes in disease symptoms to GP and/or specialist
4. Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy
5. Take/ administer the medication as prescribed
6. Undertake any monitoring as requested by the GP and/or specialist

Dispensing Pharmacist (Hospital or Community)

1. Check patient held monitoring record prior to dispensing
2. Dispensing should meet the NPSA requirements for safe dispensing
   http://www.nrls.npsa,nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=59800&p=5

Costs

Drug Product	Cost in primary care (Mims online- accessed (17/01/17)
Methotrexate 2.5mg tablets 28-tab pack	£1.77
Methotrexate 7.5mg/0.15mL injection in pre-filled pen	£14.85
Methotrexate 10mg/0.2mL injection in pre-filled pen	£15.29
Methotrexate 12.5mg/0.25mL injection in pre-filled pen	£16.50
Methotrexate 15mg/0.30mL injection in pre-filled pen	£16.57
Methotrexate 17.5mg/0.35mL injection in pre-filled pen	£17.50
Methotrexate 20mg/0.40mL injection in pre-filled pen	£17.84
Methotrexate 22.5mg/0.45mL injection in pre-filled pen	£18.45
Methotrexate 25mg/0.50mL injection in pre-filled pen	£18.48

CONTACT NUMBERS FOR ADVICE AND SUPPORT

Barking, Havering and Redbridge University Hospitals NHS Trust	
Consultant via switchboard Registrar on-call out of hours	Queens Hospital- 01708 435000 Bleep via switchboard
Dermatology Nurse Specialist; Queens Hospital	01708 435 000 – Ext. 4869
Clinical IBD Nurse Specialist; Queens Hospital Clinical IBD Nurse Specialist; KGH Hospital Rheumatology Nurse Specialists: Queens Hospital Rheumatology Nurse Specialists: KGH	01708 435 347 0208 970 8161 01708 435 000 Ext 4821 020 8970 8408
Pharmacy Medicines Information Department	01708 435 418
BHR CCG Medicines Management Team.	0208 822 3074
FAX number; King George Hospital	0208 970 8124 (Gastroenterology)
FAX number Queens Hospital	01708 435 408 (Gastroenterology) 01708 503 104 (Dermatology)

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References

1. BNF 72, September 2016- March 2017
2. NPSA Alert – Towards the safer use of oral Methotrexate
3. Summary of Product Characteristics Maxtrex tablets 2.5mg via www.medicines.org.uk accessed 17/10/2017
4. Summary of Product Characteristics Metoject injection via www.medicines.org.uk accessed 17/01/2017
5. www.rheumatology.org.uk
6. (British Thoracic Society) Interstitial Lung Disease Guideline, Thorax 2008; 63, v1-v58
7. http://www.bad.org.uk/shared/get-file.ashx?id=4020&itemtype=document

Refer to the relevant BHR CCG website to obtain the latest version of this guideline
http://www.barkingdagenhamccg.nhs.uk/About-us/Medicines-management/shared-care-guidelines.htm
http://www.haveringccg.nhs.uk/About-us/medicines-management/shared-care-guidelines.htm
http://www.redbridgeccg.nhs.uk/About-us/Medicines-management/shared-care-guidelines.htm
APPENDIX 1

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Barking, Havering and Redbridge University Hospitals NHS Trust
This form will be completed by the Hospital Specialist and given to the patient.

Shared Care information Form

You have been prescribed **methotrexate 2.5 mg tablets or methotrexate syringes**
for……..
This weekly treatment will continue until stopped by your doctor

Either
Methotrexate 2.5mg tablets
Take…… tablets (…….mg) on …….. ……..each week
Or
Methotrexate ……. Injection
Contents of one syringe (…….mg) to be given **intramuscularly / subcutaneously** (delete as applicable) on ……. …….each week

Your GP has been given all the necessary information regarding your condition and treatment.

The date for your next hospital appointment is on…… ……

The success and safety of your treatment also **depends on you.**

- You will have been given a **monitoring booklet**, which tells you all about methotrexate, what is used for and all about its side effects. It is important that you read this booklet and **take it with you to all GP and hospital appointments;** you should also show it to the pharmacist when you collect your prescription.
- Avoid excessive alcohol consumption
- Do not take anti-inflammatory medicines, such as ibuprofen or aspirin without getting advise from your doctor
- Avoid contact with chicken pox or shingles
- Your GP/ Practice Nurse needs to see you every ……

If you experience any of the following side-effects see your GP:

- Mouth ulcer, sore throat, sore mouth
- Feeling generally unwell
- Feeling sick, upset stomach, diarrhoea
- Rashes – new rash or severe itching anywhere on the body

Stop treatment and get immediate medical advice if you develop:

- An infection with fever and or chills or a severe sore throat
- Sudden shortness of breath (breathlessness)
- The whites of your eyes become yellow
- Severe itching of the skin
- New unexplained bleeding or bruising
- Severe and continuing diarrhea or vomiting
- If you think you are pregnant

If you feel you have any concerns about your treatment contact your GP or the hospital. The direct-dial telephone numbers for the department are……

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APPENDIX 2 Barking, Havering and Redbridge University Hospitals NHS Trust

Methotrexate Shared Monitoring Agreement Letter

Name of GP ……..… Address ……
Drop code of GP…… ……
..……

Dear GP

Re: Patient's name……..……

Date of birth……..……

Hospital number……..…….
NHS number……

Indication for Methotrexate……

Patient is on either
Methotrexate 2.5mg tablets
Take…… tablets (……mg) on …….. …….each week **Or Methotrexate …… Injection**
Contents of one syringe (……mg) to be given **intramuscularly / subcutaneously** (delete as applicable) on
…… ……each week

This patient is being treated with methotrexate for the above condition. This treatment will be long term. I hope that you will agree to share the care of this patient with the hospital.

Enclosed is a copy of the shared care monitoring guidelines for Methotrexate to be retained in the patient's notes. It is safer for monitoring and prescribing to be done by the same clinician. It is not possible for secondary care to do all the prescribing.
Should you agree to take over responsibility for monitoring, we will send a letter containing the details of the patient's treatment plan, the dose to be prescribed and all relevant blood results.

If you decide not to accept monitoring responsibility **you must ensure your drop code is written in the patients hand held monitoring book to ensure you receive the blood results to enable you to prescribe further methotrexate.**

Please sign below and return/ fax this letter to the Hospital Specialist if you agree to take over shared monitoring for this patient.

Hospital site to send fax to: Queens Hospital/ King George Hospital Delete as appropriate

Hospital Specialist	GP
Signature……..……...	Signature……..……...
Print Name ……..……..……...	Print Name……...
Date……..……..	Date……..…..……...

If you are not taking on the monitoring responsibility for this patient please state the reason why and return this letter to the Hospital Specialist. **You will retain the responsibility to check the blood results prior to prescribing** Please provide your drop code to enable the patients blood results to be sent to
you……
Fax number…….

Original Guideline written by: Tutu Ogunsanwo, Principal Pharmacist MI & Formulary Date: November 2011
Consulted with Dr Pranab Gyawali, Consultant Gastroenterologist & Dr Fawad Hussain, Consultant Dermatologist Date: January 2016
Addition of Pulmonary Sarcoidosis by Dr Robin H Johns, Consultant Resp Physician Date: August 2017
Addition of Rheumatoid Arthritis and Psoriatic Arthritis by Dr Louise Daniels, Rheumatology Consultant Date: August 2018
Reviewed & Updated by: Tutu Ogunsanwo, Principal Pharmacist MI & Formulary & Uma Horton, Pharmacy Clinical Business Manager Date: January 2017
Approved by: BHRUT Medicines Optimisation Group Date: September 2017
Approved by: BHR CCGs Area Prescribing sub- committees Date: September 2018
Review date: September 2021